UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-38433

Homology Medicines, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**47-3468154**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Patriots Park Bedford, MA	**01730**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 301-7277

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	FIXX	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Small reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, as of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $338.5 million. Solely for purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the registrant as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 11, 2022, there were 57,385,285 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Auditor Firm Id: 34 Auditor Name: Deloitte & Touche LLP Auditor Location: Boston, Massachusetts, USA

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, the anticipated impact of the COVID-19 pandemic on our business, anticipated use of cash, business strategy, the potential, safety, efficacy, and regulatory and clinical progress of our product candidates, prospective products, product approvals, research and development costs, anticipated timing and likelihood of success of clinical trials, expected timing of the release of clinical trial data, timing and expectations surrounding regulatory communications, the plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under "Summary Risk Factors" below and the sections in Item 1A. "Risk Factors" of Part I and Items 7 and 7A. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Quantitative and Qualitative Disclosures About Market Risk," respectively, of Part II of this Annual Report on Form 10-K.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise. Unless the context requires otherwise, we use the terms "Homology," "the Company," "we," "us," "our" and similar designations in this Annual Report on Form 10-K to refer to Homology Medicines, Inc. and its wholly-owned subsidiary.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. “Risk Factors” in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. We may never achieve or maintain profitability.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.
- We have a limited operating history and no history of commercializing genetic medicine products, which may make it difficult to evaluate the prospects for our future viability.
- We are heavily dependent on the success of HMI-102, our most advanced product candidate, and if HMI-102 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.
- We intend to identify and develop product candidates based on our novel genetic medicines platform, which makes it difficult to predict the time and cost of product candidate development. No products that utilize gene editing technology have been approved in the United States or in Europe, and there have only been a limited number of human clinical trials involving a gene editing product candidate. Moreover, none of those trials has involved our nuclease-free gene editing technology, prior to our recently initiated Phase 1 pheEDIT clinical trial.
- The clinical trial and regulatory approval processes are lengthy, time consuming and inherently unpredictable, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The COVID-19 pandemic has and could continue to adversely impact our business, including our preclinical studies and clinical trials.
- Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may delay or prevent their regulatory approval, limit the commercial profile of an approved label, or, result in significant negative consequences following marketing approval, if any.
- Adverse public perception of genetic medicine, and gene editing in particular, may negatively impact regulatory approval of, or demand for, our potential products.
- We currently contract with third parties, including the newly formed AAV vector manufacturing company, Oxford Biomedica Solutions LLC, for the manufacture of certain materials for our research programs, preclinical and clinical studies. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost or in compliance with regulatory requirements, which could delay, prevent, or impair our development or commercialization efforts.
- Our contract manufacturers, including the newly formed AAV vector manufacturing company, Oxford Biomedica Solutions LLC, are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements, as applicable and as imposed to date, and have limited capacity.
- Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize their full market potential.
- We may collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.
- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

PART I

Item 1. Business.

Overview

We are a clinical-stage genetic medicines company dedicated to transforming the lives of patients suffering from rare genetic diseases with significant unmet medical needs by addressing the underlying cause of the disease. Our proprietary platform is designed to utilize our human hematopoietic stem cell derived adeno-associated virus vectors, or AAVHSCs, to precisely and efficiently deliver single administration genetic medicines *in vivo* through our gene therapy, our nuclease-free gene editing modality, or our gene therapy to express antibodies platform, or GTx-mAb. Our clinical programs include: HMI-102, an investigational gene therapy candidate in clinical development for the treatment of adult patients with phenylketonuria, or PKU; HMI-103, an investigational gene editing candidate in clinical development for the treatment of patients with PKU; and HMI-203, an investigational gene therapy candidate in clinical development for the treatment of patients with mucopolysaccharidosis type II (MPS II), or Hunter syndrome. Additionally, we are developing a gene therapy candidate, HMI-104, from our GTx-mAb platform for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH, and we are conducting research in other diseases including metachromatic leukodystrophy, or MLD. Our diverse set of AAVHSCs allows us to precisely target, via a single injection, a wide range of disease-relevant tissues, including the liver, central nervous system, or CNS, peripheral nervous system, or PNS, bone marrow, cardiac and skeletal muscle and the eye. Our genetic medicines platform is designed to provide us the flexibility to choose the method we believe is best suited for each disease we pursue, based on factors such as the targeted disease biology, the biodistribution of our AAVHSCs to key tissues and the rate of cell division the disease-relevant tissues exhibit. Our product-development strategy is to continue to develop in parallel gene therapy and gene editing, while initially leveraging the experience from our gene therapy product candidates to further advance our gene editing. We believe our technology platform will allow us to provide transformative cures using either modality.

The unique properties of our proprietary family of 15 AAVHSCs enable us to focus on a method of gene editing called gene integration, through the replacement of an entire diseased gene in the genome with a whole functional copy by harnessing the naturally occurring deoxyribonucleic acid, or DNA, repair process of homologous recombination, or HR. We believe our HR-driven gene editing approach will allow us to efficiently perform gene editing at therapeutic levels without unwanted on- and off-target modifications to the genome, and to directly measure and confirm those modifications in an unbiased manner to ensure only the intended changes are made. By utilizing the body's natural mechanism of correcting gene defects, we also avoid the need for exogenous nucleases, or bacteria-derived enzymes used in other gene editing approaches to cut DNA, which are known to significantly increase the risk of unwanted modifications.

Clinical-Stage Product Candidates

HMI-102: Investigational Gene Therapy for the Treatment of Adult Patients with PKU

We are currently in Phase 2 of the pheNIX clinical trial with our first and lead product candidate, HMI-102, a gene therapy in development for the treatment of adults with PKU. We have received Fast Track Designation for HMI-102 from the U.S. Food and Drug Administration, or FDA, for the prevention or treatment of neurocognitive defects due to phenylalanine hydroxylase, or PAH, deficiency through normalization of circulating Phe levels.

In November 2020, we reported positive safety and efficacy clinical data from the dose-escalation phase of the trial. As of the data cutoff date of October 19, 2020, six patients in the dose-escalation phase of the trial had received HMI-102 across three dose cohorts (low-dose Cohort 1, n=2; mid-dose Cohort 2, n=2; high-dose Cohort 3, n=2). The results showed that HMI-102 was generally well-tolerated, and resulted in marked reductions in phenylalanine, or Phe, increases in tyrosine, or Tyr, and reductions in the Phe-to-Tyr ratio, at two doses. Phe is a registrable endpoint in PKU, and the Phe-to-Tyr ratio is a clinically relevant diagnostic measurement for PKU. Based on the safety and efficacy results observed in the dose-escalation phase, we selected and advanced two doses to the randomized, concurrently controlled, dose expansion Phase 2 portion of the pheNIX trial, which was designed to have the potential to be converted to a registrational trial.

In October 2021, we announced that, as of September 30, 2021, both doses in the Phase 2 portion of the trial have been generally well-tolerated and have shown evidence of biological activity, including clinically meaningful reductions in Phe levels, increases in Tyr and reductions in the Phe-to-Tyr ratio. In addition, several new clinical trials sites have been recently added to the trial for a total of 15 active sites currently, with more sites expected. Despite increased interest in pheNIX, enrollment is slower than anticipated, due in part to a COVID-19 resurgence.

On February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold due to the need to modify risk-mitigation measures in the study in response to observations of elevated liver function tests, or LFTs. On March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated LFTs observed in some

patients in the trial and modified clinical risk-mitigation measures. In patients who experienced elevated LFTs, all have resolved and no hospitalizations were required. Among the risk-mitigation methods that we intend to propose is a new, more targeted immunosuppressive regimen that is shorter in duration and includes a T-cell inhibitor used in combination with a steroid-sparing regimen that may improve patient compliance. The use of T-cell inhibitors has been shown to be effective in dampening the anticipated immune response to AAV capsids. With the additional information requested by the FDA and the planned conversion to a more targeted immunosuppressive regimen, we estimate that we will require more time to submit and receive feedback on our proposed clinical risk-mitigation strategy. As a result, we now expect to provide a program update when the path forward is established with the FDA.

HMI-103: Gene Editing Candidate for the Treatment of Patients with PKU

In October 2021, we announced the initiation of a Phase 1 trial with HMI-103, our lead gene editing candidate in development for the treatment of classical PKU and received Fast Track Designation for the treatment of neurocognitive and neuropsychiatric manifestations of PKU secondary to phenylalanine hydroxylase deficiency. The pheEDIT clinical trial is an open-label, dose escalation study evaluating the safety and efficacy of a single I.V. administration of HMI-103, and is expected to enroll up to nine patients ages 18-55 years old who have been diagnosed with classical PKU due to PAH deficiency. In addition to safety endpoints, the trial will measure serum Phe changes. The trial incorporates an immunosuppressive regimen that includes a T-cell inhibitor used in combination with a steroid-sparing regimen. We expect that the first patient in the pheEDIT clinical trial will be dosed following requisite Institutional Biosafety Committee and Institutional Review Board approvals at the clinical sites, and completion of an 82-day screening/run-in period to account for and more closely understand day-to-day Phe fluctuations of participants. If positive safety and efficacy results are established in adults, we plan to then enroll younger patients in subsequent HMI-103 clinical trials. We expect to provide an update on the pheEDIT clinical trial at the end of 2022.

In *in vivo* preclinical studies, we observed Phe reduction following a single I.V. administration of the murine surrogate of HMI-103 in the PKU disease model out to 43 weeks (end of study). In addition, using quantitative molecular methods, we have demonstrated achievement of gene integration efficiencies in a humanized murine liver model that corresponded with Phe correction in the PKU murine model.

HMI-203: Investigational Gene Therapy for the Treatment of Adult Patients with MPS II (Hunter Syndrome)

In October 2021, we announced the initiation of a Phase 1 trial with HMI-203, an investigational gene therapy in development for the treatment of adults with Hunter syndrome. Hunter syndrome is a lysosomal storage disorder caused by mutations in the iduronate 2-sulfatase, or *IDS*, gene leading to absent or deficient I2S enzymatic activity, which causes toxic lysosomal accumulation of glycosaminoglycans, or GAGs. The juMPStart clinical trial is an open-label, dose-escalation study evaluating the safety and efficacy of a single I.V. administration of HMI-203, and is expected to enroll up to nine male patients ages 18-30 years old who have been diagnosed with Hunter syndrome and are currently receiving enzyme replacement therapy, or ERT. Qualitative data on unmet medical needs obtained from ERT-treated adult MPS II patients and/or their caregivers helped inform our trial design. Patients and caregivers reported that weekly ERT infusions, surgeries and supportive therapies inadequately address range of motion and mobility, pain, and hearing loss, that there are burdens associated with ERT and other therapies, including frequency and duration of treatment, and painful and extended recoveries, that there is a high degree of anxiety regarding prognosis, longevity, need for more invasive surgeries, and financial challenges and that the expectations for a potential one-time gene therapy include the ability to maintain their current quality of life with ERT independence. Also, key opinion leaders surveyed supported our planned design for the juMPStart clinical trial, including our plan to discontinue ERT.

In addition to safety endpoints, the trial will measure plasma I2S activity, urinary GAG levels and other peripheral disease endpoints. We expect to provide an update on the juMPStart clinical trial at the end of 2022.

In preclinical studies, a single I.V. administration of HMI-203 resulted in robust biodistribution and human I2S enzyme expression, leading to significant reductions in heparan sulfate GAG levels in the cerebrospinal fluid, brain, liver, heart, spleen, lung and kidney, compared with the vehicle-treated disease model. HMI-203 also led to significant reductions in skeletal deformities compared with vehicle.

Earlier-Stage Product Candidates

In August 2021, we named a clinical development candidate for PNH, HMI-104, from our GTx-mAb platform. This platform represents an additional way that we are leveraging our AAVHSCs in an effort to deliver one-time *in vivo* gene therapy to express and secrete antibodies from the liver, which we believe may allow us to target diseases with larger patient populations.

We completed Investigational New Drug Application, or IND, -enabling studies with HMI-202, an investigational gene therapy in development for the treatment of patients with MLD. We have generated preclinical data that demonstrate that a single I.V. administration of HMI-202 crossed the blood-brain and blood-nerve-barriers and led to sustained reduction of sulfatides in all brain regions of the disease model. We are applying the learnings from the IND-enabling studies to further optimize an HMI-202 vector that we believe may lead to a better therapeutic profile.

Manufacturing

On March 10, 2022, we closed our previously announced transaction with Oxford Biomedica plc, or Oxford, to establish Oxford Biomedica Solutions LLC, a high-performing, full-scope AAV vector manufacturing company that will offer global pharmaceutical and biotechnology clients innovative manufacturing expertise in AAV and lentiviral-based cell and gene therapies. The new company incorporates our proven 'plug and play' process development and manufacturing platform, as well as our experienced team and high-quality GMP vector production capabilities that we built and have been operating since 2019. Under the terms of the agreement, we contributed our manufacturing team of 125 experts, our manufacturing facility and equipment, manufacturing-related intellectual property and know-how and certain other assets. Oxford paid us a $130.0 million upfront payment and invested $50.0 million to fund the new company in exchange for an 80-percent ownership stake, while we own 20 percent of the new company. Our agreement with Oxford establishes us as a preferred client of the new manufacturing company with the goal of reducing our costs while maintaining process development and manufacturing capabilities and dedicated manufacturing capacity to support our product candidates, while jointly continuing to advance innovations in AAV manufacturing. See “Manufacturing—Oxford Biomedica Solutions Transaction” below and Note 18 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our agreement with Oxford.

Management Team and Cash Raised

Our management team has a successful track record of discovering, developing and commercializing therapeutics with a particular focus on rare diseases. We have a robust intellectual property portfolio with issued composition of matter patents in the United States for our family of 15 AAVHSCs and we believe the breadth and depth of our intellectual property is a strategic asset that has the potential to provide us with a significant competitive advantage. We continue to build on our intellectual property estate through our ongoing product and platform-development efforts.

Since our inception in 2015, we have raised approximately $721 million in aggregate net proceeds through our initial public offering, or IPO, in April 2018, follow-on public offerings of common stock in April 2019 and April 2021, proceeds from the sale of common stock under an “at-the-market” sales agreement, equity investments, preferred stock financings and our newly announced agreement with Oxford. Included in our net proceeds is a $130.0 million up-front cash payment from our agreement with Oxford, $50.0 million from Novartis Institutes of BioMedical Research, Inc., comprised of an up-front payment of $35.0 million and a $15.0 million equity investment, and a $60.0 million equity investment from Pfizer Inc., or Pfizer, through a private placement transaction. We will require additional capital in order to advance our product candidates through clinical development and commercialization. We believe our compelling preclinical data, positive clinical data with HMI-102, scientific expertise, product-development strategy and robust intellectual property position us as a leader in the development of genetic medicines.

Our Opportunity in Genetic Medicines

We are currently focused on monogenic diseases where the genetic abnormality is known to occur in a single gene. The majority of monogenic diseases harbor thousands of individual mutations within the diseased gene, each resulting in a loss of function. Adding a functional gene to the cell where there is a missing or mutated gene, replacing an entire diseased gene with a whole functional gene, or expressing an antibody to address the underlying genetic disease mechanism, are the optimal therapeutic approaches for addressing these monogenic disorders. This can be accomplished either through a method of gene therapy called gene transfer in slowly or non-dividing cells, or through a method of gene editing called gene integration in rapidly dividing cells.

The current focus of most nuclease-based gene editing companies is gene knockout, or knocking out a diseased gene to prevent the expression of an undesired protein. Since gene knockout does not result in a fully-corrected gene, this method can only potentially address the minority of monogenic diseases where a diseased protein requires knock-down or inactivation. Our HR-driven gene editing approach aims to achieve functional gene integration into the patient’s genome and potentially address the majority of monogenic diseases by replacing an entire diseased gene with a whole functional gene. Our gene therapy approach, on the other hand, seeks to introduce a functional copy of a defective gene into a patient’s own cells, but not incorporate such copy into the patient’s genome. This method results in the expression of the therapeutic protein of interest without changing the genome.

DNA Repair Pathways

Human cells harbor two primary independent pathways to maintain the integrity of DNA: homologous recombination, or HR, and non-homologous end joining, or NHEJ, which are described below:

- ***HR*** is a process in which cells repair DNA through highly precise incorporation of correct DNA sequences that are homologous, or matching, to the site of damage. HR has evolved to repair DNA with high fidelity and avoids the introduction of unwanted mutations at the site of correction. In the late 1990s, researchers discovered that certain AAV vectors delivered long single strands of homologous DNA to specific regions in the genome and induced the HR pathway, but their low efficiency of approximately 1% limited their use as a viable option for *in vivo* therapeutics.
- ***NHEJ*** is a less selective, error-prone process that rapidly joins the ends of broken DNA resulting in a high frequency of insertions or deletions at the break site. The discovery of nuclease-based gene editing technologies provided researchers with novel tools to specifically introduce DNA breaks into the genome. Despite high potential for error, the majority of nuclease-based gene editing approaches primarily utilize the NHEJ pathway.

We believe the major limitation of nuclease-based gene editing is the preferential utilization of the error-prone NHEJ pathway instead of the HR pathway. Because of this preference, the greatest utility of nuclease-based gene editing technologies may lie in their ability to knockout genes rather than replace an entire diseased gene in the genome with a whole functional copy. Furthermore, the use of nuclease-based gene editing technologies for insertion of a corrective sequence carries the risk of unwanted mutations from NHEJ including insertions and deletions or opposite orientation insertion of the template DNA, and also requires the separate delivery of both the nuclease and the DNA template to the same location at the same time.

We believe the unique characteristics of our genetic medicines platform will allow us to focus on the HR pathway, enabling precise nuclease-free gene integration with improved efficiency and a broader set of disease targets.

Our Approach

Our product-development strategy is to continue to develop in parallel both gene therapy and gene editing modalities, and to choose the method we believe is best suited for each disease we pursue, based on such factors as the targeted disease biology, the biodistribution of our AAVHSCs to key tissues, and the rate of cell division the tissues exhibit, all while initially leveraging the experience from our gene therapy modality to further advance our gene editing modality. Refer to Figure 1 below for a graphical depiction of our platform.

Modality (*in vivo*)	GENE THERAPY	GTx-mAb	NUCLEASE-FREE GENE EDITING
Target	Slowly or Non-Dividing Cells	Slowly or Non-Dividing Cells	Dividing Cells
Method	Gene Transfer to Express Therapeutic Proteins *Does not integrate into DNA*	Gene Therapy to Produce Antibodies Throughout the Body	Gene Integration to Replace Entire Diseased Gene with Whole Functional Gene

Figure 1. Our Genetic Medicines Platform.

Our novel AAVHSCs are packaged with either a gene therapy or a gene editing construct. Our gene therapy construct includes a functional copy of the gene and a promoter sequence that is designed to enable the gene to be turned on in the cell and ultimately transcribed to express the therapeutic protein of interest without integrating into the genome. Our gene editing construct includes lengthy guide sequences, or homology arms, which are designed to enable the specific alignment to the desired genomic location and then, through the natural process of HR, enable correction of the diseased gene in the genome by replacement with a whole functional copy. While others are working on identifying and testing ways to mitigate the inherent risk in working with nucleases for gene editing, our approach avoids the use of nucleases entirely. By targeting the HR pathway, our proprietary AAVHSCs mitigate the risks of nuclease-based technologies and have the potential to overcome other AAV vector limitations by combining the precision and high fidelity of HR with highly efficient *in vivo* gene integration, which we believe is capable of providing potential cures for a wide range of rare genetic diseases. Refer to Figure 2 below for a graphical depiction of how our AAVHSCs are designed to enable each therapeutic modality.

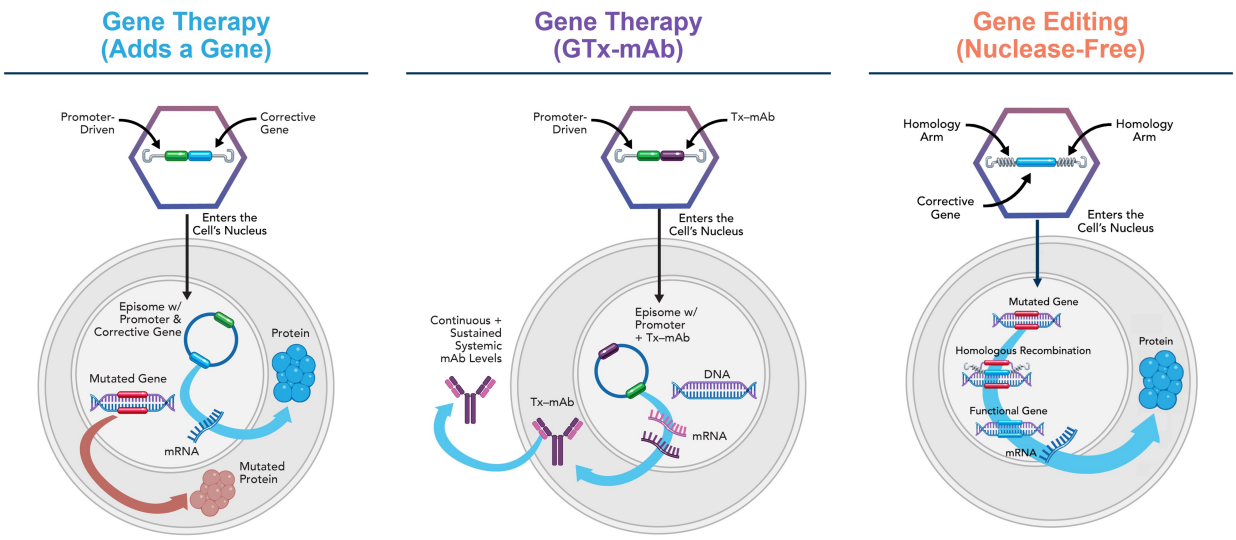


Figure 2. How our AAVHSCs are designed to enable each therapeutic modality.

We believe our approach has several key advantages, including:

- ***Our proprietary AAVHSC platform enables both gene therapy and gene editing modalities.*** Our platform provides us the flexibility to deliver genetic medicines through the best suited modality from either gene therapy or gene editing for each disease we pursue, based on such factors as the targeted disease biology, the biodistribution of our AAVHSCs to key tissues, and the rate of cell division the tissues exhibit. Our AAVHSCs are naturally occurring as they were originally isolated from normal human CD34 cells and have the potential to result in an improved safety profile.
- ***Ability to perform nuclease-free gene editing mediated by HR with high gene integration efficiency.*** Our family of 15 novel AAVHSCs are designed to enable us to take advantage of the precise and high-fidelity process of HR-directed gene insertion for nuclease-free gene editing while achieving gene integration efficiencies that we believe are in therapeutic ranges and significantly higher than both nuclease-based and other AAV-based approaches. While nuclease-based gene editing technologies have achieved high gene knockout efficiencies in preclinical studies, which is only potentially useful for the minority of monogenic diseases, they have shown limited published evidence of gene integration efficiencies to date.
- ***Ability to introduce an entire gene into the genome or the precise repair of individual mutated nucleotides in addition to gene knockout.*** Our HR-based gene editing approach provides the flexibility to introduce an entire copy of a functional gene into the genome also known as gene integration, in addition to repairing single mutations or knocking out entire genes, thus allowing us to potentially address the significant majority of monogenic diseases.
- ***High precision and lack of unwanted off-target or on-target DNA modifications.*** Our gene editing approach leverages HR, which makes DNA repairs with high fidelity, and enables us to precisely perform gene integration without unwanted off- and on-target modifications. Furthermore, we are able to directly measure and confirm those modifications throughout the entire genome to ensure only the intended changes are made.
- ***Ability to target multiple tissues.*** In preclinical studies, intravenous administration of our family of AAVHSCs has demonstrated unique biodistribution properties across the serotypes and the ability to target a wide variety of tissues including the liver, CNS, PNS, muscle, bone marrow, eye and heart, enabling us to potentially address a broad range of monogenic diseases. The diversity of our AAVHSC library of capsids can also be expanded through targeted shuffling of the capsid sequences.
- **In vivo *administration with a single component delivery system.*** Our platform is designed to perform gene editing at high efficiency without the use of a nuclease, enabling us to deliver genetic medicines *in vivo* using a single vector system that contains everything required to edit DNA. These characteristics simplify the manufacturing and delivery of our therapeutic candidates relative to existing nuclease-based gene editing approaches.

- ***Ability to target a broad range of patients given low frequency of pre-existing neutralizing antibodies.*** We believe our AAVHSCs can target a broad range of patient populations given the low prevalence of pre-existing neutralizing antibodies relative to other AAV vectors.

Our Pipeline Strategy

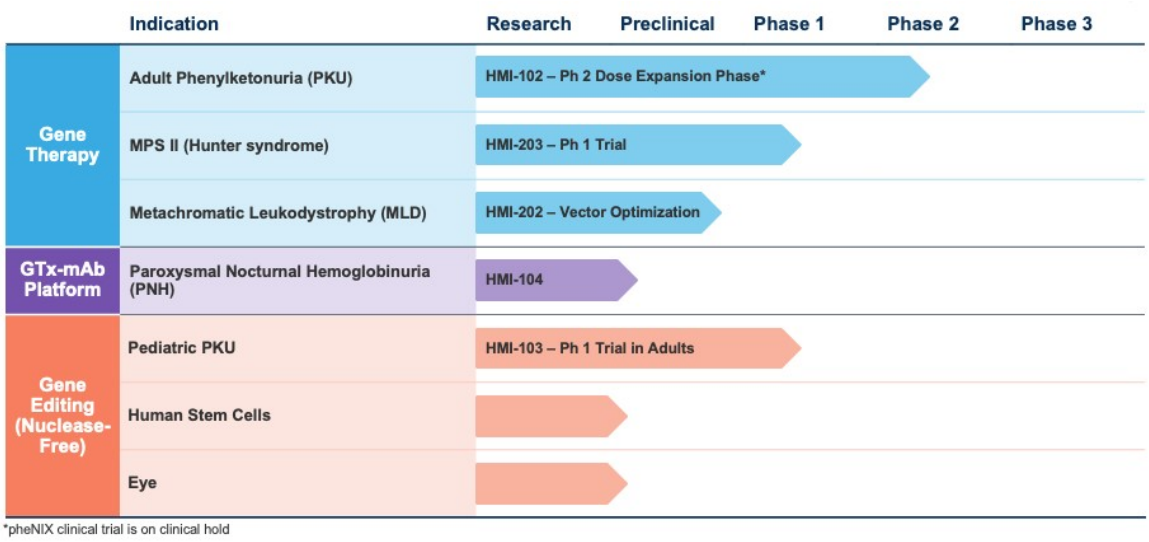
We believe our genetic medicines platform can be applied broadly to treat and potentially cure a wide range of genetic diseases, and we have carefully designed and prioritized our pipeline strategy to maximize this opportunity. We are initially pursuing monogenic diseases where we know exactly what we are seeking to correct and exactly which gene to insert into patients' cells, including delivery via our GTx-mAb platform to express and secrete antibodies from the liver. We are prioritizing monogenic diseases with significant unmet medical needs, validated regulatory pathways, well-accepted biomarkers and significant commercial opportunities. We are currently focused on developing product candidates to treat monogenic diseases in the liver, CNS and peripheral tissues, bone marrow, and the eye, given that our AAVHSCs naturally show a high degree of tropism or ability to enter cells in these organs and organ systems. These tissues are affected in many rare genetic diseases.

Our initial focus areas include developing product candidates for intracellular, inborn errors of metabolism and other genetic conditions that are especially well-suited to correction by our gene editing or gene therapy methods. In slow- or non-dividing cells (e.g., CNS and adult liver cells), gene therapy can potentially be curative, while rapidly dividing cells (e.g., hematopoietic CD34+ cells and pediatric liver cells) require a gene editing approach to provide a permanent correction in the genome that can be replicated with each cell division. We are purposefully deploying our proprietary AAVHSCs in certain indications first with a gene therapy approach followed by a gene editing approach, in order to maximize the likelihood of translating our platform into widespread clinical and commercial success.

We are building a deep pipeline across a wide range of diseases and tissue types to leverage the broad potential of our platform. We believe we have validated our AAVHSC platform in the liver based on the results observed in the dose-escalation portion of our Phase 1/2 trial with HMI-102, and we have also initiated a Phase 1 trial with HMI-103, a gene editing development candidate for pediatric PKU. We have completed a comprehensive *in vivo* biodistribution study in NHPs in which all 11 of the AAVHSCs tested crossed the blood-brain-barrier and the blood-nerve-barrier, we have initiated a Phase 1 trial with HMI-203, a gene therapy development candidate for MPS II, or Hunter syndrome, are advancing a development candidate for PNH, HMI-104, from our GTx-mAb platform through IND-enabling studies and we are further optimizing our HMI-202 vector that we believe may lead to a better therapeutic profile for the potential treatment of MLD. We continue our discovery efforts across multiple targets, including the liver, CNS, human stem cells and ophthalmology. We also may selectively enter into strategic alliances with pharmaceutical or biopharmaceutical companies to expand indications and accelerate development of programs where collaborators can contribute further disease-specific expertise to our platform.

Our Product Pipeline

The current status of our programs is summarized in the table below:



*pheNIX clinical trial is on clinical hold

Our Strategy

Our goal is to transform the lives of patients suffering from severe genetic diseases by using gene therapy and gene editing to cure the underlying cause of the disease. The critical components of our strategy to achieve this goal include:

- ***Transform the treatment paradigm for rare genetic diseases with the delivery of single-administration curative therapies.*** Utilizing our proprietary AAVHSCs, we intend to deliver genetic medicines *in vivo* via a single administration to address the underlying genetic problem in a given disease. For each of the programs in our pipeline, we have identified the mutations of a specific gene that we believe can potentially be addressed by introducing a functional copy of a defective gene via gene therapy, or by replacing an aberrant gene with a healthy one via HR-driven gene integration, resulting in specific integration into the patient's genome. Our genetic medicines platform allows us to choose the best suited modality for each disease we pursue, and we believe our nucleaise-free editing approach will provide life-long clinical benefits for patients.
- ***Advance our pipeline programs through clinical proof-of-concept and commercialization.*** We are continuing to advance the pheNIX clinical trial with investigational HMI-102 gene therapy for adults with PKU at multiple sites in the U.S. In October 2021, we announced that both doses from the dose expansion Phase 2 portion of the pheNIX trial have been generally well-tolerated and have shown evidence of biological activity, including clinically meaningful reductions in Phe levels, increases in Tyr and reductions in the Phe-to-Tyr ratio. On February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold due to the need to modify risk-mitigation measures in the study in response to observations of elevated LFTs. On March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated LFTs observed in some patients in the trial and modified clinical risk-mitigation measures. In patients who experienced elevated LFTs, all have resolved and no hospitalizations were required. Among the risk-mitigation methods that we intend to propose is a new, more targeted immunosuppressive regimen that is shorter in duration and includes a T-cell inhibitor used in combination with a steroid-sparing regimen that may improve patient compliance. The use of T-cell inhibitors has been shown to be effective in dampening the anticipated immune response to AAV capsids. With the additional information requested by the FDA and the planned conversion to a more targeted immunosuppressive regimen, we estimate that we will require more time to submit and receive feedback on our proposed clinical risk-mitigation strategy. Also in October 2021, we announced the initiation of a Phase 1 trial with HMI-103, our lead gene editing candidate in development for the treatment of classical PKU. We believe our approach of initially utilizing one of our AAVHSCs for gene therapy in adult PKU patients while, in parallel, advancing gene editing for pediatric PKU patients will maximize the efficiency of our pipeline development while providing potential solutions for the unique needs of each particular PKU patient population. Given the

well-defined nature of PKU and the concentration of treatment centers, we intend to bring HMI-102, if approved, to patients through a small, targeted internal commercial organization. Finally, in October 2021, we announced the initiation of a Phase 1 trial with HMI-203, an *in vivo* investigational gene therapy in development for the treatment of adults with Hunter syndrome, a lysosomal storage disorder.

- ***Continue to expand our pipeline within existing therapeutic areas and expand into new therapeutic areas.*** We are focused on applying the transformative potential of our genetic medicines platform to develop treatments for patients with monogenic diseases. Initially, we are targeting diseases occurring in the liver, the CNS and PNS, the eye and the hematopoietic system as well as targeting the liver for the expression of therapeutic antibodies. Given the ability of our AAVHSCs to deliver to a wide range of disease-relevant tissues, we believe there are many additional indications for which our technology may be applicable, including other inborn errors of metabolism, lysosomal storage diseases, hematological diseases, and ophthalmic diseases, as well as for *in vivo* cell therapy. We may also choose to selectively collaborate to expand the indications we can pursue and accelerate development of programs where collaborators can contribute further disease-specific expertise to our platform.
- ***Strengthen our platform by leveraging our discovery and development capabilities and selectively collaborating.*** We are committed to investing in our research and development activities to expand the capabilities of our platform, specifically our AAVHSCs as well as HR gene editing technology. We are optimizing our AAVHSC genetic medicines platform with focused efforts on AAVHSC characterization, gene therapy and editing construct design and screening, and genomic assays to characterize and quantify our editing technology. To augment our own efforts, we intend to continue to collaborate with academic institutions to pursue new scientific and therapeutic insights and strengthen our position as a leader in gene integration.
- ***Continue to leverage our manufacturing capabilities.*** We have fully integrated process development and GMP manufacturing capabilities that support the full breadth and flexibility of our AAVHSC capsid library. We have developed a process development platform that accommodates both gene therapy and gene editing technologies. We have executed our manufacturing platform with multiple product candidates at the 2,000-liter bioreactor scale. In January 2022, we announced an agreement with Oxford to establish a new AAV vector manufacturing company that incorporates our proven 'plug and play' process development and manufacturing platform, as well as our experienced team and high-quality GMP vector production capabilities that we built and have been operating since 2019. The related transactions closed on March 10, 2022. We will continue to leverage these process development and manufacturing capabilities while reducing our costs and maintaining dedicated manufacturing capacity to support our product candidates. We believe the quality, reliability and scalability of our gene therapy and gene editing manufacturing approach is a core competitive advantage crucial to our long-term success.
- ***Continue to strengthen and expand our intellectual property portfolio.*** We have exclusive worldwide rights to our technologies including issued composition of matter patents in the United States for 15 of our novel AAVHSCs for both gene therapy and gene editing. We exclusively acquired rights to this foundational intellectual property for the AAVHSCs from City of Hope, or COH, for developing and commercializing therapeutics based on these vectors. We continue to focus on strengthening our intellectual property estate through the discovery of new AAVHSCs, further characterization around our existing AAVHSCs as well as the core technology involved in delivering our product candidates to patients. To further advance our leadership in gene therapy and nuclease-free gene editing, we actively explore opportunities to collaborate with other leading scientific institutions in the field.

Our Genetic Medicines Platform

Our proprietary genetic medicines platform is built on our novel AAVHSCs, which allow us to choose the best suited modality from either gene integration or gene therapy for each disease we pursue, based on such factors as the targeted disease biology, the biodistribution of our AAVHSCs to key tissues, and the rate of cell division the target tissues exhibit. The unique characteristics of our platform enable nuclease-free gene editing, specifically gene integration, and broad, systemic tissue distribution. Our AAVHSCs are designed to directly integrate corrective DNA through HR with therapeutically relevant efficiencies. Our HR-based gene editing approach utilizes a single component AAV system that contains everything required to selectively edit DNA with no need for exogenous nucleases or editing machinery. This single-component system simplifies the manufacturing and delivery of our therapeutics. We believe our gene editing approach has the potential to be curative as it provides a permanent correction in the genome that is then replicated with each cell division so that new generations of cells will carry the corrected gene. Our AAVHSCs are naturally occurring and have been modified to be non-replicating to minimize

potential safety issues. We believe our platform's combined attributes will allow us to develop more efficient and safer therapeutics for a wide range of genetic diseases.

Homologous Recombination—A Powerful Basis for Gene Editing

Unlike other gene editing approaches, our technology is based on the natural DNA repair process of HR and is designed to enable precise and efficient gene integration without an exogenous nuclease.

Our genetic medicines platform induces the endogenous HR cellular process using our AAVHSCs to insert replacement or corrective genes into cells that contain mutated or deleterious genes (refer to Figure 3 below). We engineer our AAVHSCs to contain long, single-stranded DNA corrective sequences highly specific to the target region in the genome. These single-stranded DNA molecules are then delivered to cells in our AAVHSC vectors, which we believe results in precise and efficient gene integration via the HR pathway. The design of our long and specific sequences, up to the 4.7 kilobase packaging limit of our AAVHSCs, is intended to significantly reduce the risk of off-target integration. Based on the packaging size of our AAVHSCs, we believe our capsids are capable of accommodating and delivering up to approximately 85% of the genes in the human genome and thus have the ability to address a significant majority of genetic disorders. We typically use homology arms as long as 1,600 base pairs of DNA to target corrective gene sequences into precise regions of the genome, in contrast to the guide sequences used in CRISPR/Cas 9-based gene editing, which are typically less than 30 base pairs in length. We also benefit from the ability of our platform to utilize HR to precisely insert gene sequences into the DNA of cells, similar to how mammalian cells repair their own DNA. In order to bring about the excision and subsequent replacement that some forms of gene editing require, those other approaches must combine multiple additional techniques and deliver into the cell the requisite cellular machinery at the right place at the same time, increasing the complexity of the task, introducing the possibility of integrating the wrong DNA due to non-HR-based repair mechanisms, and reducing the likelihood of success.

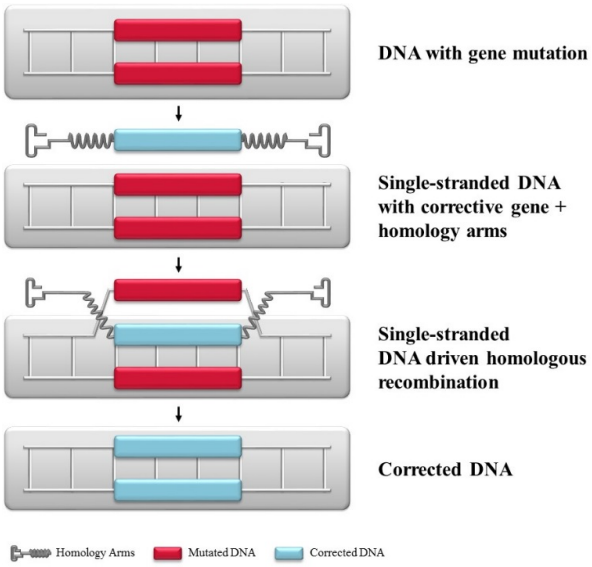


Figure 3. Schematic of homologous recombination.

Our Proprietary AAVHSCs

Our genetic medicines platform is based on a family of 15 proprietary AAVHSCs which we can deploy with either gene therapy or gene editing constructs. We have the opportunity to expand on this family through capsid shuffling. Both applications rely on the unique ability of our AAVHSCs to efficiently target multiple tissues in the body. Our AAVHSCs were isolated from human stem cells, and we believe they can direct nuclease-free gene integration with higher efficiency relative to that indicated in published data for other AAV-based gene editing approaches. Our AAVHSCs display the following advantages:

Single AAVHSC Platform for Both Gene Therapy and Gene Editing Modalities

Our platform provides us the flexibility to deliver genetic medicines through the best suited modality from either gene therapy or gene editing for each disease we pursue, based on factors such as the targeted disease biology, the biodistribution of our AAVHSCs to key tissues, and the rate of cell division the tissues exhibit.

Ability to Perform In Vivo *Nuclease-free Gene Editing Mediated by HR*

To demonstrate the utility of AAVHSC-mediated gene editing *in vivo*, we conducted a series of experiments at our headquarters. We obtained preclinical proof-of-concept for *in vivo* editing efficiency and tissue-specific expression through the design of a promoter-less luciferase construct targeting the murine Factor 8, or *F8*, locus using AAVHSC15. *F8* is a locus in the murine genome that is known to have a strong promoter but is expressed only in the liver. The editing cassette was flanked by 800bp homology arms with sequences homologous to an insertion site within intron 6 of the murine *F8* gene. The expression cassette (hereafter mF8-Luc) also included a canonical splice acceptor sequence for splicing into the endogenous *F8* transcript and a ribosomal skipping 2A element for independent translation of the *F8* and luciferase proteins. The luciferase transcript was terminated by an SV40pA element.

AAVHSC15 packaging the promoter-less F8 targeting cassette (AAVHSC15-mF8-Luc) was administered by a single intravenous injection to albino-B6 mice to evaluate the level of targeted integration and expression from the murine *F8* locus. Six- to seven-week-old albino-B6 mice were dosed with AAVHSC15-mF8-Luc and reporter expression was followed over time. High levels of lumanciferase expression in livers of mice transduced under these conditions were observed. Bioluminescence increased within a week post-dosing, reached a maximum within 1-2 months and remained significantly above that observed in vehicle-treated mice until the end of the study at 470 days post-dosing (*= P<0.0001 vs vehicle). *Ex vivo* imaging of tissues harvested on Day 470 showed highest luciferase expression within liver (*=p<0.008 vs vehicle), greater than 100-fold higher than other tissues assessed (**=P<0.0001 vs other tissues), which demonstrated specificity of tissue targeting by AAVHSC15-mF8-Luc (refer to Figure 4 below). At 470 days post-dosing, vector genome levels within livers of treated mice were on average 4.7 ± 2.7 vector genomes/allele.

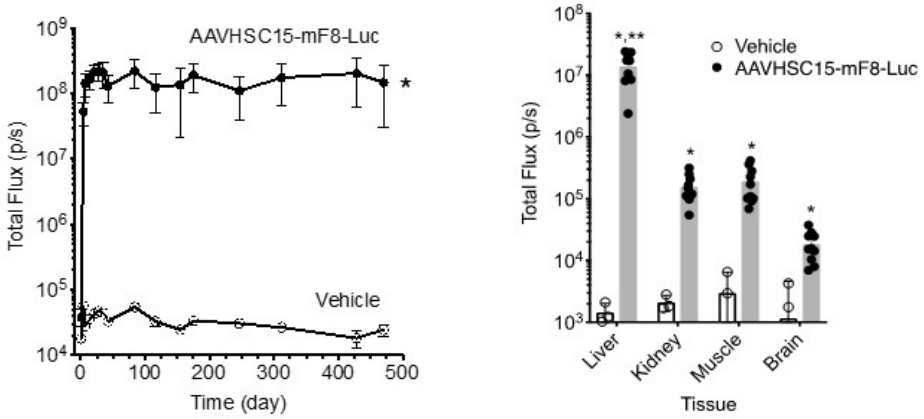


Figure 4. *In vivo* gene editing proof-of-concept at the murine F8 locus.

To molecularly characterize AAVHSC15-mF8-Luc-mediated genome editing, a ddPCR-based quantitative F8 editing assay was established. A combination of an F8 locus specific primer and probe and editing vector specific primer and probe in the FAM and HEX channel, respectively, were used to calculate the fraction of F8 loci that have an inserted luciferase transgene. Editing signal in this assay showed linear detection between 0 and 30% allele frequencies based on a standard curve of known molar ratios of edited/unedited alleles. Assay signal was specific as digestion of input DNA with HindIII prior to the ddPCR assay separated the payload from the genomic reference, causing each target to segregate independently within each droplet eliminating the editing signal.

Genomic DNA was isolated from livers of treated mice at termination of the study at 470 days post-dosing and editing of the murine F8 locus was assessed by the ddPCR editing assay. Mice treated with AAVHSC15-mF8-Luc at this initial low dose of 5e12 vg/kg showed a statistically significant increase in genome editing efficiencies with up to 2.8% of alleles edited (mean 0.8% of alleles edited with a range of editing efficiencies 0.2-2.8%; p<0.03 vs. vehicle). These data demonstrate that AAVHSC15 mediated long-term *in vivo* editing of the targeted locus within the liver of mice at this dose.

To assess whether expression from AAVHSC15-mF8-Luc was episomal, an AAVHSC15-Luc editing vector was prepared with the splice acceptor sequences removed (designated AAVHSC15-Δ2AmF8-Luc) but maintained an intact Met initiator codon. Relative to an IV injection of vehicle alone, injection of AAVHSC15-mF8-Luc increased luciferase expression at Days 3, 7, and 14 post-dosing, similar to the results described above. By contrast, luciferase expression was reduced >95% for mice that received an identical dose of AAVHSC15-Δ2AmF8-Luc (refer to Figure 5 below).

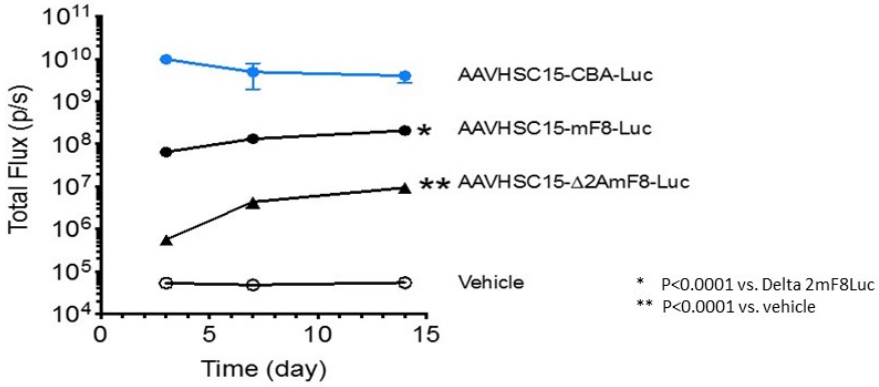


Figure 5. *In vivo* gene editing proof-of-concept at the murine F8 locus.

Ability to Introduce Entire Gene into the Genome Mediated via HR

Initial data supporting the targeted integration of entire genes using AAVHSCs into the genome have been previously published. We have expanded on those initial studies by demonstrating the targeted integration of a full-length luciferase gene into the murine F8 locus, as described above and illustrated in Figures 4 and 5. This preliminary proof of principle led to the discovery and development of a therapeutic program for pediatric PKU focused on the targeted integration of a full-length *PAH* cDNA into the human *PAH* locus. We have successfully inserted full-length cDNA encoding luciferase and PAH into two separate genomic regions *in vivo* reaching levels of efficiency required for therapeutic efficacy. HMI-103, the development candidate for pediatric PKU, is described in detail below.

The ability to introduce entire genes specifically into the genome at these efficiencies provides an opportunity to target multiple monogenic diseases where the correction of a defective gene would result in therapeutic benefit. Given that a majority of monogenic diseases harbor mutations that render the gene inactive, we believe our gene integration modality can be expanded well beyond our initial focus on liver-based inborn errors of metabolism.

High Precision and Lack of Unwanted Off-target or On-target DNA Modifications

Using next-generation sequencing technologies, we have developed methodologies to test for on-target mutations at the site of integration. Using these methods, we observed that HR using our AAVHSCs is very precise at the site of correction. We did not detect any co-incident random mutations at or above our lower limit of detection (0.5%) or inverted terminal repeat, or ITR, sequences at the site of integration.

We developed a method to enable whole genome unbiased next-generation sequencing for the detection and mapping of off-target integration sites. By leveraging the potential ability of our AAVHSCs to drive HR-based targeted integration, we can utilize next-generation sequencing technologies to identify and quantify where the inserted sequence maps. Using this method, and testing integration into the human AAVS1 locus, we estimate that 99.967% of insertions (>2.2 million reads) are at the targeted site and that the balance is within expected background of the assay. We have expanded on this assay to characterize the on-target precision of integration at the *PAH* locus in support of HMI-103, described below.

Ability to Target Multiple Tissues

In preclinical studies, intravenous administration of our family of AAVHSCs has demonstrated the ability to target a wide variety of tissues including the liver, CNS, PNS, muscle, bone marrow, eye and heart. Specifically, we have generated evidence of our AAVHSCs' ability to target a number of tissues including:

- neurons throughout the brain, spinal cord, and dorsal root ganglion by crossing the blood-brain-barrier and the blood-nerve-barrier;
- retinal ganglion cells and neurons of the retinal outer nuclear layer; we have also demonstrated the ability to target retinal tissue via intravenous injection as well as multiple layers of target cells, including photoreceptors, retinal pigment epithelial cells and horizontal cells, through sub-retinal injection;
- skeletal muscle myocytes in all skeletal muscle tissues examined, including gastrocnemius, soleus, diaphragm, esophagus, and biceps;
- cardiomyocytes throughout the heart; and
- extensive liver tropism.

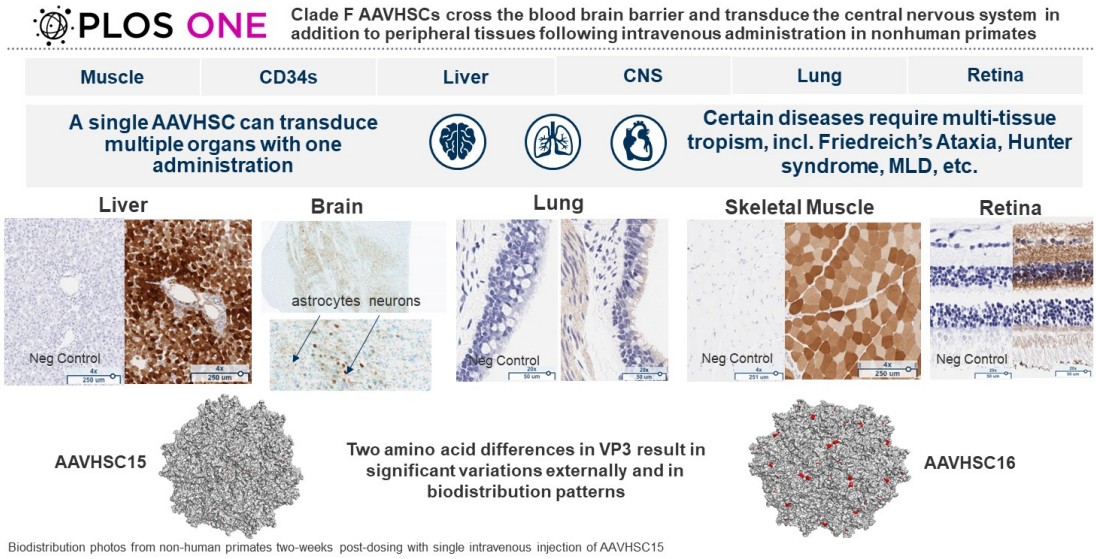


Figure 6. Our family of AAVHSCs has demonstrated the ability to target a wide variety of tissues.

In Vivo *Administration with a Single Component Delivery System*

Our platform is designed to perform gene integration at higher efficiency without the use of a nuclease, enabling us to deliver genetic medicines *in vivo* using a single vector system (refer to Figure 7 below). Existing nuclease-based gene editing technologies, when replacing a defective gene with a functional gene through gene editing, require the use of two or more different vector constructs in combination to perform their gene editing functions. One or more vector constructs house the nuclease, and the other vector construct houses the DNA template, and all vectors must reach and penetrate the specific target cell at the same time to edit the DNA. In contrast to these nuclease-based gene editing technologies, our AAVHSC technology is a single component system that contains everything required to selectively integrate DNA with no need for additional exogenous nucleases, template DNA or editing machinery.

We believe our ability to perform gene integration at efficiencies that are greater than both nuclease-based and other AAV-based approaches, coupled with our single component delivery system, enable us to administer genetic medicines *in vivo*. We believe the advantages of *in vivo* administration of therapeutics via a single component delivery system include the following:

- simpler and faster manufacturing relative to *ex vivo* resulting in reduced manufacturing costs;
- improved delivery of therapeutic as only a single vector is required to reach a cell instead of multiple vectors;
- ease of use for the patient, eliminating the need for mobilization and myeloablation, a common requirement for many *ex vivo* gene editing therapies; and
- improved safety profile, as compared to an *ex vivo* therapy.

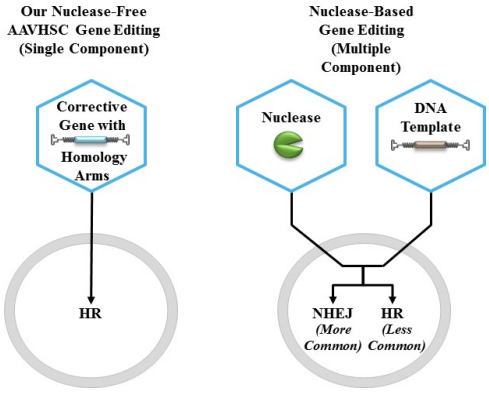


Figure 7. Our nuclease-free AAVHSC single component gene editing construct vs. nuclease-based multiple component gene editing construct for gene editing applications.

Ability to Target a Broad Range of Patients Given Low Frequency of Pre-Existing Neutralizing Antibodies

A potential concern for all AAV vectors is the presence of pre-existing neutralizing antibodies that have the potential to reduce their effectiveness. We conducted a study across 100 human serum donors representing different ethnic segments of the U.S. population. Based on the initial results, we believe the findings suggest that approximately 80% of individuals lack antibodies that recognize AAVHSCs, which is comparable to AAV9, a commonly used vector for development of other gene therapies. These findings were published in *Human Gene Therapy Clinical Development* in March 2018.

Our Product Candidates

We believe our genetic medicines platform can be applied broadly to treat and cure a wide range of genetic diseases and have carefully designed and prioritized our pipeline strategy to maximize this opportunity. We are initially pursuing diseases where the genetic abnormality is known and is found in a single gene.

HMI-102 for Treatment of PKU in Adult Patients and HMI-103 for Treatment of PKU in Pediatric Patients

Our lead program, HMI-102, is an AAVHSC vector gene therapy candidate designed to treat PAH deficiency, the underlying genetic cause of PKU. We have received orphan drug designation from the FDA and the European Commission for the use of AAVHSC15 expressing *PAH* for the treatment of PAH deficiency. In June 2019, we commenced enrollment of our Phase 1/2 pheNIX clinical trial with HMI-102 gene therapy for adults with classical PKU at multiple sites in the U.S. and reported positive clinical data in November 2020. We are currently in the dose expansion Phase 2 portion of the pheNIX trial. HMI-102 is intended to treat adult patients with deficiencies in PAH regardless of the specific underlying *PAH* mutation. On February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold and on March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated LFTs observed in the trial and modified clinical risk-mitigation measures.

In October 2021, we announced the initiation of a Phase 1 trial with HMI-103, our lead gene editing candidate in development for the treatment of classical PKU, and we received Fast Track Designation for HMI-103 for the treatment of neurocognitive and neuropsychiatric manifestations of PKU secondary to PAH deficiency. HMI-103 is designed to replace the

defective *PAH* gene through the targeted integration of a normal copy into the *PAH* genomic region. We received orphan medicinal product designation and advanced therapy medicinal product classification from the European Medicines Agency, or EMA, for HMI-103 for PKU.

PKU Disease Overview

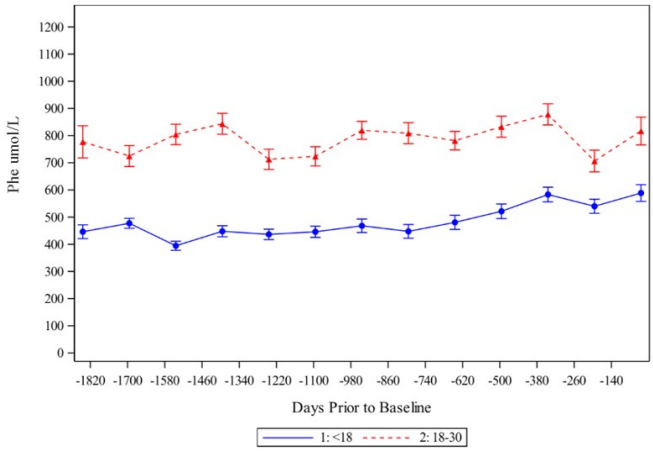
PKU is an inborn error of metabolism that results from mutations in the *PAH* gene. PAH is an enzyme that is normally expressed in the liver and is necessary to metabolize dietary phenylalanine, or Phe, to the amino acid tyrosine, or Tyr. Tyr is a product of Phe metabolism and a precursor to neurotransmitters, and its increase indicates increased enzymatic activity. PKU results from mutations in *PAH* that render its enzymatic activity deficient. If it is not metabolized by PAH, Phe builds up throughout the body, including in the blood and the nervous system. Approximately 75% of all dietary Phe is typically metabolized by PAH, so the absence of PAH leads directly to the pathological excess of Phe as well as a deficiency of Tyr. Excessive blood Phe and low levels of Tyr result in intellectual disability, which is possibly caused by a variety of mechanisms including effects on neuronal development, myelination, and neurotransmitter synthesis. Blood Phe is an easily measurable and translatable biomarker. It is also a validated clinical endpoint in clinical trials for PKU, facilitating both a rapid path to the clinic and characterization of therapeutic response.

Newborns in all 50 states are screened for PKU. It has been estimated that the incidence of PKU in the United States is one in 12,707, which translates to approximately 350 cases per year with an overall prevalence of 16,500. It has also been estimated that the prevalence of PKU in the European Union is 25,000. Worldwide, the estimated prevalence is 50,000 with 1,000 to 1,500 new cases annually.

The majority of patients are identified soon after birth and are primarily treated by dietary restriction of Phe. While Phe-restricted diets have dramatically reduced the intellectual deficiencies associated with this disease, they fail to address the cognitive and behavioral problems that continue throughout a patient's life. Lifetime adherence to a Phe-restricted diet is challenging and blood Phe within the recommended range is not achievable for the vast majority of patients. The inability to achieve recommended levels of Phe results in neurological as well as metabolic problems. Long-term studies in adults identify neurocognitive, psychosocial, quality of life, growth, nutrition, bone pathology and maternal PKU outcomes that are suboptimal despite early and continuous treatment with diet. In a retrospective study of PKU patients peer reviewed and published in the journal of *Molecular Genetics & Metabolism*, young children were adherent to Phe-restricted diet, whereas most adolescents (79%) did not achieve recommended Phe levels, and 88% of adults were no longer on a Phe-restricted diet. Relaxing of dietary restrictions beyond preschool years, or failure to adhere to physician-assigned diets, which is the current guideline for most adolescents and adults, results in loss of metabolic control and wide fluctuations in Phe levels that are both directly associated with progressive neurological damage.

We conducted a five-year retrospective chart review of PKU patients, which confirmed key elements of our proposed Phase 1/2 clinical trial design. Consistent findings from two PKU academic centers of excellence in the U.S. in 152 PKU patients showed that actively monitored patients, including those on restrictive low Phe diet, had Phe levels well-above the recommended threshold of 360 umol/L, based on current U.S. treatment guidelines, underscoring the need for treatments that restore the normal biochemical pathway (refer to Figure 8 below). Furthermore, we confirmed that Phe continues to be higher, even on standard of care, in the classical PKU population, defined as patients with Phe levels greater than 1200 umol/L (66% of

the study population) without treatment, and was significantly elevated in the adult population compared to those patients who were less than 18 years of age. These findings were published in *Molecular Genetics and Metabolism* in December 2019.



	Combined Sites
# Patients	152
% Female / Male	51% / 49%
% Classical PKU	66%
≥18	57%

Figure 8. Retrospective five-year chart review demonstrates actively monitored adult classical PKU patients across two academic centers have Phe levels >700 umol/L.

Current Treatments

There are currently no available treatments that address the core underlying genetic biochemical defect in PKU, the deficiency of PAH.

Saproterin dihydrochloride, or Kuvan, is an FDA-approved therapy to reduce elevations in serum Phe. Saproterin is a synthetic version of BH4, a cofactor that is required for PAH activity. Treatment with BH4 can activate residual PAH enzyme activity, improve the normal oxidative metabolism of Phe, and decrease Phe levels in some patients; however, clinical data suggests that saproterin is not fully effective in lowering high serum levels of Phe back to normal levels and must be used in conjunction with a low Phe diet. Worldwide sales of Kuvan were approximately $286 million in 2021. Generic versions of Kuvan are available in several countries around the world, including multiple generic versions in the U.S.

Pegvaliase, or Palynziq, is a pegylated plant-derived enzyme called phenylalanine ammonia lyase that was approved in the U.S. by the FDA in 2018 and in Europe by the EMA in 2019. This approach does not correct the underlying genetic disorder (PAH deficiency) and will not reconstitute the natural pathway. We believe Palynziq to have certain limitations including that it must be administered via daily injections and its label contains a black box warning that it can cause severe allergic reaction (anaphylaxis) that may be life-threatening and can happen at any time during treatment with Palynziq. The label states that patients must carry auto-injectable epinephrine with them at all times during Palynziq treatment. Patients in its Phase 3 trials did not meet the secondary efficacy endpoints for cognitive benefit. Worldwide sales of Palynziq were approximately $237 million in 2021.

Our Gene Therapy and Gene Editing Approaches to PKU

We are taking two approaches towards developing a potential therapy for PKU. The first is a gene therapy in which a gene construct encoding human *PAH* is delivered to liver cells where it directs production of normal PAH via episomal expression driven off a liver-specific promoter. The second potential therapy involves gene integration of a normal copy of the *PAH* gene into the defective gene of PKU patients. We believe that the gene therapy approach offers an expedited clinical development path towards delivery of a therapeutic to adult and adolescent patients where the majority of target cells are non-dividing in the liver. We believe the gene integration approach would be more suitable in newborn and pediatric patients due to the higher rate of dividing cells as the child grows. The goal of both approaches is to enable production of functional PAH, thus restoring the normal biochemical pathway of Phe metabolism. This can reduce the abnormally high levels of Phe in the blood, while also increasing Tyr levels, the product of PAH-driven Phe metabolism. Using gene editing to correct the defective *PAH* gene in young patients has the potential to provide long-term benefit as the corrected gene will persist as cells replicate. Correcting the gene has the potential to normalize not only Phe levels, but also Tyr levels, the product of the Phe metabolism and a precursor to neurotransmitter synthesis. This may allow affected children to avoid many of the serious neurological consequences associated with PKU.

We believe that an effective gene therapy or gene editing treatment for PKU has the potential to eliminate the need for Phe-restricted diet and may lead to significant improvements in the morbidity and quality of life for patients. Published estimates suggest that restoration of PAH activity to 10% or more of normal levels would lead to significant improvements in serum Phe levels and potentially represent a curative therapy.

HMI-102: Our Gene Therapy Approach for PKU

We identified HMI-102 as our lead product candidate after screening multiple vector constructs. HMI-102 consists of an AAVHSC15 vector containing the coding sequence of human *PAH* under control of a promoter designed to continuously express *PAH*, specifically in the liver. We chose AAVHSC15 as the basis of this product candidate because of its tropism for the liver, the normal site for PAH protein expression.

In June 2019, we commenced enrollment of our Phase 1/2 pheNIX clinical trial with HMI-102, which is designed to evaluate the safety and efficacy of the investigational gene therapy in a randomized, concurrently controlled, dose-escalation study in adult patients aged 18–55 years old with classical PKU. The dose-escalation phase of the trial was designed to evaluate safety and efficacy of ascending doses of HMI-102 to enable the selection of a dose for the randomized, concurrently controlled Phase 2 portion of the trial, which was designed to have the potential to be converted to a registrational trial. We enrolled six patients in the dose-escalation phase across three dose cohorts: low-dose (2E13 vg/kg) Cohort 1, n=2; mid-dose (6E13 vg/kg) Cohort 2, n=2; high-dose (1E14 vg/kg) Cohort 3, n=2.

In November 2020, we reported positive clinical data from the dose-escalation phase of the trial. Safety data from the six patients as of the cutoff date of October 19, 2020, showed HMI-102 was generally well-tolerated, and there were no treatment-related serious adverse events. There were no clinically significant changes in electrocardiogram or vital signs, no clinical signs of complement activation and no adverse events related to bilirubin. Alanine aminotransferase, or ALT, elevations, which are common in AAV-based gene therapy trials, were asymptomatic and managed with increased steroids when necessary. Efficacy data showed significant plasma Phe reductions in Cohorts 2 and 3, compared to Cohort 1 ($P<0.004$ post-hoc comparison using repeated measures MANOVA, or multivariate analysis of variance,/regression analysis), with two patients achieving target Phe levels per treatment guidelines, even while self-liberalizing diet. Compared to baseline, patients in Cohorts 2 and 3 also displayed Tyr increases and Phe-to-Tyr ratio decreases consistent with PAH enzymatic activity.

Efficacy data from the two patients in Cohort 1 did not show any meaningful reductions in plasma Phe throughout the study. We believe this first and lowest dose in this dose-escalation study was insufficient to impact Phe levels. In Cohort 2, one patient experienced a marked Phe reduction from baseline level of 1,010 μmol/L, and recorded five plasma Phe values <360 μmol/L, and many of <600 μmol/L. The mean percentage change from baseline for this patient are reported in three categories: Phe, Tyr, and the Phe-to-Tyr ratio. For patients with PKU, the goal for a therapy is to lower Phe values, increase Tyr values and lower the overall Phe-to-Tyr ratio. As of the cutoff date, this patient's mean percentage change from baseline showed a 48.6% reduction in plasma Phe, an 81.1% increase in Tyr and a 70.8% decrease in the Phe-to-Tyr ratio. We believe these results are consistent with an increase in PAH enzymatic activity and increased Phe metabolism. These results were observed even while the patient self-liberalized diet, including a mean percent change from baseline of more than a 100% increase in dietary Phe intake.

The other patient in Cohort 2 did not experience a similar reduction in plasma Phe, but this patient had pre-existing immune conditions and experienced Grade 3 ALT elevation, which we believe may have affected the results. As of the cutoff date, this patient had a mean percentage change from baseline of 13% increase in plasma Phe, with a 131.1% increase in Tyr and a 45.5% decrease in the Phe-to-Tyr ratio. This also occurred while the patient self-liberalized diet with a mean percent change from baseline of 140.5% more dietary intact protein, 289% more dietary Phe intake and 75.6% decreased dietary Tyr intake. We believe the findings in this patient may be suggestive of PAH enzymatic activity sufficient to increase the patient's Tyr concentration from its low baseline, but not sufficient to reduce this patient's Phe.

In Cohort 3, Patient 5 had pre-existing underlying immune conditions, which we believe impacted efficacy. As of the data cutoff date, Patient 5 experienced an increase in the mean percentage change from baseline in Tyr of 22.6% and a reduction in the mean percentage change from baseline in the Phe-to-Tyr ratio of 25.4%, but did not experience a similar reduction in plasma Phe. We believe the findings in this patient may also be suggestive of PAH enzymatic activity, which was enough to improve Tyr, but not enough to reduce Phe.

Patient 6 showed a marked reduction in Phe from baseline level of 1,060 μmol/L, and recorded one plasma Phe value <360 μmol/L and several plasma Phe values <600 μmol/L through the 13 weeks of observation as of the cutoff date. The mean percentage change from baseline was a 31.4% reduction in plasma Phe, a 40.3% increase in Tyr and a 52.4% decrease in the Phe-to-Tyr ratio. These results were observed while the patient self-liberalized diet, including a mean percent change from

baseline of more than 45.4% increase in dietary intact protein and a 41.8% increase in dietary Phe. This patient had the benefit of increased monitoring, which also allowed for tighter management of steroids, including additional steroids at the first observation of ALT increases.

Based on the safety and efficacy results observed in the dose-escalation phase as of the cutoff date, in early 2021 we advanced to the Phase 2 randomized, concurrently controlled, expansion phase of the pheNIX trial, which has the potential to be converted to a registrational trial. We selected two doses for the expansion phase: 6E13 vg/kg and 8E13 vg/kg. In October 2021, we announced that as of September 30, 2021, both doses in the expansion phase of the trial have been generally well-tolerated and have shown evidence of biological activity, including clinically meaningful reductions in Phe levels, increases in Tyr and reductions in the Phe-to-Tyr ratio. On February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold due to the need to modify risk-mitigation measures in the study in response to observations of elevated LFTs. On March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated LFTs observed in some patients in the trial and modified clinical risk-mitigation measures. In patients who experienced elevated LFTs, all have resolved and no hospitalizations were required. Among the risk-mitigation methods that we intend to propose is a new, more targeted immunosuppressive regimen that is shorter in duration and includes a T-cell inhibitor used in combination with a steroid-sparing regimen that may improve patient compliance. The use of T-cell inhibitors has been shown to be effective in dampening the anticipated immune response to AAV capsids, which are commonly employed to deliver genetic medicines. With the additional information requested by the FDA and the planned conversion to a more targeted immunosuppressive regimen, we estimate that we will require more time to submit and receive feedback on our proposed clinical risk-mitigation strategy. As a result, we now expect to provide a program update when the path forward is established with the FDA.

Preclinical Studies with HMI-102

The potential of an AAVHSC15-delivered *PAH* gene was assessed in a well-established mouse model of PKU called the Pah^{enu2}, or ENU2, mouse. This model contains a mutation in the murine *Pah* gene that results in abolished activity and elevated serum Phe levels. Baseline levels of serum Phe in these mice are approximately 1,500 micromoles per liter compared to normal levels of approximately 80 micromoles per liter, levels that are similar to those seen in classical PKU patients and normal controls, respectively. Single intravenous injections of HMI-102 into these PAH-deficient mice resulted in reductions of serum Phe to levels that are within the range for normal mice. As depicted in Figure 9, the reduction in serum Phe levels persisted for 48 weeks in treated mice on a normal protein diet, consistent with the lifespan of the model. In addition to a reduction in serum Phe, the administration of our gene therapy candidate also resulted in elevations of serum Tyr due to the restoration of the normal biochemical pathway.

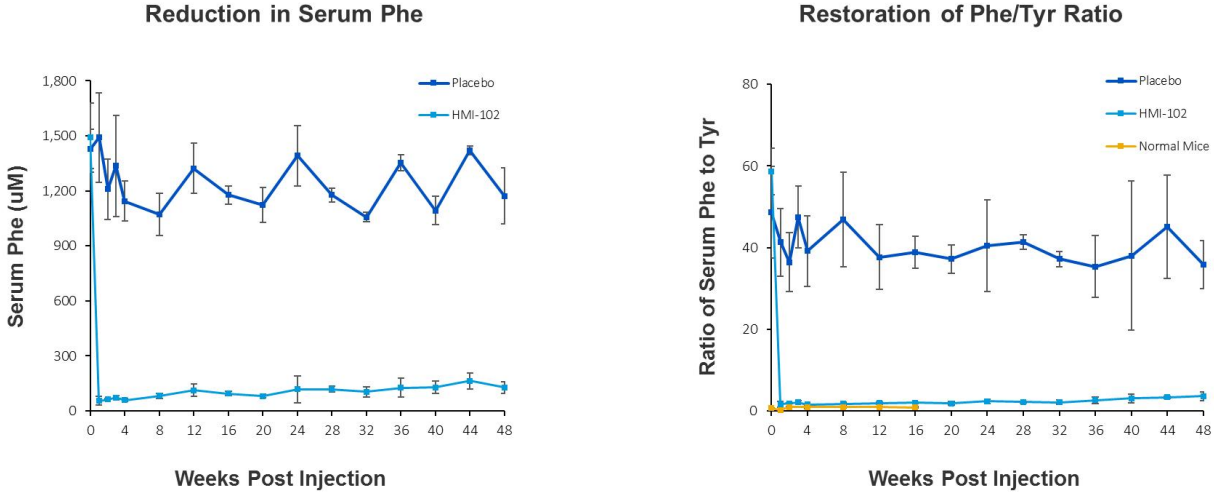


Figure 9. A single injection of HMI-102 resulted in rapid and sustained reductions in serum Phe and increased Tyr levels in PAH-deficient mice that are on a regular diet.

A subsequent study was performed to further characterize the effect of HMI-102 on normalizing levels of Phe and neurotransmitter metabolism in the brain. As shown in Figure 10, a single administration of HMI-102 in the ENU2 mouse model reduced levels of Phe in the brain to normal levels as measured at 4 weeks post-dosing. Furthermore, the brain

concentrations of 5-HIAA, a metabolite of serotonin, was increased to normal levels. These results indicate that HMI-102 administration directly impacts the metabolic pathway associated with loss of PAH.

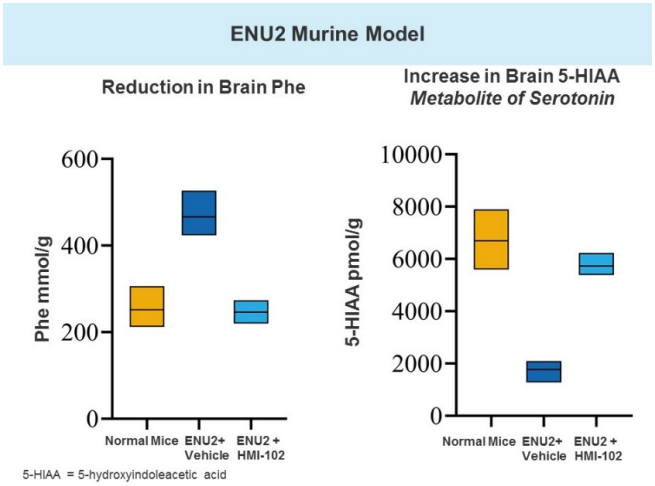


Figure 10. HMI-102 normalizes key neurological measures underscoring restoration of normal biochemical pathway.

Optimized HMI-103: Our Gene Editing Approach for PKU

In order to address the pediatric PKU population, we are developing a gene editing candidate for PKU, optimized HMI-103, that is designed to replace defective *PAH* genes with normal copies. The gene editing vector transgene is flanked by left and right homology arms, containing sequences that are identical and specific to the genomic target. The arms were designed to integrate by non-nuclease-based, AAV-mediated HR into the target human *PAH* locus. This therapy aims to correct the genetic defect within the treated liver cells then directing the expression of the PAH protein. HR-based integration via AAVHSCs is highly precise, without the introduction of insertions, deletions or viral ITRs. The corrected copy of the *PAH* gene would be retained as cells divide into daughter cells as the liver grows. Screening for PKU of all newborns in the United States allows the identification of affected individuals before serious neurological complications develop. We believe our HR approach possesses the efficacy and durability characteristics that would be appropriate to treat PKU in newly identified patients. As we further develop our expertise in treating PKU by correcting the defective *PAH* gene in the liver, we intend to develop treatments for other inborn errors of metabolism in the liver.

We have conducted *in vivo* experiments showing the integration of a human *PAH* cDNA into the human *PAH* gene locus using a humanized liver mouse model. In this model, human hepatocytes constitute the majority of the liver cells, providing an *in vivo* model to test human specific editing constructs. Injection of the human AAVHSC *PAH* gene editing candidate in this model resulted in the insertion of a codon-optimized human *PAH* cDNA into the human *PAH* locus and mRNA expression of the *PAH* cDNA. The *in vivo* integration rate at the target locus, shown in Figure 11, was calculated at a frequency of 6%. This level of editing has been shown to be sufficient to normalize Phe levels in the murine model. A second assay was also performed on DNA that was specific for human and murine hepatocytes obtained from this study. The assay provides an orthogonal approach for characterizing the frequency of targeted integration and enables testing the species-selectivity of the targeted integration. The results of this assay showed integration only in the human hepatocytes and not in the murine hepatocytes, demonstrating selectivity for the human locus. Figure 12 below shows data following I.V. administration of the murine surrogate, or the murine version of HMI-103. The human construct is designed with human-specific homology arms, so a murine surrogate is necessary for testing in the PKU murine model. As depicted, we observed that *PAH* gene integration was durable out to 43 weeks (end of study) and resulted in marked and durable serum Phe reduction.

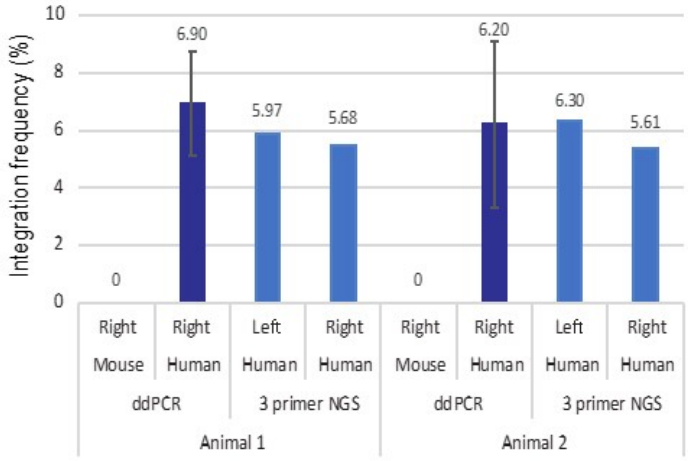


Figure 11. Human-specific AAVHSC *PAH* gene editing candidate resulted in a targeted integration rate of 6%, as measured by NGS in an *in vivo* humanized liver murine model.

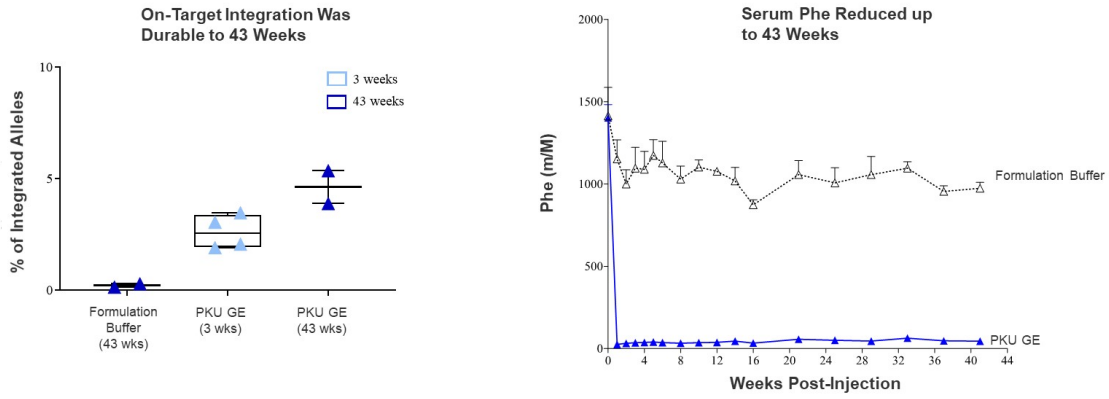


Figure 12. I.V. administration of murine surrogate (with murine homology arms) of HMI-103 showed durable gene integration in Pah^{enu2} model of PKU.

The fidelity of the integration of the cDNA into the target locus was evaluated by NGS sequencing. There were no *de novo* mutations detected in either homology arm target site. We also evaluated the samples for the presence of ITRs. Viral ITRs are non-homologous sequences that lie beyond the extent of the recombination event and thus should not be integrated into the target site. The integrated alleles were free of ITR sequence, consistent with HR as the main mechanism for integration. Together, these data showed that the targeted integration of the human *PAH* cDNA into the human *PAH* locus displayed sequence fidelity with no evidence of mutations. A genome wide integration assay using long read NGS was developed to assess for off-target HR-mediated integration in human hepatocytes. No off-target HR-mediated integration sites were detected above the limit of detection.

Based on these data, in October 2021, we announced the initiation of a Phase 1 trial with HMI-103. The pheEDIT clinical trial is an open-label, dose escalation study evaluating the safety and efficacy of single I.V. administration of HMI-103, and is expected to enroll up to nine patients ages 18-55 years old who have been diagnosed with PKU due to PAH deficiency. In addition to safety endpoints, the trial will measure serum Phe changes. The trial incorporates an immunosuppressive regimen that includes a T-cell inhibitor used in combination with a steroid-sparing regimen. We expect that the first patient in the pheEDIT clinical trial will be dosed following requisite Institutional Biosafety Committee and Institutional Review Board approvals at the clinical sites, and completion of an 82-day screening/run-in period to account for and more closely understand day-to-day Phe fluctuations of participants. If positive safety and efficacy results are established in adults, we then plan to enroll younger patients in clinical trials. We expect to provide an update on the pheEDIT clinical trial at the end of 2022.

Additional Product Opportunities

CNS Diseases

Our CNS programs are designed to take advantage of our AAVHSCs' natural ability to cross the blood-brain-barrier and blood-nerve-barrier in non-human primates.

HMI-203: Our Gene Therapy Approach for Hunter Syndrome

In October 2021, we announced the initiation of a Phase 1 trial with HMI-203, an *in vivo* investigational gene therapy in development for the treatment of adults with MPS II or Hunter syndrome, a rare, X-linked lysosomal storage disorder caused by mutations in the iduronate-2-sulfatase, or IDS, gene, which is responsible for producing the I2S enzyme that breaks down large sugar molecules, or cellular waste, called glycosaminoglycans, or GAGs. Severe Hunter syndrome results in toxic lysosomal accumulation of GAGs that causes progressive debilitation and decline in intellectual function. Hunter syndrome occurs in approximately 1 in 100,000 to 1 in 170,000 males, and the severe form leads to life expectancy of 10 to 20 years. We received orphan medicinal product designation and advanced therapy medicinal product classification from the EMA for HMI-203 for Hunter syndrome.

The juMPStart clinical trial is an open-label, dose-escalation study evaluating the safety and efficacy of a single I.V. administration of HMI-203, and is expected to enroll up to nine male patients ages 18-30 years old who have been diagnosed with Hunter syndrome and are currently receiving enzyme replacement therapy. In addition to safety endpoints, the trial will measure plasma I2S activity, urinary GAG levels and other peripheral disease manifestations. Qualitative data on unmet medical needs from ERT-treated adult MPS II patients and/or their caregivers helped inform our trial design. Patients and caregivers reported that weekly ERT infusions, surgeries and supportive therapies inadequately address range of motion and mobility, pain, and hearing loss, that there are burdens associated with ERT and other therapies, including frequency and duration of treatment, and painful and extended recoveries, that there is a high degree of anxiety regarding prognosis, longevity, need for more invasive surgeries, and financial challenges and that the expectations for a potential one-time gene therapy include the ability to maintain their current quality of life with ERT independence. Also, key opinion leaders surveyed supported our planned design for the juMPStart clinical trial, including our plan to discontinue ERT. We expect to provide an update on the juMPStart clinical trial at the end of 2022.

The standard of care for treating Hunter syndrome is enzyme replacement therapy, or ERT, which can delay some complications but does not treat CNS manifestations of Hunter syndrome since the enzyme cannot cross the blood-brain-barrier. In 2006, the recombinant form of human I2S (Elaprase), an ERT for the treatment of Hunter syndrome was approved by the FDA and subsequently approved for use internationally. In January 2021, the recombinant form of idursulfase-beta (Hunterase), an ERT for the treatment of Hunter syndrome received manufacturing and marketing approval in Japan and in March 2021, pabinafusp alfa, a recombinant iduronate-2-sulfatase ERT that delivers therapeutics across the blood-brain barrier was approved by the Ministry of Health, Labour and Welfare in Japan and has been marketed since May 2021 under the brand name "IZCARGO® I.V. Infusion 10mg." However, specific treatment to address the neurological manifestations of Hunter syndrome and prevent or stabilize cognitive decline remains a significant unmet medical need outside of Japan.

Development candidate HMI-203 is a potential one-time AAVHSC treatment designed to deliver functional copies of the *IDS* gene to multiple target organs, including the PNS and CNS, following a single I.V. administration. In preclinical studies, a single I.V. administration of HMI-203 led to robust biodistribution and sustained human I2S (hI2S) enzyme expression, which resulted in significant reductions in key Hunter syndrome biomarkers of heparan sulfate GAGs and lysosomal-associated membrane protein 1 (LAMP-1) in the brain, liver, heart, spleen, lungs and kidneys compared with the vehicle. Significant reductions in heparan sulfate GAGs in the cerebrospinal fluid (CSF) compared with vehicle were also observed, as well as ameliorated paw deformities, as shown by significant changes in measurements of ankle depth, paw width, paw depth and ankle width compared with vehicle. Finally, HMI-203 administration led to uptake of hI2S from the serum of the HMI-203-treated model in human cell lines, which demonstrated the potential for cell cross-correction. These data were presented at WORLD*Symposium*™ in 2021 and 2022. Refer to Figure 13 below.

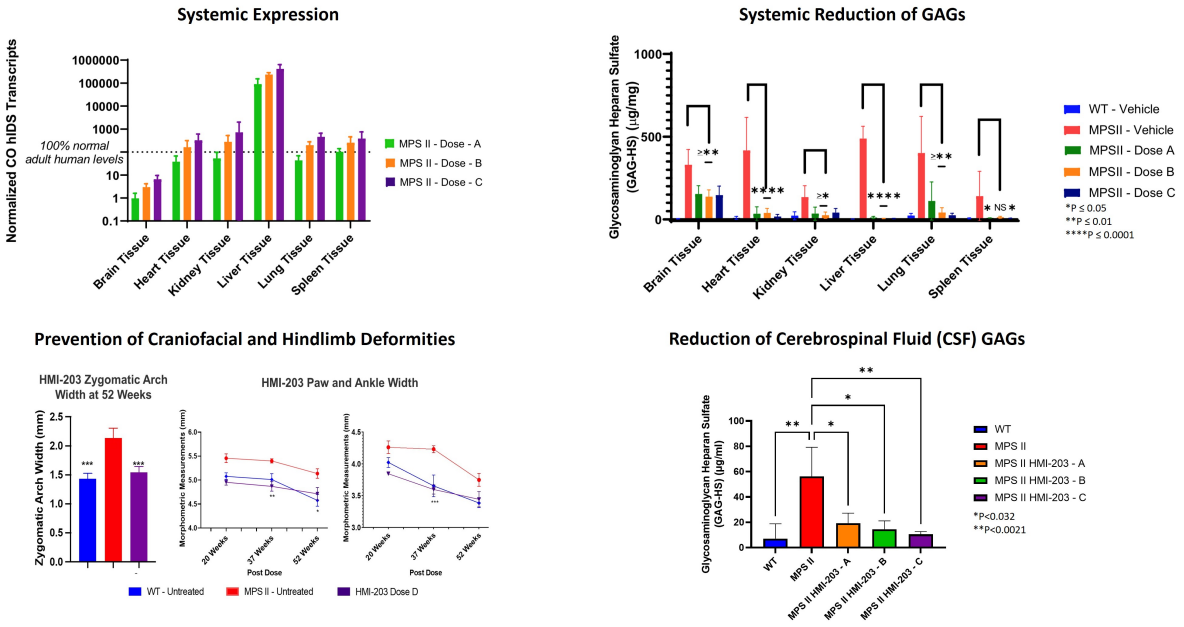


Figure 13. Single IV administration of HMI-203 demonstrated systemic expression, reduction of GAGs, and correction of phenotype in murine model.

HMI-202: Our Gene Therapy Approach for MLD

We have completed IND-enabling studies with HMI-202, our product development candidate for MLD, and we are using these data to further optimize an HMI-202 vector that we believe may lead to a better therapeutic profile. MLD is a lysosomal storage disease caused by mutation of a gene called arylsulfatase A, or *ARSA*. The protein ARSA is required for the breakdown of cellular metabolic products that in MLD accumulate in all cells of the body. Cells responsible for the production of myelin are especially sensitive to the toxic build-up of these cellular metabolic products, leading to progressive serious neurological deterioration. The late infantile form of MLD, which is the most common form, includes rapidly progressive motor and cognitive decline and loss of vision. The majority of these patients do not survive past the first decade of life.

In the United States, stem cell transplants are currently the only effective treatment for MLD, but have significant drawbacks, including the use of immunosuppression therapy, delayed onset of ARSA expression post-engraftment, conditioning regimens, and the risk of death from the stem cell transplant. In Europe, Libmeldy (autologous CD34+ cells encoding the ARSA gene), a lentiviral vector-based gene therapy for the treatment of MLD, became the first therapy approved for eligible patients with early-onset MLD in December 2020 following receipt of full (standard) market authorization by the European Commission.

We have generated preclinical data showing that a single intravenous dose of HMI-202 crossed the blood-brain-barrier and blood-nerve-barrier in a murine model and NHPs, shown in Figure 14, and had broad tissue tropism in physiologically relevant regions of the CNS and PNS, resulting in increased human ARSA enzyme activity to levels well above the therapeutic threshold when compared to average adult human enzyme activity. It is believed that levels of enzyme activity of 10 to 15% of

normal could potentially be curative, based on human data from healthy subjects with enzyme activity levels in this range. These data were presented at WORLD*Symposium*™ in 2021.

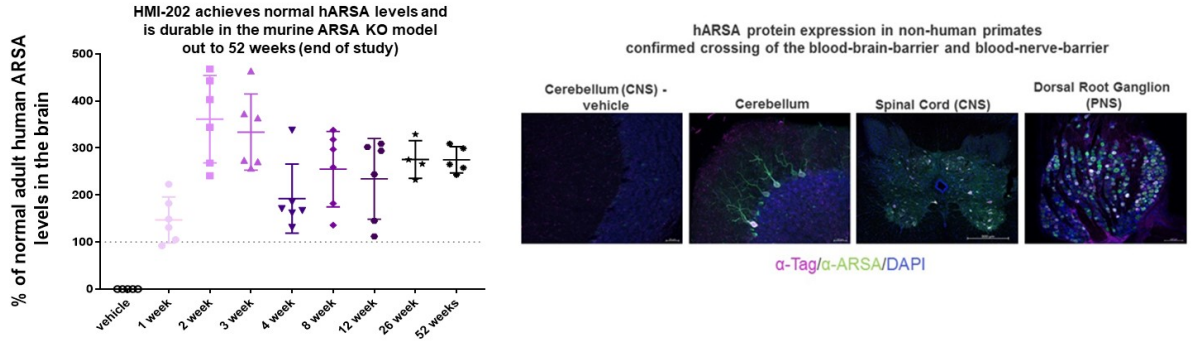


Figure 14. Single IV administration of HMI-202 crossed blood-brain-barrier and resulted in broad tissue tropism and therapeutically relevant levels of ARSA activity in the CNS of treated non-human primates.

Single IV administration of HMI-202 in the murine *Arsa* knockout model resulted in a reduction of LAMP-1 accumulation in the spinal cord and a reduction of sulfatide in the brain, both at 52 weeks post-dose (refer to Figure 15 below).

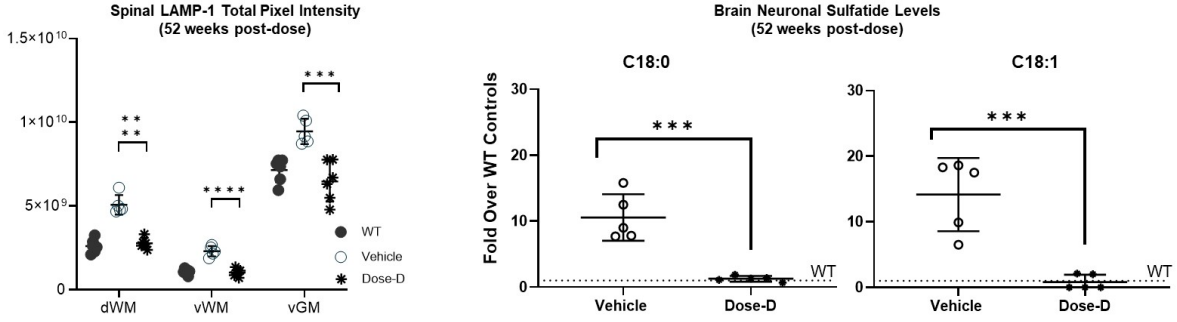
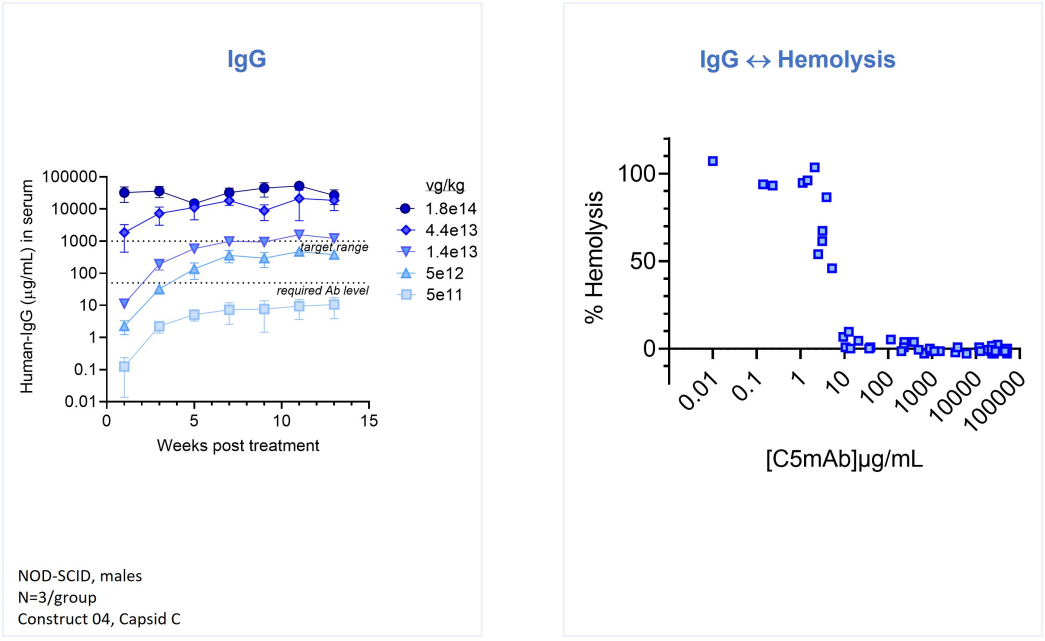


Figure 15. Single IV administration of HMI-202 resulted in reduction of LAMP-1 accumulation (52 weeks post-treatment) and reduction in sulfatide accumulation (52 weeks post-treatment) in murine model.

HMI-104: Our Gene Therapy Approach for PNH

In August 2021, we named a clinical development candidate for PNH, HMI-104, from our GTx-mAb platform. This platform represents an additional way that we are leveraging our AAVHSCs to deliver one-time *in vivo* gene therapy to express and secrete antibodies from the liver, which we believe may allow us to target diseases with larger patient populations. In support of this program, we generated and presented preclinical data targeting complement protein 5, demonstrating proof-of-concept in PNH. Our data showed that a single I.V. dose of an AAVHSC GTx-mAb showed expression of full-length antibodies from the liver consistent with anti-C5 therapeutic levels, sustained and robust IgG expression *in vivo* in a humanized murine humanized liver model and a murine NOD-SCID model and *in vivo* vector-expressed C5 mAb had potent functional activity as shown by an ex vivo hemolysis assay.



(NOD-SCID = Non-obese diabetic/severe combined immunodeficiency)

Figure 16. Single IV administration of an AAVHSC GTx-mAb demonstrated dose dependent serum expression *in vivo* in a humanized murine humanized liver model and a murine NOD-SCID model and *in vivo* vector-expressed C5 mAb had potent functional activity as shown by an ex vivo hemolysis assay.

Other CNS Diseases

We believe our gene therapy technology has the potential to address other CNS diseases, including Friedreich's ataxia or FA. In FA, mutations in a gene called frataxin, or FXN, lead to progressive deterioration of the spinal cord leading to difficulty walking and eventual complete incapacitation and shortened lifespan. Other CNS diseases include Charcot-Marie-Tooth disease, or CMT, a group of disorders that affect the peripheral nerves, the nerves running from outside the brain and spine. The primary clinical features of this disease are slowly progressive distal weakness, muscle atrophy affecting the feet and legs and sensory loss. We also believe our gene therapy technology capable of confronting frontotemporal disorders, or forms of dementia caused by a family of brain diseases known as frontotemporal lobar degeneration. Dementia is a severe loss of thinking abilities that interferes with a person's ability to perform daily activities such as working, driving, and preparing meals. Finally, in addition to Hunter syndrome, for which we are currently advancing product development candidate HMI-203, our technology has the potential to address other lysosomal storage disorders.

Other Liver Diseases and Therapeutics

We continue to pursue the liver as a target organ given the high tropism of our AAVHSCs and the initial clinical data we have collected via our pheNIX Phase 1/2 gene therapy trial for PKU. We are pursuing potential treatments that target the liver's ability to secrete proteins into the serum. We believe that by targeting the liver with genetic medicines that act via gene therapy or gene editing, there is the potential to provide long-lasting secretion of proteins. We plan to name a development program in this therapeutic area in 2021.

Hemoglobinopathies

We are also pursuing treatment of diseases that affect blood cells such as sickle cell disease and beta thalassemia using our AAVHSC vector HR technology. We believe that our potential ability to correct the defective beta globin gene in blood precursor cells may lead to long-term functional cures for affected patients. Sickle cell disease affects over 100,000 individuals and beta thalassemia over 1,000 individuals in the United States.

Ophthalmological Diseases

A number of serious, but rare diseases of the eye such as Leber's congenital amaurosis and Choroideremia, as well as more common diseases such as macular degeneration, have been targeted using gene therapy approaches by academic groups as well as the pharmaceutical industry. We evaluated the ability of our AAVHSCs to transduce retinal cells following subretinal injection in preclinical studies in mice. Expression of green fluorescent protein, or GFP, was seen in all layers of the retina including the retinal pigment epithelium, photoreceptors and the outer nuclear layer, and the AAVHSC subretinal treatment was well-tolerated. In addition, we evaluated the ability of AAVHSC17 to transduce retinal cells in a larger animal model, a mini-pig, and observed significant transduction of all layers of the retina supporting translation across two species. We believe these studies suggest that our AAVHSCs have the potential to be useful as therapeutic vectors for treating retinal diseases in humans based on significant tropism to these target cells. We believe that these vectors have the potential to deliver long-lasting therapeutic benefit to patients that may eliminate the need for the regular and burdensome intravitreal injections that are required for many current treatments.

Manufacturing

As a company committed to curing diseases, the ability to deliver our novel therapeutic vectors to patients is critical. Therefore, we have built strong scientific AAV process development and manufacturing capabilities to support our clinical development programs. We have established a commercial manufacturing platform and process that supports both gene therapy and gene editing, which is scalable from preclinical to GMP. Our process development and manufacturing strategy leverages a single platform for both gene therapy and gene editing that is scalable and facilitates rapid development to the clinic. Our development focus includes design and engineering of plasmid constructs, cell culture, transfection, purification, formulation and analytical development. We leverage our manufacturing platform across our entire pipeline, from our research programs, to our preclinical programs and now to our clinical programs. Our platform was designed from its inception to be our commercial process, allowing us to rapidly transition from research into the clinic and eventually to commercialization. Our manufacturing platform has been scaled and tested across more than 450 different constructs with more than 550 unique lots of vector successfully executed.

Our manufacturing strategy utilizes mammalian cells for our AAVHSC vector-based product candidates. All of our programs utilize HEK293 transfection in a serum-free suspension bioreactor process. HEK293 is a well-characterized and commonly used system for many clinical-stage AAV vector products. Additionally, HEK293 cells are familiar to regulatory authorities, and commercial raw materials and reagents are readily available. Our purification leverages chromatography-based operations to provide high quality vector and ensure robust commercial-scale operations. In addition to our process development, we also internally developed 45 analytical methods to test, monitor, and characterize our products. Expertise and learnings will be leveraged across gene therapy and gene editing programs.

Oxford Biomedica Solutions Transaction

On March 10, 2022, we closed our previously announced transaction with Oxford Biomedica Solutions LLC (f/k/a Roadrunner Solutions LLC), or OXB Solutions, Oxford Biomedica (US), Inc., or OXB, and Oxford Biomedica plc, or OXB Parent, and collectively with OXB, Oxford, pursuant to the Equity Securities Purchase Agreement, or the Purchase Agreement, dated as of January 28, 2022, by and among Homology, OXB Solutions and Oxford, whereby, among other things, we and Oxford have agreed to collaborate to operate OXB Solutions, which will provide AAV vector process development and manufacturing to pharmaceutical and biotechnology companies, which we refer to as the Oxford Biomedica Solutions Transaction, or the OXB Solutions Transaction. OXB Solutions incorporates our proven 'plug and play' process development and manufacturing platform, as well as our experienced team and high-quality GMP vector production capabilities that we built and have been operating since 2019. We will continue to leverage these process development and manufacturing capabilities while reducing our costs and maintaining dedicated manufacturing capacity to support our product candidates. We believe the quality, reliability and scalability of our gene therapy and gene editing manufacturing approach is a core competitive advantage crucial to our long-term success.

Pursuant to the terms of the Purchase Agreement and a contribution agreement, or the Contribution Agreement, entered into between us and OXB Solutions prior to the closing of the OXB Solutions Transaction, or the Closing, we agreed to assign and transfer to OXB Solutions all of our assets that are primarily used in the manufacturing of AAV vectors for use in gene therapy or gene editing products, but excluding certain assets related to manufacturing or testing of our proprietary AAV vectors, or collectively, the Transferred Assets, in exchange for 175,000 common equity units in OXB Solutions, or Units, and OXB Solutions assumed from us, and agreed to pay, perform and discharge when due, all of our duties, obligations, liabilities, interests and commitments of any kind under, arising out of or relating to the Transferred Assets.

Effective as of the Closing, we sold to OXB, and OXB purchased from us, 130,000 Units, or the Transferred Units, in exchange for $130.0 million. In connection with the Closing, OXB contributed $50.0 million in cash to OXB Solutions in exchange for an additional 50,000 Units. Immediately following the Closing, (i) OXB owned 180,000 Units, representing 80 percent (80%) of the fully diluted equity interests in OXB Solutions, and (ii) we owned 45,000 Units, representing 20 percent (20%) of the fully diluted equity interests in OXB Solutions.

Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB Solutions, or the OXB Solutions Operating Agreement, which was executed in connection with the Closing, at any time following the three-year anniversary of the Closing, (i) OXB will have an option to cause us to sell and transfer to OXB, and (ii) we will have an option to cause OXB to purchase from us, in each case all of our equity ownership interest in OXB Solutions at a price equal to 5.5 times the revenue for the immediately preceding 12-month period, subject to a specified maximum amount. Pursuant to the terms of the OXB Solutions Operating Agreement, we will be entitled to designate one director on the Board of Directors of OXB Solutions, which shall initially be Arthur Tzianabos, our President and Chief Executive Officer. Further, Tim Kelly, our former Chief Operating Officer, now serves as the Chief Executive Officer and Chairman of the Board of OXB Solutions.

Concurrently with the Closing, we entered into certain ancillary agreements with OXB Solutions including a license and patent management agreement whereby OXB Solutions granted certain licenses to us, a supply agreement for a term of three years which includes certain annual minimum purchase commitments, a lease assignment pursuant to which we assigned all of our right, title and interest in, to and under our facility lease to OXB Solutions, a sublease agreement whereby OXB Solutions subleased certain premises in its facility to us, as well as several additional ancillary agreements.

Competition

The biotechnology and pharmaceutical industries, including in the gene therapy and gene editing fields, are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property and proprietary products. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. Not only must we compete with other companies that are focused on gene therapy and/or gene editing technologies, any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that utilize technologies encompassing genomic medicines to create therapies, including gene therapy and gene editing. There are additional companies that are working to develop therapies in areas related to our research programs.

Our platform and product focus is the development of genetic medicines using our proprietary AAVHSCs *in vivo* either through the gene therapy or nuclease-free gene editing modality. If our current programs are approved for the indications for which we are currently planning clinical trials, they may compete with other products currently under development, including gene therapy and gene editing products or other types of therapies, such as small molecule, antibody or protein therapies. If our PKU treatments are approved, they may compete with therapies from American Gene Technologies, BioMarin, Generation Bio, Moderna, Nestlé Health Science, PTC Therapeutics, Jnana Therapeutics and Synlogic. However, we believe that only gene therapy or gene editing approaches have the potential to restore the normal Phe biochemical pathway with a single administration. As such, the major competition in this space may be limited to American Gene Technologies and BioMarin, both of which are behind our development program according to public filings.

There are a number of companies developing nuclease-based gene editing technologies using CRISPR/Cas9, TALENs, meganucleases, Mega-TALs and ZFNs, including Beam Therapeutics, bluebird bio, Caribou Biosciences, Cellectis, CRISPR Therapeutics, Editas Medicine, Intellia Therapeutics, Precision BioSciences and Sangamo Therapeutics and non-nuclease-based technology, including LogicBio Therapeutics.

If our Hunter syndrome treatment is approved, it may compete with approved products such as IZCARGO(R), a blood-brain-barrier-penetrating recombinant iduronate-2-sulfatase approved in Japan, as well as investigational product candidates from Avrobio, Denali Therapeutics and REGENXBIO, and ERTs from Takeda and/or GC Pharma. However, we believe that only a gene editing approach has the potential to address the neurological manifestations of Hunter syndrome and prevent or stabilize cognitive decline.

If our MLD treatment is approved, it may compete with approved products such as Libmeldy, a lentiviral vector-based ex vivo gene therapy approved in the EU and a select group of additional countries for the treatment of MLD from Orchard Therapeutics, as well as investigational product candidates from Takeda and Passage Bio. We believe that our *in vivo* gene therapy approach for MLD could be used early in the disease progression with the potential for earlier protein expression, offering advantages over Orchard Therapeutics' *ex vivo* approach, as well as advantages over chronic, intrathecal ERTs, such as Takeda's approach.

In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience and availability of reimbursement.

Furthermore, we rely upon a combination of patents and trade secret protection, as well as license and confidentiality agreements to protect the intellectual property related to our proprietary technologies, product candidate development programs and product development candidates. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to HMI-102 and any future product development candidates. Moreover, our industry is characterized by the existence of large numbers of patents and frequent allegations of patent infringement. If, therefore, we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained or in-licensed is not sufficiently broad or if the validity of such patent is threatened, we may not be able to compete effectively in our markets, as it could create opportunities for competitors to enter the market or dissuade other companies from collaborating with us to develop products and technology, any of which would hurt our competitive position and could impair our ability to successfully commercialize our product development candidates in any indication for which they are approved. For more information regarding these competitive risks, see Item 1A. "Risk Factors—Risks Related to Our Intellectual Property."

Intellectual Property

Our success depends in large part upon our ability to secure and maintain proprietary protection for our technologies and products and to operate without infringing the proprietary rights of others. Our policy is to protect our proprietary position by, among other methods, filing, or collaborating with our licensors to file, U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements and trademarks that are important to the development and implementation of our business. We require employees who are inventors on any company-owned patent applications to assign the rights to us. Also, we use other forms of protection, particularly where we do not believe patent protection is appropriate or obtainable. We rely on trade secrets, technical know-how, and continuing innovation to develop and maintain our competitive advantage. In addition, we rely on confidentiality agreements with our employees, consultants, and other advisors to protect our proprietary information. Our policy is to require third parties that receive material confidential information to enter into confidentiality agreements with us.

Our patent portfolio includes a combination of issued patents and pending patent applications that are licensed from third parties. As of December 31, 2021, we have an exclusive license or co-exclusive license under 18 United States issued patents, nine foreign patents and 52 patent applications, pending in the United States and internationally.

For any individual patent, the term depends on the applicable law in the country in which the patent is granted. In most countries where we have filed patent applications or in-licensed patents and patent applications, patents have a term of 20 years from the application filing date or earliest claimed non-provisional priority date. In the United States, the patent term is 20 years but may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may also be lengthened by a patent term adjustment, in order to address administrative delays by the United States Patent and Trademark Office in granting a patent.

In the United States, the term of a patent that covers an FDA-approved drug or biologic may be eligible for patent term extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the natural expiration of the patent. The patent term restoration period is generally equal to the regulatory review period for the approved product which period occurs after the date the patent issued, subject to certain exceptions. Only one patent may be extended for a regulatory review period for any product, and the application for the extension must be submitted prior to the expiration of the patent. In the future, we may decide to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant Biologics License Application, or BLA. Similarly, certain foreign jurisdictions also have mechanisms for extending patent term and, to the extent we have granted patents that are eligible, we may decide to apply for patent term extensions in those jurisdictions.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally equal to the regulatory review period for the approved product which period occurs after the date the patent issued, subject to certain exceptions. Only one patent may be extended for a regulatory review period for any product, and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to extend its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant BLA.

For patents that might expire during the BLA review phase, the patent owner may request an interim patent term extension. If eligible, an interim patent term extension may be granted for a period of not more than one year. The patent owner may apply for not more than four subsequent interim extensions. Any interim extension granted will not be longer than the maximum period of extension allowed post-approval.

Licensed Intellectual Property

Certain of our issued patents and pending patent applications are exclusively licensed to us in all fields of use from COH. Certain of our issued patents and pending patent applications are co-exclusively licensed to us in all human therapeutic applications with and from the California Institute of Technology, or Caltech.

The City of Hope Portfolio

In April 2016, we exclusively licensed two families of patents and patent applications directed to novel AAV capsids and their manufacture and methods of use, including their use in genome editing from COH.

These two families of patents and patent applications together include eleven granted patents in the United States, four foreign granted patents, and 15 pending applications in the United States, Europe, Canada, Australia and other selected countries in Latin America and Asia. The first family of issued patents and patent applications is material to HMI-102 and relates to our novel AAV vectors and their use in cellular transduction. The nine issued U.S. patents in this family are expected to expire in 2031 and may be extended by up to five years in the United States via patent term extension depending on the regulatory pathway of the products covered by such patents. The second family includes two issued U.S. patents relating to our AAV vectors and their use in genome editing. The issued patents in this family are expected to expire in 2035 and may be extended by up to five years in the United States and in certain other countries via patent term extension depending on the regulatory pathway of the products covered by such patents.

The Caltech Portfolio

In September 2016, we co-exclusively licensed, with another commercial third party, two families of patents and patent applications directed to novel AAV capsids and vectors that demonstrate enhanced blood-brain-barrier penetration for the potential treatment of CNS diseases from Caltech.

These families of patents and patent applications include seven granted patents in the United States, two granted patents in Europe, one granted patent each in Colombia, Russia and South Africa, and 19 pending applications in the United States, Europe, Canada, Australia and other selected countries in Latin America and Asia. The seven issued U.S. patents relate to novel AAV capsids and vectors and are expected to expire in 2034. Certain other patent applications directed to novel AAV capsids and vectors, if they were to issue, may have later expirations.

Trademarks

Our trademarks Homology Medicines, HMI, the H logo, the HOMOLOGY MEDICINES, INC. logo and AMENDR, are pending or registered in the United States and/or certain international countries. We currently own two registered trademarks and two pending trademark applications in the United States, 29 registered trademarks around the world, and 14 pending foreign trademark applications.

Strategic Collaborations

Collaboration and License Agreement with the Novartis Institutes for BioMedical Research, Inc.

In November 2017, we entered into a collaboration and license agreement with Novartis, pursuant to which we agreed to collaborate on researching, developing, and commercializing novel genome editing products that modulate certain gene targets. On February 26, 2021, we received notice from Novartis that they had elected to terminate the agreement with respect to the ophthalmic target, which was the only remaining target under the agreement. Accordingly, the notice served as notice of Novartis' termination of the agreement in its entirety, with an effective date of August 26, 2021. Under the terms of the agreement, Novartis was obligated to continue to reimburse the Company for certain research and development costs through August 26, 2021. Upon effectiveness of the termination, such reimbursements ceased. As a result of this notice, we regained worldwide exclusive rights from Novartis to research, develop, manufacture and commercialize our proprietary nuclease-free gene editing technology platform for the ophthalmic target. The companies believe that results of studies conducted under the agreement provide early proof-of-principle and support a nuclease-independent approach to editing of relevant cell types in the eye after sub-retinal injection.

License Agreement with the California Institute of Technology

In September 2016, we entered into a license agreement with Caltech, pursuant to which Caltech granted us a co-exclusive (subject to certain reserved non-commercial rights), sublicensable, and worldwide license under certain AAV-related patents owned by Caltech for human therapeutic applications. Under this agreement, Caltech also granted us a non-exclusive, worldwide license under certain patents and other intellectual property controlled by Caltech to develop, manufacture, commercialize, and otherwise exploit products covered by such intellectual property rights for human therapeutic applications. We may grant sublicenses under the non-exclusive license to third parties to the extent necessary or useful for our, or our sublicensees', development, manufacturing, or sale of such products.

Under the Caltech agreement, we paid Caltech an initial licensing fee of $100,000. We are also required to pay Caltech up to a total of $7.2 million in milestone payments for the first licensed product; royalties, in the low single-digit percentages on net sales of licensed products, subject to a certain annual minimum royalty; and mid to high single-digit percentages of sublicensing revenues. Subject to certain exceptions, our royalty obligations under the agreement continue on a country-by-country and licensed product-by-licensed product basis until the earliest of (a) the date on which such licensed product is no longer covered by certain intellectual property rights, (b) 10 years after the first commercial sale of such licensed product, or (c) 15 years after the effective date of the agreement. As partial consideration for the licenses granted under the agreement, we issued 101,405 shares of our common stock to Caltech.

The agreement will expire upon the expiration of the last-to-expire patent that is licensed to us or as long as royalties are due under the agreement, whichever is later. We agreed to use commercially reasonable efforts to introduce commercially, and reasonably fulfill market demand for, licensed products as soon as practicable. Either party may terminate the agreement in the event of the other party's uncured material breach and in the event of the other party's bankruptcy or insolvency. We may terminate the agreement for convenience.

City of Hope License Agreement

In April 2016, we entered into a license agreement with COH, pursuant to which COH granted us an exclusive, sublicensable, worldwide license to certain AAV vector-related patents and know-how owned by COH to develop, manufacture, use and commercialize products and services covered by such patents and know-how in any and all fields. COH

also granted us a non-exclusive, sublicensable, worldwide license to certain background patents owned by COH to develop, manufacture, use and commercialize licensed products and licensed services in any and all fields.

Under the agreement, we paid COH an initial licensing fee of $75,000, and made a subsequent payment of $4.5 million representing a percentage of sublicensing revenue. We are also required to pay COH an annual license maintenance fee; up to a total of $3.2 million in potential milestone fees; a royalty in the low single-digit percentages on net sales of licensed products or services, subject to certain reductions in certain circumstances, with a certain annual minimum royalty; and low double-digit percentages of sublicensing revenues. As partial consideration for the licenses granted under the agreement, we issued 154,837 shares of our common stock to COH.

The COH agreement will expire on a country-by-country and on a licensed patent-by-licensed patent basis upon the expiration of the last-to-expire valid claim of such patent in such country. We agreed to use commercially reasonable efforts to develop and commercialize licensed products and licensed services. If we fail to achieve certain diligence milestones, COH may terminate the agreement or convert the exclusive rights under the agreement from exclusive to non-exclusive. Either party may terminate the agreement in the event of the other party’s material breach, subject to an opportunity to cure, and in the event of the other party’s bankruptcy or insolvency. We may terminate the agreement for convenience.

On August 6, 2021, the Company received notice from COH that it did not accomplish at least one of the partnering milestones by the applicable deadline, as set forth in the COH license. This notice does not affect the Company's exclusive license in the field of mammalian therapeutics, including all human therapeutics, associated diagnostics, and target validation, (the "Mammalian Therapeutic Field"), where the Company retains exclusive rights. Instead, the notice served as written notice that the exclusive license granted pursuant to the COH license in all fields except the Mammalian Therapeutic Field converted from exclusive to non-exclusive effective as of September 20, 2021, which was forty-five days from the receipt of notice. In connection with the conversion, any royalty obligations and sublicensee fees relating to fields outside of the Mammalian Therapeutic Field shall be reduced by a certain percentage. This change to the Company's exclusive worldwide license with COH does not impact any of its current therapeutic product development candidates in development, including HMI-102, HMI-103, HMI-203, HMI-202 and HMI-104, nor will it impact any potential future therapeutic product development candidates.

Government Regulation and Product Approval

Governmental authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing, post-approval monitoring and reporting and export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, are extensive and require the expenditure of substantial time and financial resources. For the purposes of this Section, the term “gene therapy” includes both traditional gene therapy products as well as gene editing and our gene integration product candidates.

FDA Approval Process

We expect our future product candidates to be regulated as biologics. Biological products, including gene therapy products, are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the research, development, safety, testing, packaging, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biological products.

We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biological Products Development Process

The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including good laboratory practices, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to good clinical practice, or GCP, requirements and any additional requirements needed for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation and submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with GMP to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including a gene therapy product candidate, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing and controls, information about product chemistry, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. Some preclinical testing, such as reproductive toxicity tests and carcinogenicity in animals, may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, after which human clinical trials may begin unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin.

In addition to the IND submission process, under the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, the efficacy measurements to be evaluated and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all

research subjects provide informed consent. Further, each clinical study must be reviewed and approved by an independent IRB or ethics committee at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or a data monitoring committee, which provides guidance for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase I. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase II. The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase III. The biological product candidate is further evaluated for dosage, clinical efficacy, potency, and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Annual progress reports detailing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board may suspend or permanently discontinue a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or the clinical study is not being conducted in accordance with FDA regulations. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. The FDA and the IRB may also halt, terminate or impose other conditions if either believes the patients are subject to unacceptable risk.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing and distribution of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture, pharmacology, chemistry and controls of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for marketed products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first human drug application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews the submitted BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. Under PDUFA, the FDA has agreed to certain performance goals to complete the review of BLAs. For example, the FDA may give a priority review to BLAs submitted for biological products that are designed to treat a serious or life-threatening disease or condition, and if approved, would offer a significant improvement in safety or efficacy compared to marketed products. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six- and ten-month review periods are measured from the “filing” date rather than the receipt date for original BLAs, which typically adds approximately two months to the timeline for review and decision from the date of submission.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, or effective, for its intended use, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product’s identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with GCP.

After the FDA evaluates a BLA, conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced and conducts inspections at select clinical sites, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its potential risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The requirement for a REMS can materially affect the potential market and profitability of the product.

Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. The FDA may require one or more Phase IV post-market studies or surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the drug or biologic for this type of disease or condition will be recovered from its sales in the United States. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and BLA user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application, including a full BLA, to market the same drug or biologic for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan-designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of a product for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if such product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Rare Pediatric Disease Priority Review Voucher Program

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For purposes of this program, a “rare pediatric disease” is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare diseases or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2024. Consequently, sponsors of marketing applications approved after that date will not receive the voucher unless Congress reauthorizes the Rare Pediatric Disease Priority Review Voucher program before that time. However, even if the program is not reauthorized, if a drug candidate receives Rare Pediatric Disease Designation before October 1, 2024, the sponsor of the marketing application for such drug will be eligible to receive a voucher if the application for the designated drug is approved by the FDA before October 1, 2026.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a biologic product candidate may request that the FDA designate the biologic as a Fast Track product at any time during the clinical development of the product. The FDA must determine if the biologic product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor’s request. With regard to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A biological product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A biologic can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the biologic, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for marketing, including a product candidate with a Fast Track designation or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A BLA is eligible for priority review if the biological product candidate has the potential to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. Additionally, a product candidate may be eligible for accelerated approval. Biological product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that such product candidates be approved on the FDA's determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval perform adequate and well-controlled post-marketing Phase IV clinical studies to verify the predicted clinical benefit. Failure to conduct required post-approval trials, or to confirm a clinical benefit during such post-marketing trials, will allow the FDA to withdraw the approved biologic product from the market on an expedited basis. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Moreover in 2017, the FDA established the Regenerative Medicine Advanced Therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. An investigational drug is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious disease or condition; and (3) preliminary clinical evidence indicates that the investigational drug has the potential to address unmet medical needs for such disease or condition. In a February 2019 final guidance, the FDA also stated that certain gene therapies that lead to a sustained effect on cells or tissues may meet the definition of a regenerative medicine therapy. RMAT designation provides potential benefits that include more frequent

meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review of BLAs and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval if the relevant statutory conditions are met.

Fast Track designation, priority review, RMAT designation and Breakthrough Therapy designation do not change the standards for approval but may expedite the development or approval process. Even if we receive one or both of these designations for our product candidates, the FDA may later decide that our product candidates no longer meet the conditions for qualification. In addition, receiving these designations may not provide us with a material commercial advantage.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP requirements, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

To help reduce the increased risk of the introduction of adventitious agents, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHS Act also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims and transparency laws and regulations regarding drug pricing and payments and other transfers of value made to physician and other licensed healthcare professionals. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. Moreover, for drugs and biologics administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, or ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a

number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through March 31, 2022, and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the General Data Protection Regulation, or GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Government Regulation Outside of the United States

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions, for instance in the European Union, or EU, governing, among other things, clinical trials, marketing authorizations, post-marketing authorization requirements and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

In addition, ethical, social and legal concerns about gene-editing technology, gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well,

including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national regulators provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

In the EU, medicinal products can only be placed on the market after obtaining a marketing authorization, or MA. To obtain regulatory approval of an investigational biological product in the EU, we must submit a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs.

"Centralized MAs" are issued by the European Commission through the centralized procedure, based on the opinion of the EMA's CHMP, and are valid across the entire territory of the EU. The centralized procedure is compulsory for certain types of product candidates such as: (i) medicinal products derived from biotechnology processes, such as genetic engineering, (ii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) designated orphan medicines and (iv) ATMPs such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. It is very likely that the centralized procedure would apply to the products we are developing.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then considered by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the Commission may then adopt a decision to grant an MA.

In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may

be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted, but this is however not guaranteed. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

"National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member state through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the national competent authority of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the European Commission or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving a MA, reference products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more therapeutic indication with significant clinical benefit over existing therapies is approved. However, there is no guarantee that a product will be considered by the EU regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union. However, guidance from the

EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition.

The application for orphan drug designation must be submitted before the MAA. Orphan drug designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of an MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved therapeutic indication. During the ten-year market exclusivity period, the regulatory authorities cannot accept a MAA, or grant a MA, or accept an application to extend a MA, for the same indication, in respect of a similar medicinal product. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar product for the same indication at any time if (1) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (2) the applicant consents to a second orphan medicinal product application; or (3) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which an MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all member states and study results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU.

Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

The United Kingdom, or UK, left the EU on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the UK during the transition period under the terms of the EU-UK Withdrawal Agreement. The transition period, which ended on December 31, 2020, maintained access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was then crystallized in the Trade and Cooperation Agreement, or TCA, and became effective on the January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees

As of December 31, 2021, we had 224 full-time employees, including 45 employees with M.D. or Ph.D. degrees. Of these full-time employees, 197 employees are engaged in research and development activities, including technical operations, clinical, regulatory and research and development. As of March 10, 2022, the closing date of the agreement with Oxford, we had 104 full-time employees, of which 75 are engaged in research and development activities, including clinical, regulatory and research and development. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationships with our employees to be good.

Corporate Information

We were incorporated in Delaware in March 2015. Our principal executive offices are located at One Patriots Park, Bedford, MA 01730 and our telephone number is (781) 301-7277. Our website address is *www.homologymedicines.com*. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. We make available on our website at www.homologymedicines.com, under “Investors,” free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Annual Report on Form 10-K. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline. We may never achieve or maintain profitability.

We are a clinical-stage genetic medicines company with a limited operating history. We have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since beginning to develop our product candidates, including net losses of approximately $95.8 million and $128.7 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of approximately $424.1 million. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted most of our financial resources to research and development, including our preclinical development activities.

We expect to continue to incur significant additional operating losses for the foreseeable future as we seek to advance product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and, if we receive FDA or foreign regulatory authorities approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with genetic medicines product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- continue our current research programs and our preclinical development of product candidates from our current research programs;
- seek to identify, assess, acquire and/or develop additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify and develop;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- further develop our genetic medicines platform;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our operations as a public reporting company;
- acquire or in-license other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under current and any future in-license agreements; and
- further expand our Good Manufacturing Practices, or GMP, manufacturing capacity.

Furthermore, our ability to successfully develop, commercialize and license our products and generate product revenue is subject to substantial additional risks and uncertainties. Each of our programs and product candidates will require additional preclinical and clinical development, potential regulatory approval in multiple jurisdictions, securing manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. These risks are further described under "—Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval" and "—Risks Related to Commercialization." As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The

amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more of our product candidates either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our equity securities will be materially and adversely affected.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our lead product candidate, HMI-102. We will require additional capital, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources to enable us to complete the development and potential commercialization of our product candidates and any future product candidates. In addition, we may not be able to enter into any collaborations that will generate significant cash. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Based upon our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, together with the $130.0 million received from Oxford in March 2022, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2024, including, subject to the impact of the COVID-19 pandemic on our business, additional development activities related to our Phase 1/2 pheNIX clinical trial with HMI-102, our Phase 1 pheEDIT clinical trial with HMI-103, our Phase 1 juMPStart clinical trial with HMI-203, preclinical activities relating to HMI-202 and HMI-104, the continued optimization of our manufacturing processes and the expansion of our intellectual property portfolio. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of our product candidates and any future product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials for our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the costs of operating as a public company;
- the extent to which we in-license or acquire other products and technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates in regions where we choose to commercialize our products; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Moreover, market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of or product candidates or potentially discontinue operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, including under our effective Registration Statement on Form S-3, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and no history of commercializing genetic medicine products, which may make it difficult to evaluate the prospects for our future viability.

We were established and began operations in 2015. Our operations to date have been limited to financing and staffing our Company, developing our technology and identifying and developing our product candidates. We have not yet demonstrated an ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to ten years to develop a new drug from the time it enters Phase 1 clinical trials to when it is approved for treating patients, but in many cases, it may take longer. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

We are heavily dependent on the success of HMI-102, our most advanced product candidate, and if HMI-102 does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

To date, we have invested a significant portion of our efforts and financial resources in the development of HMI-102. Our future success and ability to generate product revenue is substantially dependent on our ability to successfully develop, obtain regulatory approval for and successfully commercialize this product candidate. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to HMI-102, which will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions, securing manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of HMI-102, which may never occur if HMI-102 is ultimately shown to not be associated with phenylalanine hydroxylase enzymatic activity and increased Phe metabolism, or if HMI-102 were associated with serious adverse events, or if it were found to not be efficacious. Therefore, we cannot be certain that HMI-102 will be successful in our current Phase 1/2 pheNIX trial or future clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. On February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold and on March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated liver function tests observed in the trial and modified clinical risk-mitigation measures. Even if we receive approval to market HMI-102 from the FDA or other regulatory authorities, we cannot be certain that our product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other

commercially available alternatives. Additionally, the research, testing, manufacturing, labeling, approval, sale, marketing and distribution of genetic medicine products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market HMI-102 in the United States until it receives approval of a Biologics License Application, or BLA from the FDA, or in any foreign countries until it receives the requisite approval from such countries.

We have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future.

HMI-102 is our most advanced product candidate, and because our other product candidates are based on similar technology, if HMI-102 shows unexpected adverse events or a lack of efficacy in the indications we intend to treat, or if we experience other regulatory or developmental issues, our development plans and business could be significantly harmed. Further, competitors may be developing products with similar technology and may experience problems with their products that could identify problems that would potentially harm our business.

We may not be successful in our efforts to identify additional product candidates.

Part of our strategy involves identifying novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is too complex and difficult to navigate successfully or economically.

In addition, we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify additional suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price and could potentially cause us to cease operations.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We will need to significantly expand our organization, and we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our

management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

In addition, effective as of the OXB Solutions Transaction closing date, OXB Solutions incorporated Homology's AAV manufacturing capabilities and is now operated by 125 AAV manufacturing experts formerly employed by Homology. We may not be able to effectively manage this transition and it could put additional strain on our personnel resources. See "Management's Discussion and Analysis of Financial Condition and Results of Operations-OXB Solutions Transaction" in Item 7 of Part II to this Annual Report on Form 10-K.

Many of the biotechnology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

We may be required to make significant payments in connection with our license agreements with each of the City of Hope and the California Institute of Technology.

Under our license agreements with each of COH and California Institute of Technology, or Caltech, we are subject to significant obligations, including payment obligations upon achievement of specified milestones and royalties on product sales, as well as other material obligations, including potential payments to COH if we were to sublicense the COH technology to additional strategic collaborators. If these payments become due, we may not have sufficient funds available to meet our obligations or we may have to direct funds from other development efforts, and as a result, our development efforts may be materially harmed.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing and Regulatory Approval

We intend to identify and develop product candidates based on our novel genetic medicines platform, which makes it difficult to predict the time and cost of product candidate development. No products that utilize gene editing technology have been approved in the United States or in Europe, and there have only been a limited number of human clinical trials involving a gene editing product candidate. Moreover, none of those trials has involved our nuclease-free gene editing technology, prior to our recently initiated Phase 1 pheEDIT clinical trial.

We have concentrated our research and development efforts on our genetic medicines platform, which uses both nuclease-free gene editing and gene therapy technologies. Our future success depends on the successful development of this novel therapeutic approach. To date, no product that utilizes gene editing has been approved in the United States or Europe. There have been a limited number of clinical trials of gene editing technologies, however no product candidates have been approved, and, prior to our recently initiated Phase 1 pheEDIT clinical trial, none of these clinical trials involved product candidates that utilize our novel gene correction editing technology. In addition, because our programs are all in the research, preclinical or early-clinical stage, we have not yet been able to fully assess safety in humans, and there may be long-term effects from treatment with any of our future product candidates that we cannot predict at this time. Any gene correction editing product candidates we may develop will act at the level of DNA, and, because animal DNA differs from human DNA, it will be difficult for us to test our future product candidates in animal models for either safety or efficacy. Also, animal models may not exist for some of the diseases we expect to pursue. Our genetic medicines platform is based on a family of 15 proprietary AAVHSCs which we can deploy with either gene editing or gene therapy constructs. Both applications rely on the unique ability of our AAVHSCs to efficiently target multiple tissues in the body. The mechanism of action by which these vectors target particular tissues is still not completely understood. Therefore, it is difficult for us to determine that our vectors will be able to properly integrate corrective DNA in or deliver gene transfer constructs to enough tissue cells to reach therapeutic levels. We cannot be certain that our AAVHSCs will be able to meet safety and efficacy levels needed to be therapeutic in humans or that they will not cause significant adverse events or toxicities. Furthermore, studies conducted by a third party in non-human primates suggest that intravenous delivery of certain AAV vectors at very high doses may result in severe toxicity of the dorsal root ganglion, or DRG. To date, we have not observed the severe DRG toxicities described in these publications after intravenous administration in non-human primates with our naturally occurring AAVHSC vectors, and we have not seen these toxicities in our product candidates. However, we cannot be certain that we will be able to avoid triggering toxicities in our future preclinical or clinical studies. Any such results could impact our ability to develop a product candidate. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our genetic medicines platform, or any similar or competitive gene therapy or gene editing platforms, will result in the identification, development, and regulatory approval of any medicines, or that other genetic medicine technologies will not be considered better or more attractive for the development of medicines. There can be no

assurance that any development problems we experience in the future related to our genetic medicines platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Because gene therapy and gene editing are novel and the regulatory landscape that governs any product candidates we may develop is uncertain and continues to change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

Regulatory requirements governing products created with genome editing technology or involving gene therapy treatment have changed frequently and will likely continue to change in the future. Approvals by one regulatory authority may not be indicative of what any other regulatory authority may require for approval, and there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products, cell therapy products and other products created with genome editing technology. For example, the FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, with responsibility for the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and any requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

Additionally, under NIH Guidelines supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

In the European Union, or EU, the European Medicines Agency, or EMA, has a Committee for Advanced Therapies, or CAT, that, in conjunction with the Committee for Human Medicinal Products, or CHMP, is responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products, or ATMPs. ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. The CAT's opinion is considered by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. In the EU, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs. Although these guidelines are not legally binding, we believe that our compliance with them is likely necessary to gain and maintain approval for any of our product candidates. In addition, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Similarly complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any of our gene therapy or genome editing product candidates, but that remains uncertain at this point.

The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates created with novel genome editing technology such as ours can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or comparable regulatory authorities may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the

genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory authorities administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in statute or regulations or the interpretation of new available data by applicable regulatory agencies.

Changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of such product candidates, or lead to significant post-approval limitations or restrictions. Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, or adverse public perception of the field of genome editing, may cause the FDA and other regulatory authorities to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates.

As we advance product candidates, we will be required to consult with these regulatory and advisory groups and comply with all applicable guidelines, rules and regulations. If we fail to do so, we may be required to delay or terminate development of such product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient product revenue to maintain our business.

Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and genetic medicines industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Even if our current and future clinical trials are completed as planned, we cannot be certain that their results will establish the safety, purity, potency and/or effectiveness of any of our product candidates to the satisfaction of the FDA or other regulatory authorities, even if we believe that such trials were successful.

To date, we have not completed any clinical trials for our product candidates. Although we have initiated our Phase 1/2 pheNIX trial for HMI-102, our Phase 1 pheEDIT clinical trial for HMI-103, and our Phase 1 juMPStart clinical trial for HMI-203, we may experience delays in conducting any clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, and ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- developing and validating the companion diagnostic to be used in a clinical trial, if applicable;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative safety and/or efficacy data or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, we have experienced, and may continue to experience, delays in enrolling our Phase 2 pheNIX trial as a result of the COVID-19 pandemic. In addition, on February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold and on March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated LFTs observed in the trial and modified clinical risk-mitigation measures. We could encounter further delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate

funding to continue the clinical trial. Furthermore, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of clinical trials and while we would have agreements governing their committed activities, we would have limited influence over their actual performance, as described in "—Risks Related to Our Dependence on Third Parties."

All of our product candidates will require extensive clinical testing before we are prepared to submit a BLA or similar applications seeking regulatory approval. We cannot predict with any certainty if or when we might complete the development of HMI-102 or any other product candidate and submit a BLA or similar applications or whether any such BLA or similar applications will be approved by the FDA or comparable foreign authorities. We may seek feedback from the FDA or other regulatory authorities on our clinical development program, and the FDA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as clinical research organizations, or CROs, may impact our developments plans.

It is currently unclear to what extent the United Kingdom, or UK, will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

Adverse public perception of genetic medicine, and gene editing in particular, may negatively impact regulatory approval of, or demand for, our potential products.

Some of our potential therapeutic products involve editing the human genome. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene editing and gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene editing are unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community.

Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, gene editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of gene editing technology to human embryos or the human germline. For example, in April 2015, Chinese scientists reported on their attempts to edit the genome of human embryos to modify the gene for hemoglobin beta. This is the gene in which a mutation occurs in patients with the inherited blood disorder beta thalassemia. Although this research was purposefully conducted in embryos that were not viable, the work prompted calls for a moratorium or other types of restrictions on gene editing of human eggs, sperm, and embryos. The Alliance for Regenerative Medicine in Washington, D.C. has called for a voluntary moratorium on the use of gene editing technologies in research that involved altering human embryos or human germline cells. Similarly, the NIH has announced that it would not fund any use of gene editing technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Laws in the United Kingdom prohibit genetically modified embryos from being implanted into women, but embryos can be altered in research labs under license from the Human Fertilisation and Embryology Authority. Research on embryos is more tightly controlled in many other European countries.

Although we do not use our technologies to edit human embryos or the human germline, such public debate about the use of gene editing technologies in human embryos and heightened regulatory scrutiny could prevent or delay our development of product candidates. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for any products we may develop. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing gene therapy or gene editing technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, a decrease in demand for any such product candidates and a suspension or withdrawal of approval by regulatory authorities of our product candidates.

A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a Breakthrough Therapy Designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review and rolling review of a BLA, if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

On May 1, 2019, we received Fast Track Designation for HMI-102 for the prevention or treatment of neurocognitive defects due to phenylalanine hydroxylase deficiency through normalization of circulating phenylalanine levels, and on October 25, 2021, we received Fast Track Designation for HMI-103 for the treatment of neurocognitive and neuropsychiatric manifestations of PKU secondary to phenylalanine hydroxylase deficiency. We intend to seek such designation for some or all

of our other product candidates. If a drug or biologic, in our case, is intended for the treatment of a serious or life-threatening condition and the biologic demonstrates the potential to address unmet medical needs for this condition, the biologic sponsor may apply for FDA Fast Track Designation. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Many biologics that have received Fast Track Designation have failed to obtain approval.

We may seek EMA PRIME designation or apply for other expedited regulatory pathways, designations, schemes or tools in the EU or UK for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization.

We may seek EMA PRIME (Priority Medicines) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy and Fast-Track designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened. Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

We may equally pursue some of the post-Brexit UK MHRA procedures to prioritize access to new medicines that will benefit patients, such as a 150-day assessment, a rolling review procedure and an innovative licensing and access pathway, or ILAP. ILAP aims to accelerate the time to market and to facilitate patient access to medicines, including new chemical entities, biological medicines, new indications and repurposed medicines. To benefit from ILAP, we must first apply to the MHRA for an innovation passport. Product developers that benefit from ILAP will be provided with advice on clinical trial design to ensure optimal data generation for both regulatory approval and health technology appraisal.

The competent regulatory authorities in the EU and the UK have broad discretion whether to grant access to the aforementioned schemes and designations, and even if we were to be eligible for some of these procedures, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such designation may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways or similar expedited approval pathways outside the United States. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or similar expedited approval pathways by foreign regulatory authorities, if our confirmatory trials

do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or foreign regulatory authorities may seek to withdraw accelerated approval or similar expedited approval.

We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verity and describe the drug or biologic's clinical benefit. If such post-approval studies fail to confirm such clinical benefit or if the sponsor fails to conduct such studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed. Furthermore, marketing authorizations may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where the risk-benefit ratio is no longer favorable.

Prior to seeking accelerated approval or similar expedited approval for any of our product candidates, we intend to seek feedback from the FDA or other comparable regulatory authorities and will otherwise evaluate our ability to seek and receive accelerated approval or similar expedited approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA or similar application seeking accelerated approval or similar expedited approval. Furthermore, if we decide to submit an application for accelerated approval or similar expedited approval, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We have received orphan drug designation for HMI-102 and HMI-202, and we intend to seek orphan drug designation for our other product candidates, but any orphan drug designations we receive may not confer marketing exclusivity or other expected benefits.

We have received orphan drug designation for HMI-102 in the United States and the EU for the use of AAVHSC15 expressing *PAH* for the treatment of PAH deficiency. In addition, we have received orphan drug designation for HMI-202 in the United States and EU for the use of AAVHSC15 expressing human arylsulfatase A for the treatment of metachromatic leukodystrophy, or MLD. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full BLA, to market the same drug for the same indication for seven years, except

in limited circumstances. The applicable exclusivity period is ten years in the EU. The European exclusivity period can be reduced to six years if, at the end of the fifth year, a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same indication. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same indication if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation. The same principles are valid for the EU as well.

We have received rare pediatric disease designation for HMI-202, and we may seek rare pediatric disease designation for our other product candidates, however, there is no guarantee that we will obtain such designation, and even if we do, there is no guarantee that FDA approval will result in a priority review voucher.

In 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” that meets certain criteria may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

We have received rare pediatric disease designation for HMI-202 for the treatment of MLD, and we may seek rare pediatric disease designation for our other product candidates; however, we may not be able to obtain such designation. If we are able to obtain rare pediatric disease designation for our other product candidates, there is no guarantee that we will be able to obtain a priority review voucher, even if the designated product candidate is approved by the FDA. Moreover, Congress included a sunset provision in the statute authorizing the rare pediatric disease priority review voucher program. Specifically, the FDA may not award the voucher to sponsors of marketing applications unless either (i) the drug has received rare pediatric disease designation as of September 30, 2024, and is then approved by the FDA no later than September 30, 2026; or (ii) Congress reauthorizes the program. Even though we received rare pediatric disease designation for HMI-202 by the current statutory deadline of September 30, 2024, we may not receive the voucher if we do not obtain approval by September 30, 2026. Even if legislation is enacted that extends the date by which approval of the rare pediatric disease-designated drug must obtain approval to receive a priority review voucher, we may not obtain approval by that date, and even if we do, we may not obtain a priority review voucher.

A Regenerative Medicine Advanced Therapy designation by the FDA, or Advanced Therapy Medicinal Product classification by the EMA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a Regenerative Medicine Advanced Therapy, or RMAT, designation for HMI-102 or our other product candidates. In 2017, the FDA established the RMAT designation as part of its implementation of the 21st Century Cures Act. An investigational drug is eligible for RMAT designation if: (1) it meets the definition of a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious disease or condition; and (3) preliminary clinical evidence indicates that the investigational drug has the potential to address unmet medical needs for such disease or condition. In a February 2019 final guidance, the FDA also stated that certain gene

therapies that lead to a sustained effect on cells or tissues may meet the definition of a regenerative medicine therapy. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review of BLAs and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate. RMAT-designated product candidates that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

RMAT designation does not change the standards for product approval, and there is no assurance that such designation or eligibility for such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

In the EU, a specific framework has been implemented for ATMPs to facilitate their access to the EU market. An ATMP can be classified into three main types of medicinal products: (i) gene therapy medicinal products containing genes that lead to a therapeutic, prophylactic or diagnostic effect, (ii) somatic-cell therapy medicinal products containing cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body which can be used to cure, diagnose or prevent diseases, and (iii) tissue-engineered products containing cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue. Companies developing product candidates may seek a scientific recommendation from the EMA's CAT on ATMP classification. This optional procedure allows applicants to clarify whether a given product candidate based on genes, cells or tissues meets the scientific criteria which define ATMPs, in order to address, as early as possible, questions of borderline with other areas, which may arise as science develops. ATMP classification recommendation is adopted by the EMA's CAT, after consultation with the European Commission. The EMA offers a range of advisory services and incentives to support the development of ATMPs such as contribution of the CAT's members in the discussion of the scientific advice and fee waivers. Similarly to RMAT designation, ATMP classification in the EU does not change the standards for product approval, and there is no assurance that such classification will result in expedited review or approval.

Our contract manufacturers, including the newly formed AAV vector manufacturing company, Oxford Biomedica Solutions LLC, are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements, as applicable and as imposed to date, and have limited capacity.

We currently have relationships with a limited number of suppliers for the manufacturing of our viral vectors and product candidates. In March 2022, we closed the previously announced agreement with Oxford to establish a new AAV vector manufacturing company, Oxford Biomedica Solutions LLC, that incorporates our proven 'plug and play' process development and manufacturing platform, as well as our experienced team and high-quality GMP vector production capabilities that we built and have been operating since 2019. The related transactions closed on March 10, 2022. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP or similar requirements outside the United States. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. Our contract manufacturers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's current good laboratory practices, or GLP, and GMP regulations enforced by the FDA through its facilities inspection program. Similar requirements apply in foreign jurisdictions. Some of our contract manufacturers have not produced a commercially-approved product and therefore have not obtained the requisite FDA and foreign regulatory approvals to do so. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other

potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA or foreign regulatory authorities approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA supplement and/or marketing authorization application supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may delay or prevent their regulatory approval, limit the commercial profile of an approved label, or, result in significant negative consequences following marketing approval, if any.

Serious adverse events or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or unexpected characteristics, including death. A significant risk in any gene editing product is that the edit will be "off-target" (or "on-target," but unwanted) and cause serious adverse events, undesirable side effects, toxicities or unexpected characteristics. For example, off-target cuts could lead to disruption of a gene or a genetic regulatory sequence at an unintended site in the DNA, or, in those instances where we also provide a segment of DNA to serve as a repair template, it is possible that following off-target cut events, DNA from such repair template could be integrated into the genome at an unintended site, potentially disrupting another important gene or genomic element. We cannot be certain that off-target editing will not occur in any of our planned or future clinical studies. There is also the potential risk of delayed adverse events following exposure to gene editing therapy, due to the potential for persistent biological activity of the genetic material or other product components used to carry the genetic material.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients or implement similar risk management measures;
- the product could become less competitive;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that neither our current product candidates, nor any other product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a BLA from the FDA. It is possible that the FDA may refuse to file for substantive review any BLAs, that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. Similar risks exist in foreign jurisdictions.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory authorities, that such product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA and other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. Depending on the extent of these or any other FDA- or foreign regulatory authorities-required studies, approval of any BLA or application that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available.

Of the large number of potential products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS or similar risk management measures, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. A proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) is expected to be adopted by the European Commission by the end of 2022. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (not expected before the end of 2024) may have a significant impact on the pharmaceutical industry in the long term.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the agency and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, in particular the EMA, following its relocation to

Amsterdam and related reorganization, may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with GMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP or similar regulations and standards.

In addition, any marketing approvals that we may receive for our product candidates may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome

post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our product candidates, if approved for commercial sale; and
- loss of revenue.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, umbrella, and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company will continue to make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, foreign regulatory authorities rules and regulations and other similar regulatory requirements, including those laws that require

the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our business and operations may suffer in the event of information technology system failures, cyber-attacks or deficiencies in our cyber-security.

Our information technology systems, as well as those of our CROs and other contractors and consultants, are vulnerable to failure or damage from computer viruses and malware (e.g. ransomware), unauthorized access or other cybersecurity attacks, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to human error (e.g., social engineering, phishing), a technical vulnerability, malfeasance or other disruptions. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Although, to our knowledge, we have not experienced any significant security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Initial, interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publicly disclose initial, interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the initial, top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Initial, top-line or preliminary data also remain subject to audit and verification procedures

that may result in the final data being materially different from the initial, top-line or preliminary data we previously published. As a result, initial, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we also disclose interim or initial data from our preclinical studies and clinical trials. Interim or initial data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between initial, interim, top-line or preliminary data and final data could significantly harm our business prospects. Further, disclosure of any such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the top-line, interim, initial or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how other healthcare reform measures enacted by Congress or implemented by the Biden administration will affect our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;
- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance

guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers. For instance, in the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations, are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and member states level. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. Relationships with healthcare professionals and associations are subject to stringent anti-gift statutes and anti-bribery laws, the scope of which differs across the EU. In addition, national "Sunshine Acts" may require pharmaceutical companies to report/publish transfers of value provided to healthcare professionals and associations on a regular (e.g. annual) basis.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. In the United States, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder, or collectively, HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, California enacted the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, increases data privacy obligations for covered companies and provides individual privacy rights to California consumers, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act, or CPRA, was also recently voted into law by California residents. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023, and become enforceable on July 1, 2023.

Furthermore, the Federal Trade Commission, or FTC, and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal

information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the GDPR imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Economic Area, or EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the EU, or CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the UK SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, after the end of the transition period following the UK's departure from the EU, we are also subject to the UK data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Risks Related to Commercialization

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new genetic medicine products is highly competitive. Moreover, the gene editing field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs, including PKU, MLD, Hunter syndrome, hemoglobinopathies and ophthalmological diseases. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches.

Our platform and product focus is the development of genetic medicines using our proprietary AAVHSCs *in vivo* either through the gene therapy or nuclease-free gene editing modality. If our current programs are approved for the indications for which we are currently planning clinical trials, they may compete with other products currently under development, including gene editing and gene therapy products or other types of therapies, such as small molecule, antibody or protein therapies. If our PKU treatments are approved, they may compete with therapies from American Gene Technologies, BioMarin, Censa Pharmaceuticals, Generation Bio, Nestlé Health Science, Sangamo Therapeutics and Synlogic. However, we believe that only gene therapy or gene editing approaches have the potential to restore the normal Phe biochemical pathway with a single administration. If our Hunter syndrome treatment is approved, it may compete with therapies from Shire and/or GC Pharma. If our MLD treatment is approved, it may compete with therapies from Orchard Therapeutics, Passage Bio and/or Shire. *In vivo* gene therapy approaches provide potential advantages over ex vivo approaches. There are a number of companies developing nuclease-based gene editing technologies using CRISPR/Cas9, TALENs, meganucleases, Mega-TALs and ZFNs, including but not limited to Beam Therapeutics, bluebird bio, Caribou Biosciences, Cellectis, CRISPR Therapeutics, Editas Medicine, Intellia Therapeutics, Precision BioSciences, Prime Therapeutics and Sangamo Therapeutics and non-nuclease-based technology, including LogicBio Therapeutics.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomic or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford

prescription medications such as our product candidates, assuming FDA or foreign authorities approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Moreover, for drugs and biologics administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Governments influence the price of medicinal products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very

intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if any of our product candidates receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the safety, efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenues for a substantial period, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, if approved. Moreover, provisions in our agreements with Pfizer may inhibit our ability to enter into future collaborations with third parties.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so.

We expect to build a focused sales, distribution and marketing infrastructure to market our product candidates in the United States and EU, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. Additionally, if the commercial launch of any of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain markets overseas. Therefore, our future sales in these markets will largely depend on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of our product candidates, if approved, for certain markets overseas; however, we cannot assure that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates, we may be forced to delay the potential commercialization of our product candidates or reduce the scope of our sales or marketing activities for our product candidates. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

Moreover, we have granted Pfizer a right of first refusal to acquire rights (whether through license, asset sale or otherwise) to develop or commercialize HMI-102 and/or HMI-103. This right of first refusal provision may inhibit our ability to enter into future collaborations with third parties.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates, and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any of our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and biologic approvals and rules governing drug and biologic commercialization and country-specific regulations of gene therapies in foreign countries;
- complex and restrictive import/export regulations;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- political and economic instability, including in light of the developing conflict between Russian and Ukraine;
- fluctuations in currency exchange rates; and
- higher costs of doing business internationally, including increased accounting, travel infrastructure and legal compliance costs.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the EU member states with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products in Europe to be very challenging.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the

reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Risks Related to Our Dependence on Third Parties

We currently contract with third parties, including the newly formed AAV vector manufacturing company, Oxford Biomedica Solutions LLC, for the manufacture of certain materials for our research programs, preclinical and clinical studies. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost or in compliance with regulatory requirements, which could delay, prevent, or impair our development or commercialization efforts.

We currently rely on third-party manufacturers for the manufacture of materials for research programs, preclinical and clinical studies. We do not have long-term supply agreements with all of the third-party manufacturers, and we purchase our required supply on a purchase order basis. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting;
- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- misappropriation of proprietary information, including our trade secrets and know-how;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;

- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with GMP regulations or similar regulatory requirements outside the United States. The failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects. Moreover, as a result of the COVID-19 pandemic, we began to accelerate the procurement of raw materials for future manufacturing, research and development needs to minimize potential supply chain interruptions. We continue to accelerate procurement of raw materials to meet all manufacturing needs, some of which are sourced from a single-source supplier. It is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and CMOs' ability to manufacture our product candidates or materials needed for our preclinical studies and clinical trials.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under GMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We intend to continue to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We intend to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We intend to continue to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. Our reliance on CROs for clinical development activities limits our control over these activities, but we will remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with GLP and GCP, which are regulations and guidelines enforced by the FDA and are also required by the competent authorities in the EU and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under GMP regulations. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other product development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations or fail to

meet expected deadlines, including as a result of the impact of the COVID-19 pandemic, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationship with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

We may collaborate with third parties for the development and commercialization of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

We may seek collaborative relationships for the development and commercialization of our product candidates. Failure to obtain a collaborative relationship for any of our product candidates may significantly impair the potential for the product candidate. We also will need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, such as:

- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may not devote sufficient capital or resources towards our product candidates;
- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaboration partner may terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our products or technology in such a way as to invite litigation from a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

Moreover, any collaborative partners we enter into agreements with in the future may shift their priorities and resources away from our product candidates or seek to renegotiate or terminate their relationships with us. For example, in February 2021, we received written notice from Novartis that Novartis elected to terminate our collaboration agreement with Novartis with respect to the only remaining ophthalmic target under the agreement. Accordingly, the notice served to terminate the agreement in its entirety. The termination of the collaboration agreement was effective on August 26, 2021.

We do not have multiple sources of supply for all of the components used in HMI-102, HMI-103, HMI-203 and our other product candidates. If we were to lose a supplier, it could have a material adverse effect on our ability to complete the development of HMI-102, HMI-103 and HMI-203. If we obtain regulatory approval for HMI-102, HMI-103 or HMI-203, we would need to expand the supply of components in order to commercialize them.

We do not have multiple sources of supply for all of the components used in the manufacturing of HMI-102, HMI-103 and HMI-203. We also do not have long-term supply agreements with any of our component suppliers. We are currently evaluating manufacturers that will commercially manufacture HMI-102. It is our expectation that we will only qualify one initial supplier that will need to be approved by the FDA. If for any reason we are unable to obtain product from the manufacturer we select, we would have to qualify new manufacturers. We may not be able to establish additional sources of supply for our product candidates, or may be unable to do so on acceptable terms. Furthermore, pursuant to the terms of the Supply Agreement with OXB Solutions entered into in March 2022, we have agreed to purchase from OXB Solutions at least 50% of our clinical supply requirements of AAV-based products during the initial term of the Supply Agreement. If we were to experience an unexpected loss of supply from OXB Solutions for any reason, this could result in a delay in our desired clinical and commercial timelines.

Manufacturing suppliers are subject to GMP quality and regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions in supply. Manufacturing suppliers are also subject to local, state and federal regulations and licensing requirements. Failure by any of our suppliers to comply with all applicable regulations and requirements may result in long delays and interruptions in supply.

The number of suppliers of the raw material components of our product candidates is limited. In the event it is necessary or desirable to acquire supplies from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company.

As part of any marketing approval, a manufacturer of HMI-102 is required to be licensed by the FDA or foreign regulatory authorities prior to commercialization. This licensing process normally includes inspections by regulatory authorities that must be successful prior to them being licensed. Failure of manufacturing suppliers to successfully complete these regulatory inspections will result in delays. If supply from the approved supplier is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through a BLA amendment or supplement and/or marketing authorization application amendment or supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of HMI-102 and our other product candidates or, if we obtain regulatory approval for HMI-102 or our other product candidates, to commercialize them.

If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products, technology or data from third parties, including those for HMI-102, we could lose such rights that are important to our business.

We are a party to agreements with Caltech for certain AAV vector-related patents owned by Caltech for human therapeutic applications, or the Caltech License, and COH for certain AAV vector-related patents and know-how, and we may enter into additional agreements, including license agreements, with other parties in the future that impose diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations on us.

For example, in exchange for the rights granted to us under the Caltech License, we are obligated to pay Caltech up to a total of $7.2 million in milestone payments for the first licensed product, royalties, in the low single-digit percentages, on net sales of licensed products subject to a certain annual minimum royalty, and mid single- to high single-digit percentages of sublicensing revenues. If we fail to comply with our obligations under the Caltech License, or any of our other collaborators,

our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our proprietary technologies, product candidate development programs and product candidates. Our success depends in large part on our ability to secure and maintain patent protection in the United States and other countries with respect to all current and future product candidates. We seek to protect our proprietary position by filing or collaborating with our licensors to file patent applications in the United States and abroad related to our proprietary technologies, development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our proprietary products and technology, including our product candidates in the United States or in other foreign countries, in whole or in part. Alternately, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. Even if patents do successfully issue and even if such patents cover our current product candidates or any future product candidate, third parties may challenge their validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current product candidates or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our ability to commercialize future product candidates. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions, and is characterized by the existence of large numbers of patents and frequent litigation based on allegations of patent or other intellectual property infringement or violation. In addition, the laws of jurisdictions outside the United States may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Since patent applications in the United States and other jurisdictions are confidential for a period of time after filing, we cannot be certain that we were the first to file for patents covering our inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents, or may result in the issuance of patents which fail to protect our technology or products, in whole or in part, or which fail to effectively prevent others from commercializing competitive technologies and products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may

be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our product candidates, prohibit our use of proprietary technology or sale of products or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous United States, EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a

validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information, or made a misleading statement. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop, manufacture and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could be filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and genetic medicines industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biotechnology and genetic medicines patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.
Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

We may become involved in opposition, interference, derivation, inter partes review or other proceedings challenging our or our licensors' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive

than those in the United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications while they are still pending. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications may be rejected by the relevant patent office, while substantively similar applications are granted by others. For example, relative to other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act , which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. In the EU, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

We depend on proprietary technology licensed from others. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from third parties, we may not be able to continue developing our products.

We currently in-license certain intellectual property from COH and Caltech. In the future we may in-license intellectual property from other licensors. We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which

our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

We are a party to license agreements with COH and Caltech, pursuant to which we in-license patents and technology for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations or otherwise materially breach a license agreement, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. In addition, any claims asserted against us by our licensors may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and confidential know-how are difficult to protect, and we have limited control over the protection of trade secrets and confidential know-how used by our licensors, collaborators and suppliers. Because we expect to rely on third parties to manufacture our current and future product candidates, and we expect to collaborate with third parties on the development of our current and future product candidates, we may, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. Under such circumstances, trade secrets and confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We currently own two registered trademarks and two pending trademark applications in the United States, as well as 29 registered trademarks and 14 pending trademark applications in other countries around the world. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may need to license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compositions and pre-existing pharmaceutical compositions. These pharmaceutical products may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates. These diagnostic test or tests may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our management and other employees.

Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business

The COVID-19 pandemic has and could continue to adversely impact our business, including our preclinical studies and clinical trials.

In 2020, a strain of novel coronavirus disease, COVID-19, was declared a pandemic and spread across the world, including throughout the United States, Europe and Asia. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended.

In response to the spread of COVID-19, most office-based employees were asked to from home. We implemented a return-to-work policy which provided for a hybrid of remote and in-office work, and we expect to operate on such a semi-virtual basis for at least the first half of 2022, pending the future direction of the COVID-19 pandemic. We continue to limit the number of staff in our research and development laboratories to key personnel and maintain shift schedules for our laboratories and a modified office layout to increase spacing capabilities, reduce inter-office risks and allow for business continuity. We have increased cleaning protocols throughout our entire facility, and have implemented procedures regarding office visitors to better protect our employees. Disruptions caused by the COVID-19 pandemic have resulted, and may continue to result, in delays in enrolling our Phase 1/2 pheNIX clinical trial. In addition, we could experience additional disruptions in conducting or completing the Phase 1/2 pheNIX trial or other planned preclinical and clinical trials and could incur unforeseen costs as a result of preclinical study or clinical trial delays. While we have entered into arrangements with third parties to provide remote patient visits and monitoring, we may still experience delays with the pheNIX trial. All of our ongoing and planned preclinical studies at external CROs are progressing and we have accelerated shipments of reagents and supplies to avoid any disruption of activities. However, it is possible that the COVID-19 pandemic may have an impact in the future on our CROs' ability to complete critical studies required for the progression of these programs. Moreover, while we currently do not anticipate any interruptions in our manufacturing process, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and CMOs' ability to manufacture our product candidates or materials needed for our preclinical studies and clinical trials. If the COVID-19 pandemic continues to spread in the United States and elsewhere, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies; and
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the emergence of additional new variants, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact of COVID-19

on financial markets and the global economy, the effectiveness of vaccines and vaccine distribution efforts, and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease.

While the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our liquidity. In addition, the recession or market correction resulting from the spread of COVID-19 could materially affect our business.

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Arthur Tzianabos, Ph.D., our President and Chief Executive Officer, and Albert Seymour, Ph.D., our Chief Scientific Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. We have recently experienced increased turnover of key personnel. We have also incurred increased expenses in connection with the retention of existing key personnel and hiring of new employees, and we expect these increased costs to continue. Competition to hire from the limited pool of skilled workers discussed above is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

We or the third parties upon whom we depend may be adversely affected by natural disasters public health emergencies and other natural catastrophic events, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, public health emergency, such as the COVID-19 pandemic, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

Risks Related to Our Common Stock

Our executive officers and directors and their respective affiliates, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers and directors and their respective affiliates, in the aggregate, hold shares representing approximately 18.4% of our outstanding voting stock as of December 31, 2021. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

A significant portion of our total outstanding shares are eligible, or will soon become eligible, to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have registered all shares of common stock that we may issue under our equity compensation plans, which can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Additionally, on November 9, 2020, we entered into a stock purchase agreement with Pfizer, pursuant to which Pfizer purchased 5.0 million shares of our common stock through a private placement transaction. Pfizer also has rights, subject to specified conditions, to require us to file a Registration Statement on Form S-3 to register the shares of common stock sold in the Pfizer private placement. Once any such registration statement is declared effective, these shares can be freely sold on the public market.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of our common stock. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our Company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware, subject to certain exceptions, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act of 1933, as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation and bylaws described above.

We believe these choice of forum provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Our ability to use net operating losses and research and development credits to offset future taxable income or income tax liabilities may be subject to certain limitations.

As of December 31, 2021, we had federal and state net operating loss carryforwards, or NOLs, of approximately $367.2 million and $369.0 million, respectively. Our state NOLs, and federal NOLs generated in taxable years beginning before January 1, 2018, are subject to expiration and will expire at various dates through 2041. Federal NOLs generated in taxable periods beginning after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80% of our taxable income in taxable years beginning after December 31, 2020, which may require us to pay federal income taxes in future years despite generating federal NOLs in prior years. As of December 31, 2021, we also had federal and state research and development and other tax credit carryforwards, or credits, including the orphan drug credit, of approximately $43.2 million and $10.8 million, respectively, available to reduce future income tax liabilities. The federal and state credits expire at various dates through 2041. These NOLs and credits could expire unused and be unavailable to offset future taxable income or income tax liabilities, to the extent subject to expiration. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs or credits to offset future taxable income or income tax liabilities. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation's stock exceeds 50 percentage points over a rolling three-year period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, if any. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change. Our state NOLs or credits may also be impaired or subject to limitations under state law. Accordingly, even if we attain profitability, we may not be able to utilize a material portion of our NOLs or credits.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future.

General Risk Factors

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of common stock at or above the price at which you purchased them. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to our existing or any future collaborations;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have incurred and expect to continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. We will need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could cause us to need to restate our previously issued financial statements and result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently occupy approximately 26,850 square feet of office and research and development laboratory space in Bedford, Massachusetts, under a sublease agreement with OXB Solutions that expires in 2024. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been publicly traded on The Nasdaq Global Select Market under the symbol "FIXX" since March 28, 2018. Prior to that time, there was no public market for our common stock.

Holders

As of March 11, 2022, there were approximately 57,385,285 shares of common stock outstanding with 17 holders of record. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

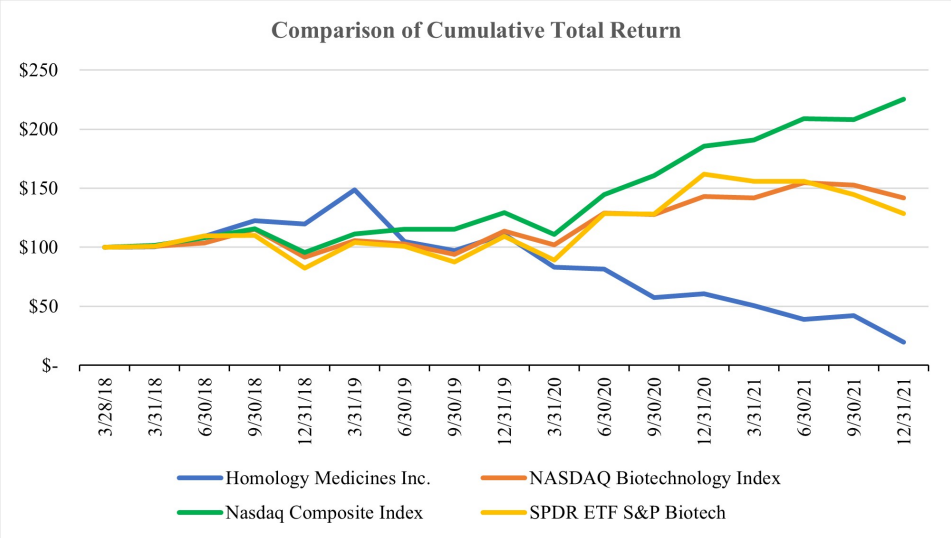
Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12, *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*, of this Annual Report on Form 10-K.

Stock Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act.

The graph set forth below compares the cumulative total stockholder return on our common stock between March 28, 2018 (the date our common stock commenced trading on The Nasdaq Global Select Market) and December 31, 2021, with the cumulative total return of (a) The Nasdaq Biotechnology Index, (b) The Nasdaq Composite Index and (c) The SPDR S&P Biotech ETF, which is an exchange-traded fund that seeks to replicate the performance of the S&P Biotechnology Select Index, over the same period. This graph assumes an initial investment of $100 on March 28, 2018 in our common stock, The Nasdaq Biotechnology Index, The Nasdaq Composite Index and The SPDR S&P Biotech ETF assumes the reinvestment of dividends, if any. The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock.



Recent Sales of Unregistered Securities; Purchases of Equity Securities by the Issuer or Affiliated Purchaser

We did not repurchase any of our equity securities or issue any securities that were not registered under the Securities Act during the quarter ended December 31, 2021.

Use of Proceeds

Not applicable.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our "Selected Consolidated Financial Data" and our consolidated financial statements, related notes and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties such as our plans, objectives, expectations and intentions. As a result of many important factors, including those set forth in the section captioned "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a clinical-stage genetic medicines company dedicated to transforming the lives of patients suffering from rare genetic diseases with significant unmet medical needs by addressing the underlying cause of the disease. Our proprietary platform is designed to utilize our human hematopoietic stem cell derived adeno-associated virus vectors, or AAVHSCs, to precisely and efficiently deliver single administration genetic medicines *in vivo* through our gene therapy, our nuclease-free gene editing modality, or our gene therapy to express antibodies platform, or GTx-mAb. Our clinical programs include: HMI-102, an investigational gene therapy candidate in clinical development for the treatment of adult patients with phenylketonuria, or PKU; HMI-103, an investigational gene editing candidate in clinical development for the treatment of patients with PKU; and HMI-203, an investigational gene therapy candidate in clinical development for the treatment of patients with mucopolysaccharidosis type II (MPS II), or Hunter syndrome. Additionally, we are developing a gene therapy candidate, HMI-104, from our GTx-mAb platform for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH, and we are conducting research in other diseases including metachromatic leukodystrophy, or MLD. Our diverse set of AAVHSCs allows us to precisely target, via a single injection, a wide range of disease-relevant tissues, including the liver, central nervous system, or CNS, peripheral nervous system, or PNS, bone marrow, cardiac and skeletal muscle and the eye. Our genetic medicines platform is designed to provide us the flexibility to choose the method we believe is best suited for each disease we pursue, based on factors such as the targeted disease biology, the biodistribution of our AAVHSCs to key tissues and the rate of cell division the disease-relevant tissues exhibit. Our product-development strategy is to continue to develop in parallel gene therapy and gene editing, while initially leveraging the experience from our gene therapy product candidates to further advance our gene editing. We believe our technology platform will allow us to provide transformative cures using either modality.

The unique properties of our proprietary family of 15 AAVHSCs enable us to focus on a method of gene editing called gene integration, through the replacement of an entire diseased gene in the genome with a whole functional copy by harnessing the naturally occurring deoxyribonucleic acid, or DNA, repair process of homologous recombination, or HR. We believe our HR-driven gene editing approach will allow us to efficiently perform gene editing at therapeutic levels without unwanted on- and off-target modifications to the genome, and to directly measure and confirm those modifications in an unbiased manner to ensure only the intended changes are made. By utilizing the body's natural mechanism of correcting gene defects, we also avoid the need for exogenous nucleases, or bacteria-derived enzymes used in other gene editing approaches to cut DNA, which are known to significantly increase the risk of unwanted modifications.

Clinical-Stage Product Candidates

HMI-102: Investigational Gene Therapy for the Treatment of Adult Patients with PKU

We are currently in Phase 2 of the pheNIX clinical trial with our first and lead product candidate, HMI-102, a gene therapy in development for the treatment of adults with PKU. We have received Fast Track Designation for HMI-102 from the U.S. Food and Drug Administration, or FDA, for the prevention or treatment of neurocognitive defects due to phenylalanine hydroxylase, or PAH, deficiency through normalization of circulating Phe levels.

In November 2020, we reported positive safety and efficacy clinical data from the dose-escalation phase of the trial. As of the data cutoff date of October 19, 2020, six patients in the dose-escalation phase of the trial had received HMI-102 across three dose cohorts (low-dose Cohort 1, n=2; mid-dose Cohort 2, n=2; high-dose Cohort 3, n=2). The results showed that HMI-102 was generally well-tolerated, and resulted in marked reductions in phenylalanine, or Phe, increases in tyrosine, or Tyr, and reductions in the Phe-to-Tyr ratio, at two doses. Phe is a registrable endpoint in PKU, and the Phe-to-Tyr ratio is a clinically relevant diagnostic measurement for PKU. Based on the safety and efficacy results observed in the dose-escalation phase, we selected and advanced two doses to the randomized, concurrently controlled, dose expansion Phase 2 portion of the pheNIX trial, which was designed to have the potential to be converted to a registrational trial.

In October 2021, we announced that, as of September 30, 2021, both doses in the Phase 2 portion of the trial have been generally well-tolerated and have shown evidence of biological activity, including clinically meaningful reductions in Phe levels, increases in Tyr and reductions in the Phe-to-Tyr ratio. In addition, several new clinical trials sites have been recently added to the trial for a total of 15 active sites currently, with more sites expected. Despite increased interest in pheNIX, enrollment is slower than anticipated, due in part to a COVID-19 resurgence.

On February 18, 2022, we announced our pheNIX gene therapy trial had been placed on clinical hold due to the need to modify risk-mitigation measures in the study in response to observations of elevated liver function tests, or LFTs. On March 17, 2022, we received the official clinical hold letter from the FDA requesting information on elevated LFTs observed in some patients in the trial and modified clinical risk-mitigation measures. In patients who experienced elevated LFTs, all have resolved and no hospitalizations were required. Among the risk-mitigation methods that we intend to propose is a new, more targeted immunosuppressive regimen that is shorter in duration and includes a T-cell inhibitor used in combination with a steroid-sparing regimen that may improve patient compliance. The use of T-cell inhibitors has been shown to be effective in dampening the anticipated immune response to AAV capsids. With the additional information requested by the FDA and the planned conversion to a more targeted immunosuppressive regimen, we estimate that we will require more time to submit and receive feedback on our proposed clinical risk-mitigation strategy. As a result, we now expect to provide a program update when the path forward is established with the FDA.

HMI-103: Gene Editing Candidate for the Treatment of Patients with PKU

In October 2021, we announced the initiation of a Phase 1 trial with HMI-103, our lead gene editing candidate in development for the treatment of classical PKU and received Fast Track Designation for the treatment of neurocognitive and neuropsychiatric manifestations of PKU secondary to phenylalanine hydroxylase deficiency. The pheEDIT clinical trial is an open-label, dose escalation study evaluating the safety and efficacy of a single I.V. administration of HMI-103, and is expected to enroll up to nine patients ages 18-55 years old who have been diagnosed with classical PKU due to PAH deficiency. In addition to safety endpoints, the trial will measure serum Phe changes. The trial incorporates an immunosuppressive regimen that includes a T-cell inhibitor used in combination with a steroid-sparing regimen. We expect that the first patient in the pheEDIT clinical trial will be dosed following requisite Institutional Biosafety Committee and Institutional Review Board approvals at the clinical sites, and completion of an 82-day screening/run-in period to account for and more closely understand day-to-day Phe fluctuations of participants. If positive safety and efficacy results are established in adults, we plan to then enroll younger patients in subsequent HMI-103 clinical trials. We expect to provide an update on the pheEDIT clinical trial at the end of 2022.

In *in vivo* preclinical studies, we observed Phe reduction following a single I.V. administration of the murine surrogate of HMI-103 in the PKU disease model out to 43 weeks (end of study). In addition, using quantitative molecular methods, we have demonstrated achievement of gene integration efficiencies in a humanized murine liver model that corresponded with Phe correction in the PKU murine model.

HMI-203: Investigational Gene Therapy for the Treatment of Adult Patients with MPS II (Hunter Syndrome)

In October 2021, we announced the initiation of a Phase 1 trial with HMI-203, an investigational gene therapy in development for the treatment of adults with Hunter syndrome. Hunter syndrome is a lysosomal storage disorder caused by mutations in the iduronate 2-sulfatase, or IDS, gene leading to absent or deficient I2S enzymatic activity, which causes toxic lysosomal accumulation of glycosaminoglycans, or GAGs. The juMPStart clinical trial is an open-label, dose-escalation study evaluating the safety and efficacy of a single I.V. administration of HMI-203, and is expected to enroll up to nine male patients ages 18-30 years old who have been diagnosed with Hunter syndrome and are currently receiving enzyme replacement therapy, or ERT. Qualitative data on unmet medical needs obtained from ERT-treated adult MPS II patients and/or their caregivers helped inform our trial design. Patients and caregivers reported that weekly ERT infusions, surgeries and supportive therapies inadequately address range of motion and mobility, pain, and hearing loss, that there are burdens associated with ERT and other therapies, including frequency and duration of treatment, and painful and extended recoveries, that there is a high degree of anxiety regarding prognosis, longevity, need for more invasive surgeries, and financial challenges and that the expectations for a potential one-time gene therapy include the ability to maintain their current quality of life with ERT independence. Also, key opinion leaders surveyed supported our planned design for the juMPStart clinical trial, including our plan to discontinue ERT.

In addition to safety endpoints, the trial will measure plasma I2S activity, urinary GAG levels and other peripheral disease endpoints. We expect to provide an update on the juMPStart clinical trial at the end of 2022.

In preclinical studies, a single I.V. administration of HMI-203 resulted in robust biodistribution and human I2S enzyme expression, leading to significant reductions in heparan sulfate GAG levels in the cerebrospinal fluid, brain, liver, heart, spleen, lung and kidney, compared with the vehicle-treated disease model. HMI-203 also led to significant reductions in skeletal deformities compared with vehicle.

Earlier-Stage Product Candidates

In August 2021, we named a clinical development candidate for PNH, HMI-104, from our GTx-mAb platform. This platform represents an additional way that we are leveraging our AAVHSCs in an effort to deliver one-time *in vivo* gene therapy to express and secrete antibodies from the liver, which we believe may allow us to target diseases with larger patient

populations. In support of this program, we generated and presented preclinical data targeting complement protein 5, demonstrating proof-of-concept in PNH. Our data showed that our AAVHSCs delivered vectors at a high efficiency to the liver and secreted antibodies throughout the body, resulting in sustained expression levels consistent with C5 antibody therapeutics in a humanized murine model.

We completed Investigational New Drug Application, or IND, -enabling studies with HMI-202, an investigational gene therapy in development for the treatment of patients with MLD. We have generated preclinical data that demonstrate that a single I.V. administration of HMI-202 crossed the blood-brain and blood-nerve-barriers and led to sustained reduction of sulfatides in all brain regions of the disease model. We are applying the learnings from the IND-enabling studies to further optimize an HMI-202 vector that we believe may lead to a better therapeutic profile.

Oxford Biomedica Solutions Transaction

On March 10, 2022, we closed our previously announced transaction with Oxford Biomedica Solutions LLC (f/k/a Roadrunner Solutions LLC), or OXB Solutions, Oxford Biomedica (US), Inc., or OXB, and Oxford Biomedica plc, or OXB Parent, and collectively with OXB, Oxford, pursuant to the Equity Securities Purchase Agreement, or the Purchase Agreement, dated as of January 28, 2022, by and among Homology, OXB Solutions and Oxford, whereby, among other things, we and Oxford have agreed to collaborate to operate OXB Solutions, which will provide AAV vector process development and manufacturing to pharmaceutical and biotechnology companies, which we refer to as the Oxford Biomedica Solutions Transaction, or the OXB Solutions Transaction. OXB Solutions incorporates our proven 'plug and play' process development and manufacturing platform, as well as our experienced team and high-quality GMP vector production capabilities that we built and have been operating since 2019. We will continue to leverage these process development and manufacturing capabilities while reducing our costs and maintaining dedicated manufacturing capacity to support our product candidates. We believe the quality, reliability and scalability of our gene therapy and gene editing manufacturing approach is a core competitive advantage crucial to our long-term success.

Pursuant to the terms of the Purchase Agreement and a contribution agreement, or the Contribution Agreement, entered into between us and OXB Solutions prior to the closing of the OXB Solutions Transaction, or the Closing, we agreed to assign and transfer to OXB Solutions all of our assets that are primarily used in the manufacturing of AAV vectors for use in gene therapy or gene editing products, but excluding certain assets related to manufacturing or testing of our proprietary AAV vectors, or collectively, the Transferred Assets, in exchange for 175,000 common equity units in OXB Solutions, or Units, and OXB Solutions assumed from us, and agreed to pay, perform and discharge when due, all of our duties, obligations, liabilities, interests and commitments of any kind under, arising out of or relating to the Transferred Assets.

Effective as of the Closing, we sold to OXB, and OXB purchased from us, 130,000 Units, or the Transferred Units, in exchange for $130.0 million. In connection with the Closing, OXB contributed $50.0 million in cash to OXB Solutions in exchange for an additional 50,000 Units. Immediately following the Closing, (i) OXB owned 180,000 Units, representing 80 percent (80%) of the fully diluted equity interests in OXB Solutions, and (ii) we owned 45,000 Units, representing 20 percent (20%) of the fully diluted equity interests in OXB Solutions.

Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB Solutions, or the OXB Solutions Operating Agreement, which was executed in connection with the Closing, at any time following the three-year anniversary of the Closing, (i) OXB will have an option to cause us to sell and transfer to OXB, and (ii) we will have an option to cause OXB to purchase from us, in each case all of our equity ownership interest in OXB Solutions at a price equal to 5.5 times the revenue for the immediately preceding 12-month period, subject to a specified maximum amount. Pursuant to the terms of the OXB Solutions Operating Agreement, we will be entitled to designate one director on the Board of Directors of OXB Solutions, which shall initially be Arthur Tzianabos, our President and Chief Executive Officer. Further, Tim Kelly, our former Chief Operating Officer, now serves as the Chief Executive Officer and Chairman of the Board of OXB Solutions.

Concurrently with the Closing, we entered into certain ancillary agreements with OXB Solutions including a license and patent management agreement whereby OXB Solutions granted certain licenses to us, a supply agreement for a term of three years which includes certain annual minimum purchase commitments, a lease assignment pursuant to which we assigned all of our right, title and interest in, to and under our facility lease to OXB Solutions, a sublease agreement whereby OXB Solutions subleased certain premises in its facility to us, as well as several additional ancillary agreements.

Corporate Headquarters Lease

In November 2021, we entered into an amendment of our December 2017 lease agreement, or the Lease Amendment, for our corporate headquarters in Bedford, Massachusetts. The Lease Amendment increases the space under lease by

approximately 23,011 square feet, or the Expansion Premises, and extends the expiration date of the existing premises under the lease from February 2027 to June 2030. The term with respect to the Expansion Premises commences on the earlier of (i) the date of the Substantial Completion of the Tenant's Work (as both terms are defined in the Lease Amendment), (ii) the Company's occupancy of any portion of the Expansion Premises, and (iii) May 1, 2022, and continues for a period of ten years and five months. The term of the Expansion Premises and the existing premises are not coterminous. Annual base rent for the existing premise under the Lease Amendment is approximately $4.7 million beginning on March 1, 2027, and increases by three percent annually; annual base rent for the Expansion Premises is approximately $1.4 million per year and increases by three percent annually. The Lease Amendment allows for a tenant improvement allowance not to exceed $5.3 million. Under the terms of the agreement with Oxford, our lease for our corporate headquarters, including the Expansion Premises, has been assigned to OXB Solutions with Homology subleasing a portion of lab and office space back from the newly created company. See Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our lease agreement.

License Agreements

On February 26, 2021, we received notice from Novartis Institutes of BioMedical Research, Inc., or Novartis, that they had elected to terminate the collaboration and license agreement with respect to the ophthalmic target, which was the only remaining target under the agreement. Accordingly, the notice served as notice of Novartis' termination of the agreement in its entirety, with an effective date of August 26, 2021, which was six months from the date of the notice. Novartis acknowledged that the data we generated support gene editing in retinal cells in a rare ophthalmic disease, providing early proof-of-principle for further research using this approach. See Note 15 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding the Novartis collaboration and license agreement.

In April 2016, we entered into an exclusive license agreement with City of Hope, or COH, pursuant to which COH granted us an exclusive, sublicensable, worldwide license, or the COH License, to certain AAV vector-related patents and know-how owned by COH to develop, manufacture, use and commercialize products and services covered by such patents and know-how in any and all fields. On August 6, 2021, we received notice from COH that we did not accomplish at least one of the partnering milestones by the applicable deadline, as set forth in the COH License. This notice does not affect our exclusive license in the field of mammalian therapeutics, including all human therapeutics, associated diagnostics, and target validation, or the Mammalian Therapeutic Field, where we retain exclusive rights. Instead, the notice served as written notice that the exclusive license granted pursuant to the COH License in all fields except the Mammalian Therapeutic Field converted from exclusive to non-exclusive effective as of September 20, 2021, which was forty-five days from the receipt of notice. In connection with the conversion, any royalty obligations and sublicensee fees relating to fields outside of the Mammalian Therapeutic Field shall be reduced by a certain percentage. This change to our exclusive worldwide license with COH does not impact any of our current therapeutic product development candidates in development, including HMI-102, HMI-103, HMI-203, HMI-202 and HMI-104, nor will it impact any potential future therapeutic product development candidates.

Management Team and Financial Overview

Our management team has a successful track record of discovering, developing and commercializing therapeutics with a particular focus on rare diseases. We have a robust intellectual property portfolio that includes a combination of issued patents and pending patent applications that are owned by us or licensed from third parties. The portfolio includes issued patents in the United States directed to our family of 15 AAVHSCs, and issued patents in the United States, Europe, Japan, and China specifically directed to gene editing using these AAVHSCs. As of December 31, 2021, we have an exclusive license or co-exclusive license under 18 United States issued patents, nine foreign granted patents and 52 patent applications pending in the United States and internationally. These licensed patent applications include two United States applications and 13 foreign applications that are co-owned with COH. In addition, we own a granted United States patent relating to our HMI-102 composition that is expected to expire in 2039 and may be eligible for patent term extension depending on the regulatory pathway of the product covered by the patent. We also own ten United States and 86 foreign patent applications that are pending. We believe the breadth and depth of our intellectual property is a strategic asset that has the potential to provide us with a significant competitive advantage.

Since our inception in 2015, we have raised approximately $721 million in aggregate net proceeds through our initial public offering, or IPO, in April 2018, follow-on public offerings of common stock in April 2019 and April 2021, proceeds from the sale of common stock under an "at-the-market" sales agreement, equity investments, preferred stock financings and our newly announced agreement with Oxford. Included in our net proceeds is a $130.0 million up-front cash payment from our agreement with Oxford, $50.0 million from a former collaboration partner, comprised of an up-front payment of $35.0 million and a $15.0 million equity investment, and a $60.0 million equity investment from Pfizer Inc., or Pfizer, through a private placement transaction. We will require additional capital in order to advance our product candidates through clinical development and commercialization. We believe that our compelling preclinical data, positive clinical data with HMI-102,

scientific expertise, product-development strategy, manufacturing platform and process and robust intellectual property position us as a leader in the development of genetic medicines.

On April 6, 2021, we completed a follow-on public offering of our common stock. We sold 6,596,306 shares of our common stock at a price of $7.58 per share and received net proceeds of $49.7 million, after deducting offering expenses. Under the terms of the underwriters' agreement, we also granted an option exercisable for 30 days to purchase up to an additional 989,445 shares of our common stock at a price of $7.58 per share. The underwriters did not exercise this option. The offering closed on April 9, 2021. The shares were sold pursuant to our effective shelf registration statement on Form S-3, as amended, and a related prospectus supplement filed with the SEC on April 8, 2021.

We were incorporated and commenced operations in 2015. Since our incorporation, we have devoted substantially all of our resources to organizing and staffing our Company, business planning, raising capital, developing our technology platform, advancing HMI-102, HMI-103 and HMI-203 through IND-enabling studies and into clinical trials, advancing HMI-202 through IND-enabling studies and HMI-104 into IND-enabling studies, researching and identifying additional product candidates, developing and implementing manufacturing processes and internal manufacturing capabilities, building out our manufacturing and research and development space, enhancing our intellectual property portfolio and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sale of common stock, through the sale of preferred stock and through funding from our collaboration partner.

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. We recognized $34.0 million and $2.7 million in collaboration revenue for the years ended December 31, 2021 and 2020, respectively. Collaboration revenue for the year ended December 31, 2021 includes the recognition of approximately $30.8 million of deferred revenue and reimbursements incurred under the collaboration and license agreement with Novartis, for which Novartis gave written notice of termination on February 26, 2021, and is therefore not expected to continue in future years. Since inception, we have incurred significant operating losses. Our net losses for the years ended December 31, 2021 and 2020 were $95.8 million and $128.7 million, respectively. As of December 31, 2021 and December 31, 2020, we had an accumulated deficit of $424.1 million and $328.4 million, respectively.

Our total operating expenses were $129.9 million and $133.0 million for the years ended December 31, 2021 and 2020, respectively. We expect our research and development expenses to increase in connection with our ongoing development activities related to our product candidates. Specifically, we anticipate that our expenses will increase due to costs associated with our Phase 1/2 pheNIX clinical trial with HMI-102, our Phase 1 pheEDIT clinical trial with HMI-103, our Phase 1 juMPStart clinical trial with HMI-203, and development activities and clinical trials associated with our other product candidates, including HMI-202, our gene therapy product candidate for MLD, for which we are focusing on optimization of the vector and HMI-104, our GTx-mAb product candidate for PNH, and research activities in additional therapeutic areas to expand our pipeline, including the addition of our GTx-mAb platform, hiring additional personnel in research, clinical and regulatory, quality and other functional areas, increased expenses incurred with contract manufacturing organizations, or CMOs, to supply us with product for our clinical studies, costs to manufacture product for preclinical and clinical studies and other costs including the maintenance and expansion of our intellectual property portfolio. In addition, we expect to continue to incur additional costs associated with operating as a public company.

We have incurred significant capital expenditures for the buildout of a facility we have leased, including research and development labs, office space and manufacturing suites and the procurement of equipment and furniture for this facility and in support of our product development candidates and research initiatives. As a result of our agreement with Oxford, we will be purchasing process development services and manufacturing product runs from the newly created OXB Solutions and therefore would expect an increase in these costs with an offsetting decrease in the total costs to run our manufacturing facility, including employee-related costs for the 125 manufacturing employees transitioning to the new company. We expect to incur significant additional capital expenditures in support of our research and development activities.

Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates and our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to predict the timing and amount of increased operating expenses and capital expenditures associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the costs, timing, and results of our ongoing research and development efforts, including clinical trials;
- the costs, timing, and results of our research and development efforts for current and future product candidates in our gene therapy and gene editing pipeline;
- the costs and timing of process development scale-up activities, and the adequacy of supply of our product candidates for preclinical studies and clinical trials through CMOs;

- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effect of competitors and market developments; and
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements for our product candidates.

We believe that cash and cash equivalents and short-term investments as of December 31, 2021, together with the $130.0 million in cash received from Oxford in March 2022, will enable us to fund our current projected operating expenses and capital expenditure requirements into the second half of 2024 including, subject to the impact of the COVID-19 pandemic on our business, additional development activities related to our Phase 1/2 pheNIX clinical trial with HMI-102, our Phase 1 pheEDIT clinical trial with HMI-103, our Phase 1 juMPStart clinical trial with HMI-203, preclinical activities relating to HMI-202 and HMI-104, the continued optimization of our manufacturing processes and the expansion of our intellectual property portfolio. We have based these estimates on assumptions that may prove to be imprecise, and we may use our available capital resources sooner than we currently expect. See "Liquidity and Capital Resources." Adequate additional funds may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. See "Risk Factors—The COVID-19 pandemic has and could continue to adversely impact our business, including our preclinical studies and clinical trials." in Item 1A of this Annual Report on Form 10-K. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights as a shareholder. Any future debt financing or preferred equity or other financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute the ownership interests of our shareholders.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Impact of the COVID-19 Pandemic

We are closely monitoring how the spread of the COVID-19 pandemic is affecting our employees, clinical trials, preclinical studies and overall operations. In response to the spread of COVID-19, we have taken steps to minimize the impact on our operations.

Operations – At the onset of the COVID-19 pandemic, to protect the health of our employees and the third parties with whom we interact, most office-based employees were asked to work from home. We have now implemented a return-to-work policy which provides for a hybrid of remote and in-office work, and we expect to operate on such a semi-virtual basis for at least the first half of 2022, pending the future direction of the COVID-19 pandemic. Essential staffing levels in our operations remain in place, including key personnel in our laboratories. For those employees on-site, we continue to maintain shift schedules for our laboratories and a modified office layout to increase spacing capabilities, reduce inter-office risks and allow for business continuity. We have increased cleaning protocols throughout our entire facility and have implemented procedures regarding office visitors to better protect our employees.

Clinical trials – We are currently in Phase 2 of our Phase 1/2 pheNIX clinical trial and are working with trial sites to mitigate COVID-19-related disruptions in order to help ensure the safety of patients and healthcare professionals. In addition, we have deployed home-health services which include home visits for patient monitoring and reporting, as well as the utilization of a centralized laboratory for testing enrolled patients. Despite our best efforts, disruptions caused by the COVID-19 pandemic have resulted, and may continue to result, in delays in enrolling our Phase 1/2 pheNIX clinical trial. In addition,

we could experience additional disruptions in conducting or completing this trial or other planned clinical trials and the incurrence of unforeseen costs as a result of these delays. We will continue to evaluate the impact of the COVID-19 pandemic on the pheNIX trial and our other clinical trials and will make adjustments, as needed.

Preclinical studies – All of our ongoing and planned preclinical studies at external CROs are progressing and we have accelerated shipments of reagents and supplies to avoid any disruption of activities. However, it is possible that the COVID-19 pandemic may have an impact in the future on our CROs' ability to complete critical studies required for the progression of these programs. In addition, any planned or potential meetings with the FDA or other regulatory authorities about any of our development programs could be delayed as these regulatory bodies respond to the COVID-19 pandemic.

At this time, there is significant uncertainty relating to the trajectory of the COVID-19 pandemic and impact of related responses and as a result, we expect that the COVID-19 pandemic may impact our business, revenues, results of operations and financial condition. The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact of COVID-19 on financial markets and the global economy, the spread of variants, the effectiveness of vaccines and vaccine distribution efforts and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. See "Risk Factors— The COVID-19 pandemic has and could continue to adversely impact our business, including our preclinical studies and clinical trials." in Item 1A of this Annual Report on Form 10-K.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. We recorded $34.0 million in collaboration revenue for the year ended December 31, 2021, primarily related to the termination of the Novartis collaboration and license agreement (see Notes 15 and 16 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding revenue recognition discussions).

Operating Expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, and other third parties that conduct research, preclinical activities and clinical trials on our behalf as well as CMOs and our internal technical operations team that manufactured our product candidates for use in our preclinical testing, our ongoing clinical trials with HMI-102, HMI-103 and HMI-203 and additional potential future clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates. These costs are included in other research and development expenses in the table below.

The following table summarizes our research and development expenses by product candidate or development program:

(in thousands)	For the Year Ended December 31, 2021	2020	Change
External development costs for clinical programs:			
HMI-102	$ 18,501	$ 36,409	$ (17,908)
HMI-103	10,034	6,476	3,558
HMI-203	11,981	6,669	5,312
Other development-stage programs' external development costs	4,035	10,480	(6,445)
Employee-related costs	45,227	38,373	6,854
Other research and development costs	3,307	1,985	1,322
Total research and development expenses	$ 93,085	$ 100,392	$ (7,307)

Research and development activities are central to our business model. We expect that our research and development expenses will increase for the foreseeable future as we advance our clinical trials for the treatment of PKU, including our Phase 2 pheNIX clinical trial with HMI-102 and our Phase 1 pheEDIT clinical trial with HMI-103, advance Phase 1 juMPStart clinical trial with HMI-203 for the treatment of Hunter syndrome, advance our product candidate HMI-202 for the treatment of MLD into clinical trials, advance our product candidate HMI-104 from our GTx-mAb platform for the treatment of PNH through IND-enabling studies and continue to discover and develop additional product candidates. However, as a result of our agreement with Oxford, we will be purchasing process development services and manufacturing product runs from the newly created OXB Solutions and therefore would expect an increase in these costs with an offsetting decrease in the total costs to run our manufacturing facility, including employee-related costs for the 125 manufacturing employees transitioning to the new company.

We cannot determine with certainty the duration and costs of future clinical trials or preclinical studies of our product candidates in development or any other future product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our product candidates in development and any other future product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of current clinical trials, as well as of any future clinical trials, and other research and development activities that we may conduct;
- uncertainties in clinical trial design and patient enrollment rates;
- any delays in clinical trials as a result of the COVID-19 pandemic;
- the actual probability of success for our product candidates, including the safety and efficacy results, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, human resources, legal, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters;

professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs, rent expense, maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support increased research and development activities relating to our product candidates in development and any other future product candidates we may develop. We also have incurred and expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, compliance with the Sarbanes-Oxley Act of 2002, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Interest Income

Interest income consists of interest income earned on our cash, cash equivalents and short-term investments. Our interest income has decreased due to lower balances in invested funds and lower yields on invested funds during the year ended December 31, 2021 as compared to the same period in 2020. Market volatility resulting from the COVID-19 pandemic has and may continue to adversely impact our interest income.

Income Taxes

Since our inception in 2015, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2021, we had federal and state net operating loss carryforwards of $367.2 million and $369.0 million, respectively, that expire at various dates through 2041. As of December 31, 2021, we also had federal and state research and development tax credit carryforwards of $43.2 million and $10.8 million, respectively, that expire at various dates through 2041. Included in the $43.2 million of federal research and development credit carryforwards is $33.9 million of orphan drug credit carryforwards.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition—We recognize revenue in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Accordingly, we recognize revenue when we obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. For example, a significant portion of

revenue recognized from our collaboration with Novartis, prior to termination, was related to research and preclinical development work performed whereby revenue was recognized as the underlying services were performed using a cost-to-cost model. Prior to the termination of the collaboration with Novartis, we measured the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Accrued Research and Development Expenses—As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel and vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to contract research organizations and other third parties in connection with performing research activities on our behalf and conducting preclinical studies and clinical trials on our behalf and contract manufacturing organizations in connection with producing product for our clinical studies, vendors in connection with preclinical development activities and vendors related to product manufacturing and development and distribution of preclinical supplies.

We base our accrued expenses related to preclinical and clinical studies on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct and manage preclinical studies and clinical trials and CMOs that manufacture product for our research and development activities on our behalf. The financial terms of these agreements are sometimes subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical milestones. In accruing fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly.

Although we do not expect our estimates to be materially different from expenses actually incurred, if our estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an “emerging growth company,” which we are, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*: Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”) to improve financial reporting by requiring more timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. ASU 2016-13 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help investors and other financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization’s portfolio. ASU 2016-13 is effective for us beginning January 1, 2023, with early application permitted. We are currently evaluating the impact the adoption of this standard will have on our consolidated financial statements.

Results of Operations

Comparison of Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

(in thousands)	For the Year Ended December 31, 2021	2020	Change
Collaboration revenue	$ 33,971	$ 2,702	$ 31,269
Operating expenses:			
Research and development	93,085	100,392	(7,307)
General and administrative	36,835	32,573	4,262
Total operating expenses	129,920	132,965	(3,045)
Loss from operations	$ (95,949)	$ (130,263)	$ 34,314
Other income:			
Interest income	185	1,569	(1,384)
Total other income	185	1,569	(1,384)
Net loss	$ (95,764)	$ (128,694)	$ 32,930

Collaboration Revenue

Collaboration revenue for the year ended December 31, 2021 was $34.0 million, compared to $2.7 million for the year ended December 31, 2020. Collaboration revenue in both periods includes the recognition of deferred revenue and reimbursements incurred under the collaboration and license agreement with Novartis, which terminated in August 2021. As a result of the termination, all remaining deferred revenue pursuant to the collaboration and license agreement with Novartis was recognized as we performed the final activities under the collaboration and license agreement through the termination date. In addition, for the year ended December 31, 2021, we recognized collaboration revenue of $3.2 million related to the Stock Purchase Agreement with Pfizer.

Research and Development Expenses

(in thousands)	For the Year Ended December 31, 2021	2020	Change
External development costs for clinical programs:			
HMI-102	$ 18,501	$ 36,409	$ (17,908)
HMI-103	10,034	6,476	3,558
HMI-203	11,981	6,669	5,312
Other development-stage programs' external development costs	4,035	10,480	(6,445)
Employee-related costs	45,227	38,373	6,854
Other research and development costs	3,307	1,985	1,322
Total research and development expenses	$ 93,085	$ 100,392	$ (7,307)

Research and development expenses for the year ended December 31, 2021 were $93.1 million, compared to $100.4 million for the year ended December 31, 2020. The decrease of $7.3 million was primarily due to a decrease of $17.9 million in direct research expenses for HMI-102 including costs incurred with our CRO to conduct and manage our Phase 2 pheNIX clinical trial due to a slow-down in trial enrollment, as well as lower manufacturing costs in 2021 as we had accelerated procurement of raw materials and production runs in 2020 to mitigate potential supply chain interruptions and relied entirely on our internal manufacturing capabilities for clinical supply in 2021. Additionally, there was a $6.4 million decrease in direct research expenses related to our other development-stage programs, primarily due to higher spending on HMI-202 in the prior year as we completed IND-enabling studies. Partially offsetting these decreases was a $3.6 million and a $5.3 million increase in direct research expenses for HMI-103 and HMI-203, respectively, as we advanced both programs into the clinic in 2021, as well as an increase of $6.9 million in employee-related costs due to additional employee headcount to support our ongoing development programs, research initiatives, technology platform and manufacturing capabilities resulting in increases in salaries, payroll taxes, stock-based compensation expense and recruiting costs. Other research and development costs related to

laboratory supplies and research materials for our early-stage research programs and platform-development work increased $1.3 million over the prior year.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2021 were $36.8 million, compared to $32.6 million for the year ended December 31, 2020. The increase of $4.2 million was due to an increase of $1.6 million of stock-based compensation expense, an increase in market research of $0.5 million, an increase in legal costs and other professional fees of $1.4 million, and an increase in recruiting fees of $0.5 million. Additionally, there was an increase in licensed software of $0.5 million and an increase in insurance costs of $0.4 million. These increases were partially offset by a decrease in facilities costs of $0.8 million.

Interest Income

Interest income for the year ended December 31, 2021 was $0.2 million, compared to $1.6 million for the year ended December 31, 2020. The decrease was the result of lower invested balances in cash, cash equivalents and short-term investments for the year ended December 31, 2021 compared to the year ended December 31, 2020, as well as significantly lower yields on invested funds.

Net Loss

Net loss for the year ended December 31, 2021 was $95.8 million, compared to $128.7 million for the year ended December 31, 2020. The decrease in net loss was primarily due to the increase in collaboration revenue discussed above.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs and our capital expenditures will increase in connection with conducting preclinical studies and clinical trials for our product candidates, contracting with CMOs to support preclinical studies and clinical trials, expanding our research and development laboratories and manufacturing facility, expanding our intellectual property portfolio, and providing general and administrative support for our operations. However, as a result of our agreement with Oxford, we will be purchasing process development services and manufacturing product runs from the newly created OXB Solutions and therefore would expect an increase in these costs with an offsetting decrease in the total costs to run our manufacturing facility, including employee-related costs for the 125 manufacturing employees transitioning to the new company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the sale of common stock, the sale of preferred stock and through an up-front payment and funding of research candidates from a collaboration partner. Since our inception in 2015, we have raised approximately $721 million in aggregate net proceeds through our IPO in April 2018, follow-on public offerings of common stock in April 2019 and April 2021, proceeds from the sale of common stock under an “at-the-market” sales agreement, equity investments, preferred stock financings and our newly announced agreement with Oxford. Included in our net proceeds is $130.0 million up-front cash payment from our agreement with Oxford, $50.0 million from a former collaboration partner, comprised of an up-front payment of $35.0 million and a $15.0 million equity investment and a $60.0 million equity investment from Pfizer through a private placement transaction.

Equity Offerings and ATM Program

In March 2020, we entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $150 million in "at-the-market" offerings, or the ATM, under our Registration Statement on Form S-3 (File No. 333-237131) filed with the SEC on March 12, 2020 (as amended, the Shelf). In connection with the filing of certain post-effective amendments to the Shelf, the sales agreement prospectus supplement now covers the offering, issuance and sale by us of up to an aggregate $148.4 million of our common stock. Sales of common stock, if any, pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through The Nasdaq Global Market or on any other existing trading market for our common stock. During the year ended December 31, 2021, we sold 114,914 shares of common stock under the Sales Agreement, at an average price of

approximately $14.00 per share, raising aggregate net proceeds of approximately $1.5 million after deducting an aggregate commission of 3% and issuance costs. As of December 31, 2021, there was $148.4 million of common stock remaining available for sale under the ATM.

On April 6, 2021, we completed a follow-on public offering of our common stock. We sold 6,596,306 shares of our common stock at a price of $7.58 per share and received net proceeds of approximately $49.7 million, after deducting estimated offering expenses. Under the terms of the underwriting agreement, we also granted the underwriter an option exercisable for 30 days to purchase up to an additional 989,445 shares of our common stock at a price of $7.58 per share. The underwriters did not exercise this option. The offering closed on April 9, 2021. The shares were sold pursuant to our effective shelf registration statement on Form S-3, as amended, and a related prospectus supplement filed with the SEC on April 8, 2021.

Oxford Biomedica Solutions Transaction

On March 10, 2022, we closed our previously announced transaction with Oxford pursuant to the Purchase Agreement, dated as of January 28, 2022, by and among Homology, OXB Solutions and Oxford, whereby, among other things, we and Oxford have agreed to collaborate to operate OXB Solutions, which will provide AAV vector process development and manufacturing to pharmaceutical and biotechnology companies. Pursuant to the terms of the agreements entered into as part of the OXB Solutions Transaction, we have assigned and transferred to OXB Solutions all of our assets that are primarily used in the manufacturing of AAV vectors for use in gene therapy or gene editing products. Oxford paid us $130.0 million upfront and invested $50.0 million to fund the new company in exchange for an 80-percent ownership stake, while we own 20 percent of the new company. See Part I, Item 1. “Manufacturing—Oxford Biomedica Solutions Transaction” and Note 18 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding the OXB Solutions Transaction.

Strategic Collaborations and Investments

On November 9, 2020, we entered into the Stock Purchase Agreement with Pfizer, pursuant to which Pfizer purchased 5,000,000 shares of our common stock through a private placement transaction at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million. Under the Stock Purchase Agreement, Pfizer was granted an exclusive right of first refusal, or ROFR, for a 30-month period beginning on the date of the closing of the private placement to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103. Pfizer may exercise its right of first refusal under the ROFR one time for each of HMI-102 and HMI-103 during the ROFR period. In addition to the ROFR, the Stock Purchase Agreement provided for an information sharing committee comprised of representatives of each company which will serve as a forum for sharing information regarding the development of HMI-102 and HMI-103 during the ROFR period. Additionally, Pfizer has designated a member to join our Scientific Advisory Board to participate in matters related to the development of these programs.

See Part I, Item 1. “Strategic Collaborations—Collaboration and License Agreement with the Novartis Institutes for BioMedical Research, Inc.” for additional information about our collaboration and license agreement with Novartis.

Cash Flows

Our cash, cash equivalents and short-term investments totaled $155.9 million and $217.4 million as of December 31, 2021 and 2020, respectively. We had no indebtedness as of December 31, 2021 and 2020.

The following table summarizes our sources and uses of cash for the period presented:

	For the Year Ended December 31,	
(in thousands)	**2021**	**2020**
Net cash used in operating activities	$ (109,751)	$ (94,332)
Net cash provided by (used in) investing activities	(50,788)	204,896
Net cash provided by financing activities	52,169	53,093
Net change in cash and cash equivalents	$ (108,370)	$ 163,657

Cash Flows for the year ended December 31, 2021

Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was $109.8 million, driven primarily by our net loss of $95.8 million as we incurred expenses associated with research and development activities on HMI-102, HMI-103 and HMI-203, including the Phase 2 pheNIX trial for our HMI-102 program, and research activities on other applications for our technology, a decrease in deferred revenue of $33.4 million, and a decrease in operating lease liabilities of $2.4 million. These items were partially offset by net non-cash expenses of $27.8 million, which includes $17.2 million of stock-based compensation expense and $8.4 million of depreciation expense.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 was $50.8 million, attributable to maturities of short-term investments of $49.0 million, offset by purchases of short-term investments of $97.4 million and purchases of property and equipment of $2.4 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 was $52.2 million, primarily due to $49.7 million of net proceeds from the issuance of common stock in follow-on public offerings and $1.5 million of net proceeds from the issuance of common stock pursuant to ATM financing.

Cash Flows for the year ended December 31, 2020

Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $94.3 million, driven primarily by our net loss of $128.7 million as we incurred expenses associated with research and development activities on HMI-102, HMI-103, HMI-203, and HMI-202, including the Phase 1/2 pheNIX trial for our HMI-102 program, and research activities on other applications for our technology, and a decrease in operating lease liabilities of $2.3 million. These items were partially offset by net non-cash expenses of $22.8 million, which includes $13.2 million of stock-based compensation expense and $8.0 million of depreciation expense, and a decrease in working capital of $13.8 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2020 was $204.9 million, attributable to maturities of short-term investments of $228.6 million, partially offset by purchases of short-term investments of $20.0 million and purchases of property and equipment of $3.7 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was $53.1 million, primarily due to $52.0 million of net proceeds from the issuance of common stock in a private placement transaction with Pfizer in November 2020.

Funding Requirements

Though our operating expenses decreased in 2021, research and development expenses are expected to increase in future years in connection with our ongoing activities, particularly as we advance our Phase 1/2 pheNIX clinical trial with HMI-102, our Phase 1 pheEDIT clinical trial with HMI-103, our Phase 1 juMPStart clinical trial with HMI-203 and our preclinical activities including IND-enabling studies, continue to optimize our manufacturing processes, engage with CMOs and initiate additional human clinical trials. However, as a result of our agreement with Oxford, we will be purchasing process development services and manufacturing product runs from the newly created OXB Solutions and therefore would expect an increase in these costs with an offsetting decrease in the total costs to run our manufacturing facility, including employee-related costs for the 125 manufacturing employees transitioning to the new company. We have incurred, and expect to continue to incur additional costs associated with operating as a public company. We also expect our capital expenditures to increase as we expand our operations.

Specifically, our expenses will increase as we:

- pursue the preclinical and clinical development of our product candidates;
- pursue the preclinical and clinical development of other product candidates based on our gene therapy and gene editing technology;
- further optimize our manufacturing processes and contract with CMOs to support our preclinical studies and clinical trials of our product candidates;
- operate our business in our facility with expanded research and development labs and manufacturing suites and purchase additional equipment for our operations;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel in research, manufacturing and regulatory and clinical development as well as management personnel; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our operations as a public company.

We believe that our existing cash and cash equivalents, together with the $130.0 million received from Oxford in March 2022, will enable us to fund our current projected operating expenses and capital expenditure requirements into the second half of 2024, including, subject to the impact of the COVID-19 pandemic on our business, additional development activities related to our Phase 1/2 pheNIX clinical trial with HMI-102, the advancement of HMI-103, our lead gene editing product candidate for PKU, through IND-enabling studies and into a Phase 1/2 clinical trial, HMI-203, our lead CNS/PNS gene therapy product candidate for Hunter syndrome, through IND-enabling studies and into a Phase 1/2 clinical trial, and HMI-202, a CNS gene therapy product candidate for MLD, through additional preclinical studies as we focus on optimizing the program's vector, the continued optimization of our manufacturing processes and the expansion of our intellectual property portfolio. We have based these estimates on assumptions that may prove to be imprecise, and we may use our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our preclinical development and initial clinical trials for HMI-102, including the pheNIX Phase 1/2 clinical trial, HMI-103, HMI-203, and HMI-202;
- the progress, costs and results of our additional research and preclinical development programs in gene therapy and gene editing;
- the costs, scope and timing of process development and manufacturing activities with CMOs associated with our lead product development programs and other programs we advance through preclinical and clinical development;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of any product candidates that we may derive from our platform technology or any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

In addition, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements is uncertain as of the filing date of this Annual Report on Form 10-K, as the pandemic continues to evolve globally. See "Impact of the COVID-19 Pandemic" above and "Risk Factors— The COVID-19 pandemic has and could continue to adversely impact our business, including our preclinical studies and clinical trials." in Item 1A of this Annual Report on Form 10-K for a further discussion of the possible impact of the COVID-19 pandemic on our business.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements and marketing and distribution arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

As of December 31, 2021, we had non-cancelable operating leases with total future minimum lease payments of $48.2 million, of which $3.3 million will be payable in 2022. These minimum lease payments exclude our share of the facility operating expenses, real-estate taxes and other costs that are reimbursable to the landlord under the leases. These payments are for operating leases for our corporate headquarters in Bedford, Massachusetts, comprised of office, manufacturing and lab space that expire in June 2030 and May 2032. Under the terms of the OXB Solutions Transaction, our leases for this space has been assigned to OXB Solutions effective March 10, 2022, with Homology subleasing a portion of lab and office space back from the newly created company. This assignment significantly decreases our contractual obligations under our operating leases to approximately $3.8M through 2024 when the sublease expires. See Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our lease agreement.

Our agreements with certain institutions to license intellectual property include potential milestone and success fees, sublicense fees, royalty fees, licensing maintenance fees, and reimbursement of patent maintenance costs that we may be required to pay. Our agreements to license intellectual property include potential milestone payments that are dependent upon the development of products using the intellectual property licensed under the agreements and contingent upon the achievement of development or regulatory approval milestones, as well as commercial milestones. These potential obligations are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty. For further information regarding these agreements, please see Part I, Item 1. “Strategic Collaborations.”

We enter into contracts in the normal course of business with CROs and CMOs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice of 30 days and, as a result, are not included in the table of contractual obligations above. Pursuant to the terms of the Supply Agreement with OXB Solutions entered into in March 2022, we have agreed to purchase from OXB Solutions at least 50% of our clinical supply requirements of AAV-based products during the initial term of the Supply Agreement. We are committed to purchase a minimum of nine production runs and $12.5 million of process development services in 2021 under the Supply Agreement. The Supply Agreement will provide for an initial term of three years, which period may be extended for an additional one-year term. After the initial term, we will have the right to terminate the Supply Agreement for convenience or other reasons specified in the Supply Agreement upon prior written notice. Either Party may terminate the Supply Agreement upon an uncured material breach by the other Party or upon the bankruptcy or insolvency of the other Party.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents, and short-term investments of $155.9 million, or 73.6% of our total assets at December 31, 2021, and $217.4 million, or 82.4% of our total assets at December 31, 2020. Interest income earned on these assets was $0.2 million in 2021 and $1.6 million in 2020. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. If a 10% change in interest rates were to have immediately occurred on December 31, 2021, this change would not have had a material effect on the fair value of our investment portfolio as of that date. At December 31, 2021, our cash equivalents consisted of bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. We had no debt outstanding as of December 31, 2021 and 2020.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on effectiveness of controls and procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2021.

Management’s annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in “Internal Control - Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

Attestation report of the registered public accounting firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors and Executive Officers

The following table sets forth the name, age and position of each of our executive officers and directors.

Name	Age	Position
Executive Officers:		
Arthur O. Tzianabos, Ph.D.	58	President and Chief Executive Officer and Director
W. Bradford Smith	66	Chief Financial and Business Officer and Treasurer
Albert Seymour, Ph.D.	54	Chief Scientific Officer
Paul Alloway, Ph.D., J.D.	51	Chief Legal Officer and Secretary
Michael Blum	54	Chief Commercial Officer
Directors:		
Steven Gillis, Ph.D. [3]	68	Director
Richard J. Gregory, Ph.D. [2]	64	Director
Kush M. Parmar, M.D., Ph.D. [2]	41	Chairman of the Board
Matthew R. Patterson [1]	50	Director
Jeffrey V. Poulton [1]	54	Director
Alise S. Reicin, M.D. [3]	61	Director
Mary Thistle [1]	62	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Arthur O. Tzianabos, Ph.D. has served as our President, Chief Executive Officer and member of our board of directors since April 2016. Dr. Tzianabos joined Homology from OvaScience, Inc., a biotechnology company (which has since merged with and into Millendo Therapeutics, Inc.), where he served as President and Chief Scientific Officer from September 2013 to March 2016. Prior to OvaScience, Dr. Tzianabos spent eight years at Shire plc, a biotechnology company, where he served in positions of increasing responsibility, including Senior Director, Discovery Research, Vice President, Program Management and Senior Vice President and Head, Research and Early Development. From 1992 to 2005, Dr. Tzianabos was a faculty member at Harvard Medical School and maintained laboratories at the Channing Laboratory, Brigham and Women's Hospital and the Department of Microbiology and Molecular Genetics at Harvard Medical School. Dr. Tzianabos has served as a director of Stoke Therapeutics, Inc., a public biotechnology company, since April 2018 and is Chairman of the board of directors of Akouos, Inc., a public biotechnology company, since July 2018. Dr. Tzianabos previously served as a director of BIND Therapeutics, Inc., a biotechnology company, from October 2015 to July 2016. Dr. Tzianabos holds a B.S. in Biology from Boston College and a Ph.D. in Microbiology from the University of New Hampshire. We believe Dr. Tzianabos' extensive academic and clinical experience, as well as his knowledge of the industry, qualifies him to serve on our board of directors.

W. Bradford Smith has served as our Chief Financial Officer and Treasurer since April 2017 and our Secretary from July 2017 to June 2020. From March 2014 to April 2017, Mr. Smith was Chief Financial Officer of Ocular Therapeutix, Inc., a biopharmaceutical platform company. Prior to joining Ocular Therapeutix, Inc., Mr. Smith served as the Chief Financial Officer of OmniGuide, Inc., a medical device company, from July 2008 to March 2014. Mr. Smith has served as a member of the Board of Directors of Lyra Therapeutics, Inc., clinical-stage therapeutics company, since November 2019. Mr. Smith holds a B.S. in Biology from Tufts University and an M.B.A. from the Whittemore School of Business and Economics at the University of New Hampshire.

Albert Seymour, Ph.D. has served as our Chief Scientific Officer since April 2016. Prior to joining Homology, Dr. Seymour was Senior Vice President, Head of Global Research and Nonclinical Development at Shire plc, a biotechnology company, from 2011 to 2016. Since February 2021, Dr. Seymour has served on the board of directors of Ensoma Inc., a private gene therapy startup company. Dr. Seymour received his B.A. in Biology from the University of Delaware, an M.S. from Johns Hopkins University School of Medicine and his Ph.D. in Human Genetics from the University of Pittsburgh.

Paul Alloway, Ph.D., J.D. has served as our Chief Legal Officer since March 2022 and our Secretary since June 2020 and prior to that, he served as our Senior Vice President, General Counsel from May 2020 to March 2022. Prior to joining

Homology, Dr. Alloway was Vice President, Head of Legal and Corporate Secretary at Foghorn Therapeutics, a clinical-stage biotechnology company, from July 2018 to April 2020. Prior to joining Foghorn Therapeutics, Dr. Alloway served as Vice President and Senior Counsel at DRI Capital, a Canadian private-equity firm that specializes in pharmaceutical healthcare royalty investments, from October 2015 to June 2018. Dr. Alloway obtained his B.Sc. in Biology from the University of Toronto, his Ph.D. in Molecular and Cellular Biology from Dartmouth College and his J.D. from Suffolk University Law School.

Michael Blum has served as our Chief Commercial Officer since March 2022 and prior to that, he served as our Senior Vice President, Commercial Strategy from January 2020 to March 2022 and prior to that, he served as our Vice President, Commercial Strategy from November 2017 to January 2020. Prior to joining Homology, Mr. Blum was Head of Commercial Operations at Zafgen, Inc., a biopharmaceutical company, from April 2015 to November 2017. Prior to joining Zafgen, Inc., Mr. Blum was Head of Global Access for Sarepta Therapeutics from October 2013 to April 2015. Mr. Blum holds a B.A. in English from the College of the Holy Cross and an M.B.A. from Babson College.

Directors

Steven Gillis, Ph.D. has served as a member of our board of directors since 2016. Since 2005, Dr. Gillis has been a managing director at ARCH Venture Partners, a venture capital firm. From 1994 to 2005, Dr. Gillis served as Chief Executive Officer and chairman of the board of directors of Corixa Corporation, which he co-founded in October 1994. Previously, Dr. Gillis served as Director, Head of Research and Development, Chief Scientific Officer and acting Chief Executive Officer of Immunex Corporation, which he co-founded, from 1981 until his departure in 1994. As a former director and chairman of Trubion Pharmaceuticals, Inc., Dr. Gillis led its acquisition by Emergent BioSolutions in the fall 2010. Dr. Gillis has served as a director of Takeda Pharmaceutical Company Limited (and as director of Shire plc prior to its acquisition by Takeda) since January 2019. In addition, Dr. Gillis has also served as a director and chairman of VBI Vaccines Inc. since May 2016 and as a director of Codiak Biosciences, Inc. since November 2015. Dr. Gillis also currently serves as a director of several private companies. Dr. Gillis previously served as a director at Pulmatrix, Inc. from 2008 to 2020, at PhaseRx, Inc. from 2008 to 2018 and at bluebird bio, Inc. from 2011 to 2015. Dr. Gillis received his B.A. in Biology and English from Williams College and his Ph.D. in Biological Science from Dartmouth College. We believe that Dr. Gillis's knowledge of immunology and experience in the venture capital industry, particularly with biotechnology and pharmaceutical companies, qualifies him to serve as a member of our board of directors.

Richard J. Gregory, Ph.D. has served as a member of our board of directors since 2015. Prior to his retirement, Dr. Gregory served as Executive Vice President and Chief Scientific Officer of ImmunoGen, Inc., a biotechnology company, from 2015 until August 2019. Prior to joining ImmunoGen, Inc., he spent 25 years at Genzyme Corporation, a biotechnology company, in roles of increasing responsibility, including Senior Vice President and Head of Research from 2003 until Genzyme Corporation's acquisition by Sanofi in 2011, and Head of Research and Development for Genzyme from 2011 through 2014. Dr. Gregory has served as a director of ProMIS Neurosciences, Inc. since October 2016 and as a director of CANbridge Pharmaceuticals Inc. since April 2020. Dr. Gregory received his B.A. in Science from Virginia Tech and holds a Ph.D. from the University of Massachusetts, Amherst, and completed his post-doctoral work at the Worcester Foundation for Experimental Biology. We believe that Dr. Gregory's knowledge of immunology qualifies him to serve as a member of our board of directors.

Kush M. Parmar, M.D., Ph.D. has served as a member of our board of directors since 2015 and as Chairman of the Board since March 2018. Dr. Parmar is a Managing Partner at 5AM Venture Management LLC, an early stage venture capital firm focused on the life sciences, where he has been since 2010. Before joining 5AM, from 2002 to 2010, he was at Harvard Medical School, where he was an NIH-sponsored M.D./Ph.D. physician scientist fellow in the joint Harvard-MIT Health Sciences and Technology Program. Dr. Parmar has served on the boards of 5:01 Acquisition Corp. since September 2020, Akouos, Inc., since October 2017, Entrada Therapeutics, Inc. since October 2016, Rallybio Corporation since April 2018, Vor Biopharma Inc. since February 2019, and Syngene International Ltd. since July 2020. He has also served on the boards of numerous private companies. He previously served as a board member or observer for Arvinas, Inc., Achaogen, Inc., Audentes Therapeutics, Inc. (acquired by Astellas Pharma Inc.), Pulmatrix, Inc. and scPharmaceuticals Inc. He is a member of the scientific advisory boards of Penn Medicine, Princeton University's Department of Molecular Biology, and the Grace Science Foundation, and is a fellow of the Society of Kauffman Fellows. Before joining 5AM, Dr. Parmar completed clinical clerkships at the Massachusetts General & Brigham and Women's Hospitals, attended courses at Harvard Business School and consulted for an oncology startup. He also founded a non-profit international development organization, the Cruz Blanca Initiative. He holds an A.B. in Molecular Biology and Medieval Studies from Princeton University, a Ph.D. in Experimental Pathology from Harvard University, and an M.D. from Harvard Medical School. We believe that Dr. Parmar's experience in the life sciences industry, his experience as a venture capitalist and senior executive, as well as his service on the boards of directors of numerous companies provide him with the qualifications to serve as a director of our company.

Matthew R. Patterson has served as a member of our board of directors since 2018. Mr. Patterson has served as Executive Chairman of the board of directors at Remix Therapeutics, a biotechnology company, since April 2021 and as Executive Chairman of the board of directors at Iris Medicine, Inc. Therapeutics, a biotechnology company, since January 2022. Mr. Patterson is the co-founder of Audentes Therapeutics, Inc., a biotechnology company, and served in the role of Strategic Advisor from January 2020 to April 2021. Previously, he served as its Chief Executive Officer from November 2012 until Audentes' acquisition by Astellas Pharma Inc. in January 2020. Mr. Patterson also served as Audentes' Chairman of the board of directors and formerly served as President until May 2018. Prior to that, Mr. Patterson was the Entrepreneur-In-Residence at OrbiMed Advisors LLC. Prior to OrbiMed, Mr. Patterson served in roles at Amicus Therapeutics, Inc., BioMarin Pharmaceutical Inc. and Genzyme Corporation. Mr. Patterson has served as a director of Vor Biopharma, Inc. since October 2020 and 5:01 Acquisition Corp. since September 2020. Mr. Patterson holds a B.A. from Bowdoin College. We believe that Mr. Patterson's experience in the biotechnology and biopharmaceutical industries, as well as his service on the board of directors of a public company provide him with the qualifications to serve as a director of our company.

Jeffrey V. Poulton has served as a member of our board of directors since July 2020. Mr. Poulton has served as Executive Vice President and Chief Financial Officer at Alnylam Pharmaceuticals, Inc., a biopharmaceutical company, since August 2019. Prior to joining Alnylam, Mr. Poulton served as Chief Financial Officer of Indigo Agriculture, a plant microbiome company, from January 2018 to April 2019, where he supported the initial commercial scale-up of the business, including expansion outside the U.S. Between 2003 and December 2017, Mr. Poulton held various roles of increasing responsibility at Shire plc, most recently as Chief Financial Officer and a member of Shire's Executive Committee and Board of Directors from January 2015 to December 2017. During his tenure at Shire, Mr. Poulton also led Shire's rare disease U.S., LATAM and Asia Pacific commercial operations, as well as Shire's global rare disease business unit. Prior to Shire, Mr. Poulton led corporate finance and business development initiatives in both the gas and electric utilities industry and the materials manufacturing sector, serving in financial leadership positions at Cinergy Corp. and PPG Industries. Mr. Poulton also served in the United States Navy as a Commissioned Officer. Mr. Poulton holds a B.A. in Economics from Duke University and an M.B.A. from Indiana University. We believe that Mr. Poulton is qualified to serve on our board of directors due to his finance background and industry experience.

Alise Reicin, M.D. has served as a member of our board of directors since July 2019. Dr. Reicin has served as Chief Executive Officer of Tectonic Therapeutic, Inc., a biotechnology company, since August 2020. Prior to Tectonic. Dr. Reicin served as President, Global Clinical Development at Celgene Corporation, a pharmaceutical company, from November 2018 to December 2019. Prior to Celgene, she served as Head of Global Clinical Development at EMD Serono, a pharmaceutical company, from May 2015 through October 2018. Prior to EMD Serono, Dr. Reicin served as VP, Program Leadership Oncology at Merck and Co., a pharmaceutical company. She holds a B.A. in Biochemistry from Barnard College of Columbia University and an M.D. from Harvard Medical School. We believe that Dr. Reicin's clinical expertise and leadership roles in the biotechnology and biopharmaceutical industries provide her with the qualifications to serve as a director of our Company.

Mary Thistle has served as a member of our board of directors since 2018. Ms. Thistle has served as Special Advisor to the Bill & Melinda Gates Medical Research Institute, a non-profit biotech organization, since the fall of 2020, and previously served as the organization's Chief of Staff from January 2018 until assuming her current role. Prior to that, she held senior leadership positions at Dimension Therapeutics, Inc., a gene therapy company, including Chief Operating Officer from 2016 to 2017 and Chief Business Officer from 2015 to 2016. Prior to joining Dimension Therapeutics, Inc., she spent six years at Cubist Pharmaceuticals, Inc., a biopharmaceutical company, where she held various leadership positions, including Senior Vice President, Business Development from 2014 to 2015, Vice President, Business Development from 2012 to 2013 and Senior Director, Business Development from 2009 to 2012. Prior to that, she held various positions at ViaCell, Inc. and PerkinElmer Inc. Ms. Thistle has served on the board of directors of Ziopharm Oncology, Inc. since November 2020 and Entrada Therapeutics, Inc. since May 2021. Ms. Thistle holds a B.S. in Accounting from the University of Massachusetts, Boston and is a former Certified Public Accountant. We believe that Ms. Thistle is qualified to serve on our board of directors due to her finance background and industry experience.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and stockholders who beneficially own more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act (collectively, the "Reporting Persons") to file initial statements of beneficial ownership of securities and statements of changes in beneficial ownership of securities with respect to our equity securities with the SEC. Based on our review of the copies of such forms filed with the SEC and upon any written representations of the Reporting Persons received by us, we believe that there have been five late Form 4 filings in January 2022 for Arthur O. Tzianabos, W. Bradford Smith, Albert Seymour, Tim Kelly and Gabriel M. Cohn, each reporting three transactions.

Code of Ethics

We have a written Code of Business Conduct and Ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the code on our website at *www.homologymedicines.com* in the "Investors" section under "Corporate Governance." In addition, we intend to post on our website all disclosures that are required by law or the listing standards of The Nasdaq Stock Market LLC ("Nasdaq") concerning any amendments to, or waivers from, any provision of the code. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

Audit Committee and Audit Committee Financial Expert

We have a separately-designated standing audit committee ("Audit Committee"). The members of the Audit Committee are Matthew R. Patterson, Jeffrey V. Poulton and Mary Thistle. Ms. Thistle serves as the Chairperson of the Audit Committee. The members of our Audit Committee meet the requirements for financial literacy under the applicable rules of the SEC and Nasdaq. Our board of directors has determined that Ms. Thistle is an "audit committee financial expert" as defined by Item 407(d)(5)(ii) of Regulation S-K.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Item 11. Executive Compensation.

This section discusses the material components of our 2021 compensation program for our principal executive officer and next three most highly compensated executive officers who are named in the 2021 Summary Compensation Table below. These "named executive officers" and their positions are:

- Arthur O. Tzianabos, Ph.D., President and Chief Executive Officer;
- Albert Seymour, Ph.D., Chief Scientific Officer; and
- W. Bradford Smith, Chief Financial Officer.

2021 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the years ended December 31, 2021 and 2020:

Name and principal position	Fiscal Year	Salary $	Bonus $	Option Awards $ (1)	Stock Awards $ (2)	Non-Equity Incentive Plan Compensation $	All Other Compensation $ (3)	Total $
Arthur O. Tzianabos, Ph.D.	2021	583,100	—	2,116,074	578,760	320,705	8,700	3,607,339
President and Chief Executive Officer	2020	563,200	—	—	—	309,760	13,000	885,960
Albert Seymour, Ph.D.	2021	450,000	—	649,818	179,140	180,000	8,700	1,467,658
Chief Scientific Officer	2020	426,800	—	—	—	170,720	10,057	607,577
W. Bradford Smith	2021	445,300	120,000	1,016,382	275,600	178,120	12,377	2,047,779
Chief Financial Officer, Treasurer and Secretary	2020	406,700	—	—	—	162,680	13,000	582,380

(1) Amounts reflect the full grant date fair value of stock options granted during the applicable year computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all option awards in Note 12 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) Amounts reflect the full grant date fair value of restricted stock units granted during the applicable year computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all restricted stock units in Note 12 to our consolidated financial statements included in this Annual Report on Form 10-K.

(3) Amount shown represents 401(k) matching contributions. For additional information, refer to the discussion below under the heading "Narrative Disclosure to Summary Compensation Table —Retirement Plans."

Narrative Disclosure to Summary Compensation Table

The primary elements of compensation for our named executive officers are base salary, annual performance bonuses and long-term equity-based compensation awards. The named executive officers also generally participate in employee benefit plans and programs that we offer to our other full-time employees on the same basis.

2021 Salaries

The named executive officers receive a base salary to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. The following table shows the annual base salaries for 2022 and 2021 of our named executive officers. The 2022 annual base salaries became effective January 1, 2022.

Name	2022 Annual Base Salary ($)	2021 Annual Base Salary ($)
Arthur O. Tzianabos, Ph.D.	603,500	583,100
Albert Seymour, Ph.D.	465,800	450,000
W. Bradford Smith	460,900	445,300

2021 Bonuses

We offer our named executive officers the opportunity to earn annual cash bonuses to compensate them for attaining short-term company and individual goals as approved by our board of directors. For 2021, bonuses were based on attaining corporate goals relating to product development, manufacturing processes, and raising equity capital and individual goals related to each named executive officer's area of responsibility within the Company. The 2021 target bonus amounts, expressed as a percentage of annual base salary, of our named executive officers were 55% for Dr. Tzianabos, 40% for Dr. Seymour and 40% for Mr. Smith.

In January 2021, our board of directors approved a $120,000 retention bonus for Mr. Smith. The bonus was subject to repayment if Mr. Smith resigned other than for "good reason" under his employment agreement with the Company within one year after payment.

In December 2021, our board of directors met to review performance against the 2021 bonus goals and, based on its determination that the corporate and individual goals had been achieved at 100% of target level, approved cash bonuses for the named executive officers in the amounts set forth in the Non-Equity Incentive Plan Compensation column of the 2021 "Summary Compensation Table" above.

In February 2022, our compensation committee approved the following 2022 target bonus amounts, expressed as a percentage of annual base salary, of our named executive officers: 60% for Dr. Tzianabos, 40% for Dr. Seymour and 40% for Mr. Smith.

Equity Compensation

We generally offer stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Stock options allow our employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant. Initial stock option grants to newly hired employees generally vest as to 25% of the underlying shares on either the first anniversary of the date of grant or a specified vesting commencement date and in equal monthly installments over the following 36 months, subject to the holder's continued service with us. Stock options granted from time to time as periodic awards to existing employees generally vest in 48 equal monthly installments on the first day of each calendar month following the vesting commencement date, subject to the holder's continued service with us through the applicable vesting dates. Historically, our stock options have been intended to qualify as "incentive stock options" to the extent permitted under Internal Revenue Code of 1986, as amended.

Beginning in 2021, we also offer restricted stock units to our employees, including our named executive officers, as an additional long-term incentive component to our compensation program. Each restricted stock unit represents a contingent right to receive one share of the Company's common stock upon vesting. In general, restricted stock units vest annually in three equal installments on January 1st of each year after the grant date.

We maintain the 2018 Incentive Award Plan to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our Company and to enable our Company to obtain and retain services of these individuals.

In February 2021, our named executive officers were granted the stock options and restricted stock units set forth in the table below under our 2018 Incentive Award Plan. Stock options were granted with exercise prices equal to the fair market value of our common stock on the date of grant, as determined under the terms of our 2018 Incentive Award Plan, and are subject to the standard vesting schedule for periodic awards described above. Restricted stock units are subject to the standard vesting schedule described above.

	February 5, 2021	
Named Executive Officer	Stock Options Granted	Restricted Stock Units Granted
Arthur O. Tzianabos, Ph.D.	254,000	42,000
Albert Seymour, Ph.D.	78,000	13,000
W. Bradford Smith	122,000	20,000

Please refer to our Outstanding Equity Awards at 2021 Fiscal Year End table below for additional information regarding the stock options and restricted stock units held by our named executive officers.

Retirement Plans

We maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) Plan on the same terms as other full-time employees. We provide matching contributions under the plan of 50% of the first 6% of each participant's eligible compensation contributed. Employee contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their own contributions. Employer contributions vest over three years according to the employees' years of service. We believe that providing a vehicle for tax deferred retirement savings though our 401(k) Plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

Employee Benefits

Our named executive officers are eligible to participate in our employee benefit plans and programs, which include medical, dental, and vision benefits, health spending accounts, and short- and long-term disability, accidental death and dismemberment, and life insurance, to the same extent as our other full-time employees generally, subject to the terms and eligibility requirements of those plans.

Outstanding Equity Awards at 2021 Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2021.

	Option Awards						Stock Awards	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable (1)		Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Per Share Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(2)	Market Value of Shares or Units of Stock That Have Not Vested ($)(3)
Arthur O. Tzianabos, Ph.D.	4/1/2016	462,135		—	0.47	4/22/2026	—	—
	1/1/2018	503,917		10,736	6.63	12/7/2027	—	—
	3/27/2018	86,580		5,796	16.00	3/27/2028	—	—
	1/1/2019	148,020		54,980	24.28	12/14/2028	—	—
	1/1/2020	171,541		186,459	19.92	12/11/2029	—	—
	1/1/2021	58,208		195,792	13.78	2/5/2031	—	—
	—	—		—	—	—	42,000	152,880
Albert Seymour, Ph.D.	1/1/2018	74,817		1,600	6.63	12/7/2027	—	—
	3/27/2018	62,325		4,176	16.00	3/27/2028	—	—
	1/1/2019	53,958		20,042	24.28	12/14/2028	—	—
	1/1/2020	52,708		57,292	19.92	12/11/2029	—	—
	1/1/2021	17,875		60,125	13.78	2/5/2031	—	—
	—	—		—	—	—	13,000	47,320
W. Bradford Smith	4/5/2017	89,904		—	0.63	4/6/2027	—	—
	1/1/2018	62,171		1,325	6.63	12/7/2027	—	—
	3/27/2018	46,575		3,136	16.00	3/27/2028	—	—
	1/1/2019	64,166		23,834	24.28	12/14/2028	—	—
	1/1/2020	53,187		57,813	19.92	12/11/2029	—	—
	1/1/2021	27,958		94,042	13.78	2/5/2031	—	—
	—	—		—	—	—	20,000	72,800

(1) Stock options have a term of ten years from the grant date and vest and become exercisable in 48 equal monthly installments based upon the executive's completion of each full month of service following the vesting commencement date, subject to the named executive officer's continued employment with the Company through each applicable vesting date and potential accelerated vesting as described under the heading "Employment Agreements" below.

(2) Represents unvested restricted stock units granted pursuant to the Company's 2018 Incentive Award Plan. Each restricted stock unit represents a contingent right to receive one share of the Company's common stock upon vesting. Restricted stock units vest annually in three equal installments on the first three anniversaries of January 1.

(3) Market value calculated using the closing price per share of our common stock on December 31, 2021 of $3.64.

Employment Agreements

We have entered into employment agreements with each of our named executive officers. The employment agreements are for unspecified terms. Under their respective employment agreements, if we terminate Dr. Tzianabos, Dr. Seymour or Mr. Smith without "cause" or he resigns for "good reason," subject to his timely executing a release of claims and continued compliance with a separate restrictive covenant agreement, he is entitled to receive (i) base salary continuation for a period of nine months (or, for Dr. Tzianabos, 12 months), (ii) payment of all bonuses earned but unpaid as of the date of termination and (iii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to nine months (or, for Dr. Tzianabos, 12 months), less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date.

If we terminate Dr. Tzianabos, Dr. Seymour or Mr. Smith without "cause" or he resigns for "good reason," in either case, on or within 12 months following a change in control, then, in lieu of the severance benefits described above, subject to his timely executing a release of claims, he is entitled to receive (i) an amount in cash equal to 1.0 times (or, for Dr. Tzianabos, 1.5 times) the sum of his base salary plus target annual bonus for the year of termination, (ii) payment of all bonuses earned but unpaid as of the date of termination, (iii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to 12 months (or, for Dr. Tzianabos, 18 months), less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date, and (iv) accelerated vesting of all unvested equity or equity-based awards that vest solely based on the passage of time, with any such awards that vest based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement.

Each of our named executive officers has agreed to refrain from competing with us or soliciting our employees, in each case, while employed and following his termination of employment for any reason for a period of 12 months.

For purposes of the employment agreements, “cause” generally means the named executive officer’s refusal to substantially perform the duties associated with his position with our Company or to carry out the reasonable and lawful instructions of the board of directors concerning duties or actions consistent with his position, his breach of a material provision of the employment agreement which remains uncured (to the extent capable of cure) for a period of 30 days following written notice from our Company, his conviction, plea of no contest or nolo contendere or imposition of unadjudicated probation for any felony or crime involving moral turpitude, his unlawful use (including being under the influence) or possession of illegal drugs on our premises or while performing his duties and responsibilities under the employment agreement, or his commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against us.

For purposes of the employment agreements, “good reason” generally means, subject to certain cure rights, the named executive officer’s termination of employment due to a reduction in salary or target bonus, a material decrease in authority or areas of responsibility, our Company’s breach of any one or more of the material provisions of the employment agreement, or a relocation by our Company of the named executive officer’s primary office to a location more than 25 miles from the named executive officer’s primary office on the date of the agreement.

Non-Employee Director Compensation

The following table sets forth in summary form information concerning the compensation that was earned by or paid to each of our non-employee directors during the year ended December 31, 2021. Dr. Tzianabos, our Chief Executive Officer, received no compensation for his service as a director during the year ended December 31, 2021.

2021 Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)		Total ($)
Steven Gillis, Ph.D.	48,000	73,487	(2)	121,487
Richard J. Gregory, Ph.D.	45,000	73,487	(2)	118,487
Kush M. Parmar, M.D., Ph.D.	85,000	73,487	(2)	158,487
Matthew R. Patterson	47,500	73,487	(2)	120,987
Jeffrey V. Poulton	47,500	73,487	(2)	120,987
Alise S. Reicin, M.D.	44,000	73,487	(2)	117,487
Mary Thistle	55,000	73,487	(2)	128,487

(1) Amounts reflect the grant date fair value of stock options granted during the applicable year computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all option awards in Note 12 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) Consistent with our non-employee director compensation program described below, each non-employee director was granted an option to purchase 18,000 shares of our common stock granted to each then-current non-employee director on June 17, 2021 with an exercise price of $7.26 per share.

The table below shows the aggregate numbers of shares subject to option awards held as of December 31, 2021 by each non-employee director. None of our non-employee directors held any other outstanding equity awards as of December 31, 2021.

Name	Total Options Outstanding
Steven Gillis, Ph.D.	82,740
Richard J. Gregory, Ph.D.	82,740
Kush M. Parmar, M.D., Ph.D.	82,740
Matthew R. Patterson	83,690
Jeffrey V. Poulton	54,000
Alise S. Reicin, M.D.	67,160
Mary Thistle	82,740

We maintain a compensation program for our non-employee directors under which each non-employee director receives the following amounts for service on our board of directors. Our non-employee director compensation program provides for the following:

- an option to purchase 36,000 shares of our common stock upon the director's initial election or appointment to our board of directors (the "Initial Award"),
- if the director has served on our board of directors for at least six months as of the date of an annual meeting of stockholders, an option to purchase 18,000 shares of our common stock on the date of the annual meeting (the "Annual Award"),
- an annual director fee of $40,000, and
- if the director serves on a committee of our board of directors or in the other capacities stated below, an additional annual fee as follows:
    - chairman of the board or lead independent director, $35,000,
    - chairman of the audit committee, $15,000,
    - audit committee member other than the chairman, $7,500,
    - chairman of the compensation committee, $10,000,
    - compensation committee member other than the chairman, $5,000,
    - chairman of the nominating and corporate governance committee, $8,000, and
    - nominating and corporate governance committee member other than the chairman, $4,000.

Stock options granted to our non-employee directors under the program have an exercise price equal to the fair market value of our common stock on the date of grant and expire not later than ten years after the date of grant. Stock options granted upon a director's initial election or appointment vest in three equal installments on each of the first three anniversaries of the date of grant. Stock options granted annually to directors vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options vest in full upon the occurrence of a change in control.

Director fees under the program are payable in arrears in four equal quarterly installments not later than the 15th day following the final day of each calendar quarter, provided that the amount of each payment is prorated for any portion of a quarter that a director is not serving on our board.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Equity Compensation Plan Information

The following table provides information on our equity compensation plans as of December 31, 2021.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights		Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans(4)
Equity compensation plans approved by security holders (1)	7,624,306	(2)	$ 14.25	(3)	3,689,005
Equity compensation plans not approved by security holders	—		—		—
Total	7,624,306		$ 14.25		3,689,005

(1) Consists of the 2015 Stock Incentive Plan, as amended (the "2015 Plan"), the 2018 Incentive Award Plan (the "2018 Plan") and the 2018 Employee Stock Purchase Plan (the "2018 ESPP").

(2) Includes 1,599,232 outstanding options to purchase stock under the 2015 Plan and 6,025,074 outstanding options to purchase stock under the 2018 Plan.

(3) As of December 31, 2021, the weighted-average exercise price of outstanding options under the 2015 Plan was $0.84 and the weighted-average exercise price of outstanding options under the 2018 Plan was $13.41.

(4) Includes 2,257,623 shares available for future issuance under the 2018 Plan and 1,431,382 shares available for issuance under the 2018 ESPP (of which 147,871 shares were issued with respect to the purchase period in effect as of December 31, 2021, which purchase period ended on February 28, 2022). As of March 26, 2018, in connection with our initial public offering, no further grants are made under the 2015 Plan. The 2018 Plan provides for an annual increase on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028, by an amount equal to the lesser of (i) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by our board of directors (but no more than 20,887,347 shares may be issued upon the exercise of incentive stock options), plus any shares that were subject to awards outstanding under the 2015 Plan as of the effective date of the 2018 Plan which are forfeited, expire, lapse for any reason or are settled for cash without the issuance of shares. The 2018 ESPP provides for an annual increase on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028, by an amount equal to the lesser of (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by our board of directors, provided that no more than 4,778,738 shares of our common stock may be issued under the 2018 ESPP.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to holdings of our common stock by (i) stockholders who beneficially owned more than 5% of the outstanding shares of our common stock, and (ii) each of our directors (which includes all nominees), each of our named executive officers and all directors and executive officers as a group as of March 11, 2022, unless otherwise indicated. The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 57,385,285 shares of common stock outstanding as of March 11, 2022. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 11, 2022 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is One Patriots Park, Bedford, MA 01730. We believe, based on information provided to us that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage
5% or Greater Stockholders		
Entities affiliated with ARCH Venture Fund [(1)]	5,768,694	10.1%
TLS Beta Pte. Ltd. [(2)]	5,650,996	9.8%
Pfizer Inc. [(3)]	5,000,000	8.7%
Entities affiliated with 5AM Ventures [(4)]	4,535,919	7.9%
BlackRock, Inc. [(5)]	3,587,777	6.3%
Named Executive Officers and Directors		
Arthur O. Tzianabos, Ph.D. [(6)]	1,647,006	2.8%
Albert Seymour, Ph.D. [(7)]	437,062	*
W. Bradford Smith [(8)]	396,778	*
Steven Gillis, Ph.D. [(1)(9)]	5,833,434	10.2%
Richard J. Gregory, Ph.D. [(10)]	75,546	*
Kush M. Parmar, M.D., Ph.D. [(4)(11)]	4,600,659	8.0%
Matthew R. Patterson [(12)]	65,690	*
Jeffrey V. Poulton [(13)]	11,880	*
Alise S. Reicin, M.D. [(14)]	38,565	*
Mary Thistle [(15)]	64,740	*
All executive officers and directors as a group (12 persons) [(16)]	**13,390,397**	**22.2%**

*Less than 1%

(1) Based on a Schedule 13G/A filed with the SEC on February 13, 2020 and the Company's records. Consists of 4,631,031 shares of common stock held by ARCH Venture Fund VIII, L.P. (“ARCH Fund VIII”) and 1,137,663 shares of common stock held by ARCH Venture Fund VIII Overage, L.P. (“ARCH Fund Overage”). The sole general partner of ARCH Fund VIII is ARCH Venture Partners VIII, L.P. (“ARCH Partners VIII”), which may be deemed to beneficially own the shares held by ARCH Fund VIII. The sole general partner of ARCH Partners VIII and ARCH Fund Overage is ARCH Venture Partners VIII, LLC (“ARCH VIII LLC”), which has shared voting and dispositive power over the shares of common stock held by each of ARCH Fund VIII and ARCH Fund Overage. ARCH Partners VIII and ARCH VIII LLC disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The managing directors of ARCH VIII LLC are Keith L. Crandell, Clinton Bybee and Robert Nelsen, and they may be deemed to have shared voting and dispositive power over the shares of common stock held by ARCH Fund VIII and ARCH Fund Overage. Messrs. Crandell, Bybee and Nelsen disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Steven Gillis, M.D., Ph.D., one of our directors, is a managing director at ARCH Venture Partners. Director Steven Gillis owns an interest in ARCH Partners VIII but does not have voting or investment control over the shares held by ARCH Fund VIII, and disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of ARCH Fund VIII and ARCH Fund Overage is 8755 West Higgins Road, Suite 1025, Chicago, Illinois 60631.

(2) Based on a Schedule 13G/A filed with the SEC on February 14, 2022, Temasek Holdings (Private) Limited, Fullerton Management Pte Ltd and Temasek Life Sciences Private Limited each has shared voting and dispositive power over 5,650,996 shares of common stock, V-Sciences Investments Pte Ltd has shared voting and dispositive power over 3,055,703 shares of common stock, and TLS Beta Pte. Ltd. has shared voting and dispositive power over 2,595,293 shares of common stock. The principal business address of Temasek Holdings (Private) Limited, Fullerton Management Pte Ltd, Temasek Life Sciences Private Limited, V-Sciences Investments Pte Ltd and TLS Beta Pte. Ltd. is 60B Orchard Road #06-18 Tower 2, The Atrium@Orchard, Singapore 238891.

(3) Based on a Schedule 13G filed with the SEC on November 19, 2020, Pfizer Inc. has sole voting and dispositive power over all 5,000,000 shares. The address of Pfizer Inc. is 235 East 42nd Street, New York, NY 10017.

(4) Based on a Schedule 13G/A filed with the SEC on February 16, 2021 and the Company's records. Consists of 4,354,484 shares of common stock held by 5AM Ventures IV, L.P. (“Ventures IV”), as to which Ventures IV has shared voting and dispositive power, and 181,435 shares of common stock held by 5AM Co-Investors IV, L.P. (“Co-Investors IV”), as to which Co-Investors IV has shared voting and dispositive power. 5AM Partners IV, LLC (“Partners IV”) is the sole general partner of Ventures IV and Co-Investors IV. Dr. John Diekman, Andrew J. Schwab and Dr. Scott M. Rocklage, are the managing members of Partners IV and, along with Partners IV, have shared voting and investment power over the shares beneficially owned by Ventures IV and Co-Investors IV. Kush M. Parmar, M.D., Ph.D., one of our directors, is an affiliate of Ventures IV. Each of Partners IV, Dr. Diekman, Mr. Schwab and Dr. Rocklage disclaim beneficial ownership of such shares except to the extent of its or their recurring interest therein. The address of all entities affiliated with 5AM Ventures is 501 2nd Street, Suite 350, San Francisco, CA 94107.

(5) Based on a Schedule 13G/A filed with the SEC on February 3, 2022, Blackrock, Inc. has sole voting power over 3,519,362 shares and sole dispositive power over 3,587,777 shares. The address of Blackrock, Inc. is 55 East 52nd Street, New York, NY 10055.

(6) Includes options to purchase 1,560,995 shares of common stock that are or will be immediately exercisable by Dr. Tzianabos within 60 days of March 11, 2022.

(7) Includes options to purchase 305,416 shares of common stock that are or will be immediately exercisable by Dr. Seymour within 60 days of March 11, 2022.

(8) Consists of options to purchase 392,360 shares of common stock that are or will be immediately exercisable by Mr. Smith within 60 days of March 11, 2022.

(9) Includes options to purchase 64,740 shares of common stock that are or will be immediately exercisable by Dr. Gillis within 60 days of March 11, 2022.

(10) Includes options to purchase 64,740 shares of common stock that are or will be immediately exercisable by Dr. Gregory within 60 days of March 11, 2022.

(11) Includes options to purchase 64,740 shares of common stock that are or will be immediately exercisable by Dr. Parmar within 60 days of March 11, 2022.

(12) Consists of options to purchase 65,690 shares of common stock that are or will be immediately exercisable by Mr. Patterson within 60 days of March 11, 2022.

(13) Consists of options to purchase 11,880 shares of common stock that are or will be immediately exercisable by Mr. Poulton within 60 days of March 11, 2022.

(14) Consists of options to purchase 38,565 shares of common stock that are or will be immediately exercisable by Ms. Reicin within 60 days of March 11, 2022.

(15) Consists of options to purchase 64,740 shares of common stock that are or will be immediately exercisable by Ms. Thistle within 60 days of March 11, 2022.

(16) Includes options to purchase 2,835,897 shares of common stock that are or will be immediately exercisable within 60 days of March 11, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written Related Person Transaction Policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. Under the policy, our finance department is primarily responsible for developing and implementing processes and procedures to obtain information regarding related persons with respect to potential related person transactions and then determining, based on the facts and circumstances, whether such potential related person transactions do, in fact, constitute related person transactions requiring compliance with the policy. If our finance department determines that a transaction or relationship is a related person transaction requiring compliance with the policy, our Chief Financial Officer is required to present to the audit committee all relevant facts and circumstances relating to the related person transaction. Our audit committee must review the relevant facts and circumstances of each related person transaction, including if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the extent of the related person's interest in the transaction, take into account the conflicts of interest and corporate opportunity provisions of our code of business conduct and ethics, and either approve or disapprove the related person transaction. If advance audit committee approval of a related person transaction requiring the audit committee's approval is not feasible, then the transaction may be preliminarily entered into by management upon prior approval of the transaction by the chair of the audit committee subject to ratification of the transaction by the audit committee at the audit committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. If a transaction was not initially recognized as a related person, then upon such recognition the transaction will be presented to the audit committee for ratification at the audit committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. Our management will update the audit committee as to any material changes to any approved or ratified related person transaction and will provide a status report at least annually of all then current related person transactions. No director may participate in approval of a related person transaction for which he or she is a related person.

The following are certain transactions, arrangements and relationships with our directors, executive officers and stockholders owning 5% or more of our outstanding common stock since January 1, 2020.

Stock Purchase Agreement with Pfizer

On November 9, 2020, we entered into a stock purchase agreement, or the Stock Purchase Agreement, with Pfizer Inc., or Pfizer, which holds approximately 8.7% of our common stock as of March 11, 2022, pursuant to which Pfizer purchased 5,000,000 shares of our common stock through a private placement transaction at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million. Under the Stock Purchase Agreement, Pfizer was granted an exclusive ROFR for a 30-month period beginning on the date of the closing of the private placement to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103. Pfizer may exercise its right of first refusal under the ROFR one time for each of HMI-102 and HMI-103 during the ROFR period. Additionally, Pfizer has designated a member to join our

Scientific Advisory Board to participate in matters related to the development of these programs. For more information regarding Pfizer and its equity holdings, see Part III, Item 12. “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Security Ownership of Certain Beneficial Owners and Management.”

Employment Agreements

We have entered into employment agreements with our named executive officers. For more information regarding these agreements, see Item 11. “Executive Compensation—Narrative Disclosure to Compensation Tables—Employment Agreements.”

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

Director Independence

Steven Gillis, Ph.D., Richard J. Gregory, Ph.D., Kush M. Parmar, M.D., Ph.D., Matthew R. Patterson, Alise S. Reicin, M.D., Jeffrey V. Poulton and Mary Thistle each qualify as “independent” in accordance with the listing requirements of Nasdaq. The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director’s business and personal activities and relationships as they may relate to us and our management, including that Dr. Gillis and Dr. Parmar are affiliated with certain of our significant stockholders. Arthur O. Tzianabos, Ph.D. is not independent because he is the President and Chief Executive Officer of Homology. There are no family relationships among any of our directors or executive officers.

Item 14. Principal Accountant Fees and Services.

The following table summarizes the fees of Deloitte & Touche LLP, our independent registered public accounting firm, billed to us in each of the last two fiscal years for audit services and billed to us in each of the last two fiscal years for other services:

	2021	2020
Fee Category	**(in thousands)**	
Audit Fees	$ 662	$ 598
Tax Fees	154	20
All Other Fees	2	2
Total	$ 818	$ 620

Audit Fees

Audit fees consist of fees for the audit of our consolidated financial statements, the review of the unaudited interim financial statements included in our quarterly reports on Form 10-Q and other professional services provided in connection with statutory and regulatory filings or engagements and services associated with the issuance of comfort letters and the issuance of consents on registration statements.

Tax Fees

Tax fees consist of fees for tax compliance, tax advice, and tax planning services.

All Other Fees

All other fees consist of an annual license fee for use of accounting research software.

Audit Committee Pre-Approval Policy and Procedures

The Audit Committee has adopted a policy (the "Pre-Approval Policy") that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage Deloitte & Touche LLP to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the Audit Committee ("specific pre-approval") or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy ("general pre-approval"). Unless a type of service to be provided by Deloitte & Touche LLP has received general pre-approval under the Pre-Approval Policy, it requires specific pre-approval by the Audit Committee or by a designated member of the Audit Committee to whom the committee has delegated the authority to grant pre-approvals. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the Audit Committee will consider whether such services are consistent with the SEC's rules on auditor independence. The Audit Committee will also consider whether the independent auditor is best positioned to provide the most effective and efficient service, for reasons such as its familiarity with the Company's business, people, culture, accounting systems, risk profile and other factors, and whether the service might enhance the Company's ability to manage or control risk or improve audit quality. All such factors will be considered as a whole, and no one factor should necessarily be determinative. On an annual basis, the Audit Committee reviews and generally pre-approves the services (and related fee levels or budgeted amounts) that may be provided by Deloitte & Touche LLP without first obtaining specific pre-approval from the Audit Committee. The Audit Committee may revise the list of general pre-approved services from time to time, based on subsequent determinations.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The following documents are included on pages F-1 through F-26 attached hereto and are filed as part of this Annual Report on Form 10-K.

Index to Consolidated Financial Statements

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

		Incorporated by Reference				
Exhibit Number	**Description of Exhibit**	**Form**	**File No.**	**Exhibit**	**Filing date**	**Filed Herewith**
3.1	Restated Certificate of Incorporation of Homology Medicines, Inc.	8-K	001-38433	3.1	4/3/18	
3.2	Amended and Restated Bylaws of Homology Medicines, Inc.	8-K	001-38433	3.1	12/18/20	
4.1	Amended and Restated Investors' Rights Agreement, dated July 28, 2017, by and among Homology Medicines, Inc. and the investors named therein, as amended	10-Q	001-38433	4.1	11/09/20	
4.2	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-223409	4.2	3/19/18	
4.3	Form of Indenture	S-3	333-230664	4.3	4/1/19	
4.4	Description of Securities	10-K	001-38433	4.4	3/11/21	
10.1#	2015 Stock Incentive Plan, as amended, and forms of agreements thereunder	S-1/A	333-223409	10.1	3/19/18	
10.2#	2018 Incentive Award Plan, and forms of awards thereunder	10-K	001-38433	10.2	3/11/21	
10.3#	2018 Employee Stock Purchase Plan	S-1/A	333-223409	10.3	3/19/18	
10.4#	2018 Employee Stock Purchase Plan – Offering Document	10-Q	001-38433	10.1	11/13/18	
10.5#	Non-Employee Director Compensation Program	10-K	001-38433	10.5	3/12/20	
10.6#	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-223409	10.5	3/19/18	
10.7	Lease Agreement, dated December 21, 2017, by and between Homology Medicines, Inc. and Patriots Park Owner, LLC, as amended by the First Amendment to Lease, dated February 8, 2019, the Second Amendment to Lease, dated March 15, 2019, and the Third Amendment to Lease, dated November 9, 2021	10-Q	001-38433	10.1	11/15/21	
10.8	Assignment and Assumption Agreement, dated March 10, 2022, between Homology Medicines, Inc. and Roadrunner Solutions LLC					*
10.9	Sublease Agreement, dated March 10, 2022, between Homology Medicines, Inc. and Roadrunner Solutions LLC					*

10.10#	Employment Agreement, dated March 18, 2018, by and between Homology Medicines, Inc. and Albert Seymour	S-1/A	333-223409	10.12	3/19/18	
10.11#	Employment Agreement, dated March 18, 2018, by and between Homology Medicines, Inc. and Bradford Smith	S-1/A	333-223409	10.13	3/19/18	
10.12#	Employment Agreement, dated March 18, 2018, by and between Homology Medicines, Inc. and Arthur Tzianabos, Ph.D.	S-1/A	333-223409	10.14	3/19/18	
10.13#	Employment Agreement, dated March 18 2020, by and between Homology Medicines, Inc. and Paul Alloway, Ph.D.					*
10.14#	Employment Agreement, dated September 1, 2021, by and between Homology Medicines, Inc. and Michael Blum					*
10.15†	Collaboration and License Agreement, dated November 6, 2017, between Homology Medicines, Inc. and Novartis Institutes for BioMedical Research, Inc.	S-1/A	333-223409	10.15	3/23/18	
10.16†	Amendment to Collaboration and License Agreement, dated December 17, 2018, between Homology Medicines, Inc. and Novartis Institutes for BioMedical Research, Inc.	10-Q	001-38433	10.1	08/10/20	
10.17†	Second Amendment to Collaboration and License Agreement, dated October 30, 2020, between Homology Medicines, Inc. and Novartis Institutes for BioMedical Research, Inc.	10-Q	001-38433	10.1	11/09/20	
10.18†	Exclusive License Agreement, dated April 28, 2016, between Homology Medicines, Inc. and City of Hope	S-1/A	333-223409	10.16	3/19/18	
10.19†	License Agreement, dated September 14, 2016, between Homology Medicines, Inc. and California Institute of Technology	S-1/A	333-223409	10.17.1	3/19/18	
10.20†	First Amendment to License Agreement, dated May 16, 2017, between Homology Medicines, Inc. and California Institute of Technology	S-1	333-223409	10.16.2	3/2/18	
10.21†	Letter Agreement, dated November 14, 2017, between Homology Medicines, Inc. and California Institute of Technology	S-1	333-223409	10.16.3	3/2/18	
10.22^	Stock Purchase Agreement, dated November 9, 2020, by and between Homology Medicines, Inc. and Pfizer Inc.	8-K	001- 38433	10.1	11/09/20	
10.23	Equity Securities Purchase Agreement, dated January 28, 2022, by and among Homology Medicines, Inc., Roadrunner Solutions LLC, Oxford Biomedica (US), Inc. and, solely for purposes of Article IX thereof, Oxford Biomedica plc					*
10.24	Amendment No. 1 to Equity Securities Purchase Agreement dated as of January 28, 2022 by and among Homology Medicines, Inc., Roadrunner Solutions LLC, Oxford Biomedica (US), Inc. and, solely for purposes of Article IX thereof, Oxford Biomedica plc					*
10.25	Contribution Agreement, dated March 10, 2022, between Homology Medicines, Inc. and Roadrunner Solutions LLC					*
10.26^	Amended and Restated Limited Liability Company Agreement, dated March 10, 2022, by and among Oxford Biomedica Solutions LLC (f/k/a Roadrunner Solutions LLC), Homology Medicines, Inc. and Oxford Biomedica (US) Inc.					*
10.27^	Manufacturing and Supply Agreement, dated March 10, 2022, by and among Homology Medicines, Inc., Roadrunner Solutions LLC and, solely for purposes of Section 2.3(b)(iii) thereof, Oxford Biomedica UK Limited					*
21.1	Subsidiaries of Homology Medicines, Inc.	S-1	333-223409	21.1	3/2/18	
23.1	Consent of Deloitte & Touche LLP, independent registered public accountant					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*

32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
101.INS	Inline XBRL Instance Document – the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document	*
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.

** Furnished herewith.

# Indicates management contract or compensatory plan or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment.

^ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv).

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Homology Medicines, Inc.

Date: March 23, 2022

By: /s/ Arthur O. Tzianabos, Ph.D.
Arthur O. Tzianabos, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Arthur O. Tzianabos, Ph.D. **Arthur O. Tzianabos, Ph.D.**	President, Chief Executive Officer and Director *(principal executive officer)*	March 23, 2022
/s/ W. Bradford Smith **W. Bradford Smith**	Chief Financial and Business Officer and Treasurer *(principal financial and accounting officer)*	March 23, 2022
/s/ Kush M. Parmar, M.D., Ph.D. **Kush M. Parmar, M.D., Ph.D.**	Chairman of the Board of Directors	March 23, 2022
/s/ Steven Gillis, Ph.D. **Steven Gillis, Ph.D.**	Director	March 23, 2022
/s/ Richard J. Gregory, Ph.D. **Richard J. Gregory, Ph.D.**	Director	March 23, 2022
/s/ Matthew R. Patterson **Matthew R. Patterson**	Director	March 23, 2022
/s/ Jeffrey V. Poulton **Jeffrey V. Poulton**	Director	March 23, 2022
/s/ Alise S. Reicin, M.D. **Alise S. Reicin, M.D.**	Director	March 23, 2022
/s/ Mary Thistle **Mary Thistle**	Director	March 23, 2022

HOMOLOGY MEDICINES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Homology Medicines, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Homology Medicines, Inc. and its subsidiary (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 23, 2022

We have served as the Company's auditor since 2017.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 108,382	$ 217,431
Short-term investments	47,491	—
Assets held for sale	28,907	—
Prepaid expenses and other current assets	7,129	2,133
Total current assets	191,909	219,564
Property and equipment, net	2,252	37,002
Right-of-use assets	15,607	5,897
Restricted cash	1,953	1,274
Total assets	$ 211,721	$ 263,737
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,366	$ 4,722
Accrued expenses and other liabilities	11,406	9,803
Operating lease liabilities	246	2,501
Deferred revenue	3,208	5,632
Total current liabilities	17,226	22,658
Non-current liabilities:		
Operating lease liabilities, net of current portion	23,688	12,941
Deferred revenue, net of current portion	1,156	32,143
Total liabilities	42,070	67,742
Stockholders’ equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2021 and 2020; 57,150,274 and 50,268,666 shares issued as of December 31, 2021 and 2020, respectively; and 57,150,274 and 50,265,575 shares outstanding as of December 31, 2021 and 2020, respectively	6	5
Additional paid-in capital	593,784	524,358
Accumulated other comprehensive gain	(7)	—
Accumulated deficit	(424,132)	(328,368)
Total stockholders’ equity	169,651	195,995
Total liabilities and stockholders' equity	$ 211,721	$ 263,737

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	For the Year Ended December 31,	
	2021	**2020**
Collaboration revenue	$ 33,971	$ 2,702
Operating expenses:		
Research and development	93,085	100,392
General and administrative	36,835	32,573
Total operating expenses	129,920	132,965
Loss from operations	(95,949)	(130,263)
Other income:		
Interest income	185	1,569
Total other income	185	1,569
Net loss	$ (95,764)	$ (128,694)
Net loss per share-basic and diluted	$ (1.73)	$ (2.80)
Weighted average common shares outstanding-basic and diluted	55,283,318	45,910,787

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	For the Year Ended December 31,	
	2021	2020
Net loss	$ (95,764)	$ (128,694)
Other comprehensive gain (loss):		
Change in unrealized gain (loss) on available for sale securities, net	(7)	(183)
Total other comprehensive gain (loss)	(7)	(183)
Comprehensive loss	$ (95,771)	$ (128,877)

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share amounts)

	Common Stock $0.0001 Par Value		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2020	45,116,742	$ 4	$ 457,994	$ 183	$ (199,674)	258,507
Vesting of common stock from option exercises	18,575	—	24	—	—	24
Issuance of common stock from option exercises	46,410	—	176	—	—	176
Issuance of common stock pursuant to employee stock purchase plan	83,848	—	938	—	—	938
Issuance of common stock pursuant to private placement	5,000,000	1	51,978	—	—	51,979
Stock-based compensation	—	—	13,248	—	—	13,248
Other comprehensive loss	—	—	—	(183)	—	(183)
Net loss	—	—	—	—	(128,694)	(128,694)
Balance at December 31, 2020	50,265,575	$ 5	$ 524,358	$ —	$ (328,368)	$ 195,995
Issuance of common stock in follow-on offering, net of discounts and issuance costs	6,596,306	1	49,743	—	—	49,744
Vesting of common stock from option exercises	3,091	—	13	—	—	13
Issuance of common stock from option exercises	59,465	—	145	—	—	145
Issuance of common stock pursuant to employee stock purchase plan	110,923	—	826	—	—	826
Issuance of common stock pursuant to ATM, net of discounts and issuance costs	114,914	—	1,454	—	—	1,454
Stock-based compensation	—	—	17,245	—	—	17,245
Other comprehensive loss	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(95,764)	(95,764)
Balance at December 31, 2021	57,150,274	$ 6	$ 593,784	$ (7)	$ (424,132)	$ 169,651

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (95,764)	$ (128,694)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8,353	7,965
Noncash lease expense	1,191	939
Stock-based compensation expense	17,245	13,248
Amortization of premium (accretion of discount) on short-term investments	894	(198)
Loss on disposal of property and equipment	133	888
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,996)	2,056
Accounts payable	(2,487)	2,459
Accrued expenses and other liabilities	1,500	2,432
Deferred revenue	(33,411)	6,824
Operating lease liabilities	(2,409)	(2,251)
Net cash used in operating activities	(109,751)	(94,332)
Cash flows from investing activities:		
Purchases of short-term investments	(97,392)	(19,991)
Maturities of short-term investments	49,000	228,620
Purchases of property and equipment	(2,396)	(3,733)
Net cash provided by (used in) investing activities	(50,788)	204,896
Cash flows from financing activities:		
Proceeds from issuance of common stock in follow-on public offering, net of discounts and issuance costs	49,744	—
Proceeds from issuance of common stock pursuant to ATM financing, net of discounts and issuance costs	1,454	—
Proceeds from issuance of common stock in private placement	—	51,979
Proceeds from issuance of common stock from option exercises	145	176
Proceeds from issuance of common stock pursuant to employee stock purchase plan	826	938
Net cash provided by financing activities	52,169	53,093
Net change in cash, cash equivalents and restricted cash	(108,370)	163,657
Cash, cash equivalents and restricted cash, beginning of period	218,705	55,048
Cash, cash equivalents and restricted cash, end of period	$ 110,335	$ 218,705
Supplemental disclosures of noncash investing and financing activities:		
Reclassification of liability for common stock vested	$ 13	$ 24
Property and equipment additions included in accounts payable	$ 241	$ 110
Property and equipment additions included in accrued expenses and other liabilities	$ 116	$ —
Unrealized (loss) gain on available for sale securities, net	$ (7)	$ (183)

See notes to consolidated financial statements.

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business—Homology Medicines, Inc. (the "Company") is a clinical-stage genetic medicines company dedicated to translating proprietary gene therapy and gene editing technology into novel treatments for patients with rare genetic diseases with significant unmet medical needs by curing the underlying cause of the disease. The Company was founded in March 2015 as a Delaware corporation. Its principal offices are in Bedford, Massachusetts.

Since its inception, the Company has devoted substantially all of its resources to recruiting personnel, developing its technology platform and advancing its pipeline of product candidates, developing and implementing manufacturing processes, building out internal manufacturing and research and development space, and maintaining and building its intellectual property portfolio. The Company is subject to a number of risks similar to those of other companies conducting high-risk, early-stage research and development of product candidates. Principal among these risks are dependency on key individuals and intellectual property, competition from other products and companies, and the technical risks associated with the successful research, development and manufacturing of its product candidates. The Company's success is dependent upon its ability to continue to raise additional capital in order to fund ongoing research and development, conduct clinical trials, obtain regulatory approval of its products, further expand access to manufacturing capacity, successfully commercialize its products, generate revenue, meet its obligations, and, ultimately, attain profitable operations.

On April 2, 2018, the Company completed its initial public offering ("IPO") with the sale of 10,350,000 shares of its common stock, including shares issued upon the exercise in full of the underwriters' over-allotment option, at a public offering price of $16.00 per share, resulting in net proceeds of $150.8 million, after deducting underwriting discounts and commissions and offering expenses. Upon the closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 24,168,656 shares of common stock at the applicable conversion ratio then in effect.

On April 12, 2019, the Company completed a follow-on public offering of its common stock. The Company sold 5,555,556 shares of its common stock at a public offering price of $22.50 per share and received net proceeds of $116.9 million, after deducting underwriting discounts and commissions and offering expenses. In addition, on April 26, 2019 and May 7, 2019, in connection with the exercise in full of the underwriters' option to purchase additional shares, the Company issued an aggregate of 833,333 shares of its common stock at a public offering price of $22.50 per share and received net proceeds of $17.6 million, after deducting underwriting discounts and commissions.

On April 6, 2021, the Company completed a follow-on public offering of its common stock. The Company sold 6,596,306 shares of its common stock at a price of $7.58 per share and received net proceeds of $49.7 million, after deducting offering expenses of $0.3 million. Under the terms of the underwriting agreement, the Company also granted the underwriter an option exercisable for 30 days to purchase up to an additional 989,445 shares of its common stock at a price of $7.58 per share. The underwriters did not exercise this option. The offering closed on April 9, 2021. The shares were sold pursuant to the Company's effective shelf registration statement on Form S-3, as amended, and a related prospectus supplement filed with the SEC on April 8, 2021.

On March 12, 2020, the Company filed a Registration Statement on Form S-3 (File No. 333-237131) (as amended, the "Shelf") with the Securities and Exchange Commission ("SEC") in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for a period up to three years from the date of the filing. The Shelf became effective on March 12, 2020. The Company also simultaneously entered into a sales agreement with Cowen and Company, LLC ("Cowen"), as sales agent, providing for the offering, issuance and sale by the Company of up to an aggregate $150.0 million of its common stock from time to time in "at-the-market" offerings under the Shelf (the "ATM"). In connection with the filing of certain post-effective amendments to the Shelf, the sales agreement prospectus supplement now covers the offering, issuance and sale by the Company of up to an aggregate $148.4 million of its common stock. During the year ended December 31, 2021, the Company sold 114,914 shares of common stock under the Sales Agreement, at an average price of approximately $14.00 per share, raising aggregate net proceeds of approximately $1.5 million after deducting an aggregate commission of 3% and issuance costs of $0.1 million. As of December 31, 2021, there remained $148.4 million of common stock available for sale under the ATM.

On January 28, 2022, the Company announced an agreement with Oxford Biomedica plc, or Oxford, to establish a new adeno-associated virus, or AAV, vector manufacturing company that will provide AAV vector process development and manufacturing to pharmaceutical and biotechnology companies. Under the terms of the agreement, the Company contributed its manufacturing team of 125 experts, manufacturing facility and equipment, manufacturing-related intellectual property and

know-how and certain other assets. Oxford paid the Company $130.0 million upfront and invested $50.0 million to fund the new company in exchange for an 80 percent ownership stake, while Homology will own 20 percent of the new company (see Note 18).

On November 9, 2020, the Company entered into a common stock purchase agreement (the "Stock Purchase Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which the Company agreed to issue and sell to Pfizer 5,000,000 shares of the Company's common stock through a private placement transaction (the "Private Placement") at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million (see Note 16).

To date, the Company has not generated any revenue from product sales and does not expect to generate any revenue from the sale of product in the foreseeable future. Through December 31, 2021, the Company has financed its operations primarily through public offerings of its common stock, the issuance of convertible preferred stock, and with proceeds from its collaboration and license agreement with Novartis Institutes of BioMedical Research, Inc. ("Novartis") (see Note 15) and its private placement with Pfizer. During the year ended December 31, 2021, the Company incurred a net loss of $95.8 million and as of December 31, 2021, had $424.1 million in accumulated deficit. The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future.

Based on current projections, management believes that existing cash and cash equivalents, together with the $130.0 million received from Oxford in March 2022, will enable the Company to continue its operations for at least one year from the date of this filing. In the absence of a significant source of recurring revenue, the continued viability of the Company beyond that point is dependent on its ability to continue to raise additional capital to finance its operations. There can be no assurance that the Company will be able to obtain sufficient capital to cover its costs on acceptable terms, if at all.

Basis of Presentation—The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation—The Company's consolidated financial statements include the accounts of the Company and its subsidiary, Homology Medicines Securities Corporation, a wholly owned Massachusetts corporation, for the sole purpose of buying, selling, and holding securities on the Company's behalf. All intercompany balances and transactions have been eliminated in the consolidated financial statements.

Use of Estimates—The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition and accrued research and development expenses. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Comprehensive Income (Loss) —Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale investments.

Cash and Cash Equivalents and Restricted Cash—Cash and cash equivalents consist of standard checking accounts, money market accounts and certain investments. The Company considers all highly liquid investments with original or remaining maturities at the time of purchase of 90 days or less to be cash equivalents. Restricted cash consists of cash serving as collateral for letters of credit issued for security deposits for the Company's facility leases in Bedford, Massachusetts.

The following table provides a reconciliation of cash, cash equivalents and restricted cash to amounts shown in the consolidated statements of cash flows:

	December 31,	
	2021	2020
	(in thousands)	
Cash and cash equivalents	$ 108,382	$ 217,431
Restricted cash	1,953	1,274
Total cash, cash equivalents and restricted cash	$ 110,335	$ 218,705

Short-Term Investments—Short-term investments represent holdings of available-for-sale marketable securities in accordance with the Company's investment policy and cash management strategy. Short-term investments have maturities of greater than 90 days at the time of purchase and mature within one-year from the balance sheet date. Investments in marketable securities are recorded at fair value, with any unrealized gains and losses, reported within accumulated other comprehensive income as a separate component of stockholders' equity until realized or until a determination is made that an other-than-temporary decline in market value has occurred. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the underlying security. Such amortization and accretion, together with interest on securities, are included in interest income in the Company's consolidated statements of operations. The cost of marketable securities sold is determined based on the specific identification method and any realized gains or losses on the sale of investments are reflected as a component of other income.

Concentrations of Credit Risk—Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. We believe that we are not exposed to significant credit risk as our deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. We regularly invest excess cash with major financial institutions in money market funds, U.S. government and corporate debt securities and commercial paper, all of which can be readily purchased and sold using established markets. As of December 31, 2021, the Company's cash and cash equivalents were held with two financial institutions. We believe that the market risk arising from our holdings of these financial instruments is mitigated based on the fact that many of these securities are either government-backed or of high credit rating.

Offering Costs—The Company capitalizes incremental legal, professional accounting and other third-party fees that are directly associated with equity financings as other current assets until the transactions are completed. After equity financings are complete, these costs are recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering.

Leases— In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which eliminated the tests for lease classification under prior U.S. GAAP and requires lessees to recognize right-of-use assets and related lease liabilities on the balance sheet. The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01 – *Leases* (Topic 842): *Land Easement Practical Expedient for Transition to Topic 842*, ASU No. 2018-10 – *Codification Improvements to Topic* 842, *Leases*, ASU No. 2018-11 – *Leases* (Topic 842): *Targeted Improvements*, ASU No. 2018-20 – *Leases* (Topic 842): *Narrow-Scope Improvements for Lessors*, and ASU No. 2019-01 – *Leases* (Topic 842): *Codification Improvements*. The Company adopted these amendments with ASU 2016-02 (collectively, the new leasing standards) effective January 1, 2020.

The Company adopted the new leasing standards using the modified retrospective approach, as of January 1, 2020, with no restatement of prior periods or cumulative adjustments to accumulated deficit. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allows the Company to carry forward the historical lease classification. In addition, the Company elected the practical expedient not to apply the recognition requirements in the leasing standards to short-term leases (a lease that at commencement date has a lease term of 12 months or less and does not contain a purchase option that it is reasonably certain to exercise) and the practical expedient that permits lessees to make an accounting policy election (by class of underlying asset) to not separate lease components of a contract from non-lease components.

The Company determines if an arrangement is a lease at contract inception. The Company's contracts are determined to contain a lease when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company's lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis. Variable lease cost is recognized as incurred.

Through October 2021 when the lease and sublease expired, the Company acted as sublessor related to a sublease of the Company's former headquarters. Fixed sublease payments received were recognized on a straight-line basis over the sublease term as a reduction to rent expense. Right-of-use assets were periodically evaluated for impairment.

The expected lease term for those leases commencing prior to January 1, 2020 did not change with the adoption of the new leasing standards. The expected lease term for leases commencing after the adoption of the new leasing standards includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

As a result of the adoption of the new leasing standards, on January 1, 2020, the Company recorded non-cash transactions to recognize a right-of-use asset of $6.8 million, operating lease liabilities of $17.7 million and the derecognition of deferred rent of $10.9 million originally accounted for under legacy guidance. The adoption did not have a material impact on the consolidated statement of operations. For additional information on the adoption of the new leasing standards, refer to Note 8.

	January 1, 2020 (in thousands)		
	Prior to adoption of new leasing standards	Adjustment for adoption of new leasing standards	As Adjusted
Right-of-use assets (1)(2)	$ —	$ 6,835	$ 6,835
Deferred rent (2)	$ 1,313	$ (1,313)	$ —
Deferred rent, net of current portion (2)	$ 9,544	$ (9,544)	$ —
Operating lease liabilities (3)	$ —	$ 2,251	$ 2,251
Operating lease liabilities, net of current portion (3)	$ —	$ 15,441	$ 15,441

(1) Represents capitalization of operating right-of-use assets
(2) Represents reclassification of deferred rent and incentives as a reduction to operating right-of-use assets
(3) Represents recognition of operating lease liabilities

Guarantees and Indemnifications—As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2021, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related liabilities have been established.

Property and Equipment—Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred. When assets are retired or disposed of, the assets and related accumulated depreciation are derecognized from the accounts, and any resulting gain or loss is included in the determination of net loss. Depreciation is provided using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.

Computer equipment and software	3 years
Laboratory equipment and office furniture	5 years
Manufacturing equipment	5 - 7 years
Leasehold improvements	Shorter of the lease term or estimated useful life

Assets Held for Sale—The Company classifies assets as held for sale when the following conditions are met: (1) management has committed to a plan to sell, (2) the assets are available for immediate sale in their present condition, (3) the Company has initiated an active program to identify a buyer, (4) it is probable that a sale will occur within one year, (5) the assets are actively marketed for sale at a reasonable price in relation to their current fair value, and (6) there is a low likelihood of significant changes to the plan or that the plan will be withdrawn. If all of the criteria are met as of the balance sheet date, the assets are presented separately in the consolidated balance sheet as held for sale at the lower of the carrying amount or fair value less costs to sell. The assets are then no longer depreciated or amortized while classified as held for sale.

Impairment of Long-Lived Assets—The Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. To date, no impairments have been recognized for these assets.

Research and Development Costs—Research and development costs are charged to expense as incurred. Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical and clinical expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expense or accrued research and development expense.

Income Taxes—The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. Since inception, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the net deferred tax assets has not been determined to be more likely than not.

Segment Information—Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's Chief Executive Officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is dedicated to translating proprietary gene editing and gene therapy technology into novel treatments for patients with rare genetic diseases. All of the Company's tangible assets are held in the United States.

Revenue Recognition— Revenue is recognized in accordance with FASB Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements would likely consist of a license, rights to the Company's intellectual property or research, development and manufacturing services and participation in committees.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of consideration to which the Company expects to be entitled to. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts may include development and regulatory milestone payments that are assessed under the most likely amount method and constrained until it is probable that a significant revenue reversal would not occur. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and regulatory milestones and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from the Company's collaboration arrangement.

The Company allocates the transaction price based on the estimated standalone selling price of each performance obligation. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress for its over-time arrangements at each reporting period and, if necessary, updates the measure of progress and revenue recognized.

Stock-based Compensation—The Company recognizes compensation expense for awards to employees and non-employees based on the grant date fair value of stock-based awards on a straight-line basis over the period during which an award holder provides service in exchange for the award. The fair value of options on the date of grant is calculated using the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on the trading price of the Company's stock, historical data, peer company data and judgment regarding future trends and factors. The Company recognizes forfeitures as they occur.

The purchase price of common stock under the Company's employee stock purchase plan ("ESPP") is equal to 85% of the lesser of (i) the fair market value per share of the common stock on the first business day of an offering period and (ii) the fair market value per share of the common stock on the purchase date. The fair value of the look-back provision under the ESPP is calculated using the Black-Scholes option pricing model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 180-day purchase period.

Fair Value Measurements—Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or

most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Net Loss per Share—Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and unvested shares of common stock.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recent Accounting Pronouncements—The Jumpstart Our Business Startups Act of 2012 permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. As an emerging growth company, the Company has elected to take advantage of this extended transition period.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") to improve financial reporting by requiring more timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. ASU 2016-13 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help investors and other financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization's portfolio. ASU 2016-13 is effective for the Company beginning January 1, 2023, with early application permitted. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements.

All other new accounting pronouncements issued, but not yet effective or adopted have been deemed to be not relevant to the Company and, accordingly, are not expected to have a material impact once adopted.

3. CASH AND CASH EQUIVALENTS

From time to time, the Company may have cash balances in financial institutions in excess of federal deposit insurance limits. The Company has never experienced any losses related to these balances. The Company considers only those investments that are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents.

The following table summarizes the Company's cash and cash equivalents:

	December 31,	
	2021	2020
	(in thousands)	
Cash	$ 59	$ 250
Money market funds	108,323	217,181
Total cash and cash equivalents	$ 108,382	$ 217,431

4. SHORT-TERM INVESTMENTS

The Company may invest its excess cash in fixed income instruments denominated and payable in U.S. dollars including U.S. treasury securities, commercial paper, corporate debt securities and asset-backed securities in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The Company has designated all investments as available-for-sale and therefore such investments are reported at fair value and classified as short-term investments on the Company's consolidated balance sheets. Unrealized gains or losses on investments are recorded in accumulated other comprehensive income or loss, a component of stockholders' equity, on the Company's consolidated balance sheets.

The following table summarizes the Company's short-term investments as of December 31, 2021:

As of December 31, 2021	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
Commercial paper	$ 27,992	$ —	$ —	$ 27,992
Corporate debt securities	19,506	—	(7)	19,499
Total	$ 47,498	$ —	$ (7)	$ 47,491

The Company had no short-term investments as of December 31, 2020.

The Company utilizes the specific identification method in computing realized gains and losses. The Company had no realized gains and losses on its short-term investments for the years ended December 31, 2021 and 2020. The contractual maturity dates of all of the Company's investments are less than one year.

5. FAIR VALUE MEASUREMENTS

The Company's financial instruments consist of cash and cash equivalents, short-term investments, restricted cash and accounts payable. The carrying amount of cash, restricted cash and accounts payable are each considered a reasonable estimate of fair value due to the short-term maturity.

Assets measured at fair value on a recurring basis were as follows:

Description	December 31, 2021	Quoted Prices (Unadjusted) in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Cash equivalents:				
Money market mutual funds	$ 108,323	$ 108,323	$ —	$ —
Total cash equivalents	$ 108,323	$ 108,323	$ —	$ —
Short-term investments:				
Commercial paper	$ 27,992	$ —	$ 27,992	$ —
Corporate debt securities	19,499	—	19,499	—
Total short-term investments	$ 47,491	$ —	$ 47,491	$ —
Total financial assets	$ 155,814	$ 108,323	$ 47,491	$ —

Description	December 31, 2020	Quoted Prices (Unadjusted) in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Cash equivalents:				
Money market mutual funds	$ 217,181	$ 217,181	$ —	$ —
Total financial assets	$ 217,181	$ 217,181	$ —	$ —

Short-term securities are valued using models or other valuation methodologies that use Level 2 inputs. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, default rates, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

There were no transfers between fair value measure levels during the years ended December 31, 2021 and 2020.

6. PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

	December 31,	
	2021	2020
	(in thousands)	
Laboratory equipment	$ 5,857	$ 12,703
Manufacturing equipment	—	7,754
Computers and purchased software	1,596	1,596
Furniture and fixtures	645	1,363
Leasehold improvements	—	29,961
Property and equipment, at cost	8,098	53,377
Less accumulated depreciation and amortization	(5,846)	(16,375)
Property and equipment, net	$ 2,252	$ 37,002

Depreciation expense for the years ended December 31, 2021 and 2020 was approximately $8.4 million and $8.0 million, respectively. The Company disposed of $0.1 million and $0.9 million of property and equipment, net during the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company has classified an additional $28.9 million of property and equipment, net in assets held for sale (see Note 17).

7. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	December 31,	
	2021	2020
	(in thousands)	
Accrued compensation and benefits	$ 7,805	$ 6,902
Accrued research and development expenses	2,193	2,393
Accrued professional fees	1,371	291
Accrued unvested common stock subject to repurchase	—	13
Accrued other	37	204
Total accrued expenses and other liabilities	$ 11,406	$ 9,803

8. COMMITMENTS AND CONTINGENCIES

Operating Leases—In September 2016, the Company entered into a noncancelable operating lease beginning in November 2016 for office, laboratory and manufacturing space in Bedford, Massachusetts, that expired in October 2021, with an option for an additional three-year term that was not exercised. In 2018, the Company entered into a sublease agreement for the entire leased premises. The rent commencement date of the sublease was December 2018, and the sublease terminated on the scheduled termination date of the original lease. Under the terms of the sublease, the subtenant was obligated to pay the Company aggregate base rent of approximately $2.7 million over the term of the sublease, based on the same level of rent the Company was obligated to pay the landlord, in addition to a passthrough of operating expenses and real estate taxes charged by the landlord.

In December 2017, the Company entered into a noncancelable operating lease for approximately 67,000 square feet of research and development, manufacturing and general office space in Bedford, Massachusetts. The lease expires in February

2027 with an option for an additional five-year term. Rent became due under the lease in two phases; rent on the first 46,000 square feet started in September 2018 and rent on the remaining 21,000 square feet started in March 2019. The initial annual base rent was $39.50 per square foot and increases by three percent annually. The Company is obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises. The lease agreement entered into in December 2017 allowed for a tenant improvement allowance not to exceed $10.9 million, which the Company received in full, to be applied to the total cost of tenant improvements to the leased premises. The unamortized balance of the tenant improvement allowance was included in deferred rent incentives and has been recorded as a reduction to operating right-of-use asset upon adoption of the new leasing standards.

In November 2021, the Company entered into an amendment of its December 2017 lease agreement (the “Lease Amendment”) for its corporate headquarters in Bedford, Massachusetts. The Lease Amendment increases the space under lease by approximately 23,011 square feet (the "Expansion Premises") and extends the expiration date of the existing premises under the lease from February 2027 to June 2030. The payment term with respect to the Expansion Premises commences on the earlier of (i) the date of the Substantial Completion of the Tenant’s Work (as both terms are defined in the Lease Amendment), (ii) the Company’s occupancy of any portion of the Expansion Premises, and (iii) May 1, 2022, and continues for a period of ten years and five months. The term of the Expansion Premises and the existing premises are not coterminous. Annual base rent for the existing premise under the Lease Amendment is approximately $4.7 million beginning on March 1, 2027, and increases by three percent annually; annual base rent for the Expansion Premises is approximately $1.4 million per year and increases by three percent annually. The Lease Amendment allows for a tenant improvement allowance not to exceed $5.3 million. The Lease Amendment was accounted for as a lease modification and the right-of-use asset and lease liability for the existing premises were remeasured at the modification date resulting in an increase of $10.9 million to both the right-of-use asset and lease liabilities.

The Company maintains letters of credit, secured by restricted cash, for security deposits totaling $2.0 million and $1.3 million as of December 31, 2021 and 2020, respectively, in conjunction with its current leases.

The following table summarizes operating lease costs and variable lease costs, as well as sublease income for the year ended December 31, 2021:

	Years ended December 31,	
	2021	2020
	(in thousands)	
Operating lease costs	$ 2,592	$ 2,492
Variable lease costs	2,127	2,355
Sublease income	(861)	(913)
Net lease cost	$ 3,858	$ 3,934

The maturities of our operating lease liabilities as of December 31, 2021 were as follows:

For the Years Ending December 31,	Amount (in thousands)
2022	3,326
2023	4,444
2024	4,578
2025	4,715
Thereafter	31,123
Total undiscounted lease payments	$ 48,186
Less: imputed interest	(17,932)
Less: estimated lease incentives	(6,320)
Present value of operating lease liabilities	$ 23,934

The following table summarizes the lease term and discount rate as of December 31, 2021:

	As of December 31, 2021
Weighted-average remaining lease term (years)	
Operating leases	8.9
Weighted-average discount rate	
Operating leases	10.5%

The following table summarizes the supplemental cash flow information related to the Company's operating leases for the year ended December 31, 2021.

	Years ended December 31,	
	2021	2020
	(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities	$ 3,810	$ 3,804
Increase in lease liabilities and right-of-use assets due to lease remeasurement	$ 10,901	$ —

9. LICENSE AGREEMENTS

City of Hope

In April 2016, the Company entered into a license agreement with City of Hope (“COH”), an academic research and medical center. The license term extends until the last to expire patent, unless terminated earlier by either party under certain provisions. The Company is required to pay an annual license fee of $25,000, reimburse COH for patent costs incurred, pay amounts up to $3.2 million upon the achievement of certain development and commercialization milestones for each product under the license, pay royalties on future sales in the low single-digits and royalties on sublicense revenue in the low double-digits, if any. During the year ended December 31, 2020, the Company paid $75,000 plus interest to COH in connection with achievement of a milestone event. Other than the annual license fee, there were no payments to COH in 2021.

On August 6, 2021, the Company received notice from COH that it did not accomplish at least one of the partnering milestones by the applicable deadline, as set forth in the COH license. This notice does not affect the Company's exclusive license in the field of mammalian therapeutics, including all human therapeutics, associated diagnostics, and target validation, (the "Mammalian Therapeutic Field"), where the Company retains exclusive rights. Instead, the notice served as written notice that the exclusive license granted pursuant to the COH license in all fields except the Mammalian Therapeutic Field converted from exclusive to non-exclusive effective as of September 20, 2021, which was forty-five days from the receipt of notice. In connection with the conversion, any royalty obligations and sublicensee fees relating to fields outside of the Mammalian Therapeutic Field shall be reduced by a certain percentage. This change to the Company's exclusive worldwide license with COH does not impact any of its current therapeutic product development candidates in development, including HMI-102, HMI-103, HMI-203, HMI-202 and HMI-104, nor will it impact any potential future therapeutic product development candidates.

California Institute of Technology

In September 2016, the Company entered into a co-exclusive license agreement with the California Institute of Technology (“Caltech”), an academic research institute. The license term extends until the expiration, revocation, invalidation or unenforceability of the licensed patent rights. The Company is required to pay an annual minimal royalty fee of $20,000, reimburse for patent costs incurred, pay an amount up to $7.2 million upon the achievement of certain development and regulatory milestones and pay royalties on future sales in the low single-digits and royalties on sublicense revenue in the mid to high single-digits, if any.

10. INCOME TAXES

A reconciliation between the U.S. federal statutory tax rate and the Company’s effective tax rate is summarized as follows:

	For the Year Ended December 31,	
	2021	2020
Federal statutory rate	21.0%	21.0%
Tax credits	9.3%	10.6%
State taxes, net of federal tax benefit	8.6%	8.0%
Non-deductible expenses	(1.4%)	(1.8%)
Other	2.6%	—%
Change in valuation allowance	(40.1%)	(37.8%)
Effective income tax rate	—%	—%

The principal components of the Company's deferred tax assets and liabilities consist of the following:

	December 31,	
	2021	2020
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 100,417	$ 72,838
R&D credits	51,705	39,888
Equity compensation	6,919	1,368
Operating lease liabilities	6,520	4,219
Accrued expense and other	2,072	1,914
Deferred revenue	1,189	8,251
Capitalized R&D costs	868	1,039
Total deferred tax assets	169,690	129,517
Deferred tax liabilities:		
Right-of-use assets	(4,252)	(1,611)
Depreciation	(1,541)	(2,115)
Other	(503)	(757)
Total deferred tax liabilities	(6,296)	(4,483)
Valuation allowance	(163,394)	(125,034)
Net deferred taxes	$ —	$ —

The Company has no income tax expense due to the operating loss incurred for the years ended December 31, 2021 and 2020. The Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the net deferred tax assets is not determined to be more likely than not.

At December 31, 2021, the Company had $367.2 million and $369.0 million of federal and state net operating loss carryforwards, respectively. Federal net operating loss carryforwards of $31.5 million, generated before 2018, will begin expiring in varying amounts through 2037 unless utilized. The remaining federal net operating loss carryforwards of $335.7 million, generated after 2017, will be carried forward indefinitely. The state net operating losses will begin expiring in varying amounts through 2041 unless utilized. At December 31, 2021, the Company had $43.2 million and $10.8 million of federal and state research and development credit carryforwards, respectively, that expire at various dates through 2041. Included in the $43.2 million of federal research and development credit carryforwards is $33.9 million of orphan drug credit carryforwards. The valuation allowance increased in 2021 and 2020 by $38.4 million and $47.2 million, respectively, due to the increase in the deferred tax assets by the same amounts, primarily due to the net operating loss carryforwards and research and development tax credits not utilized.

For all years through December 31, 2021, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards. Since a full valuation allowance has been provided against the Company's research and development credits, any reduction in the gross deferred tax asset established for the research and development credit carryforwards would not result in any net impact to the Company's consolidated financial statements.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards that could be used annually to offset future taxable income. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and because there could be additional changes in control in the future. As a result, the Company is not able to estimate the effect a change in control would have, if any, on the Company's ability to utilize its net operating loss and research and development credit carryforwards in the future.

The Company files tax returns in the United States and Massachusetts. All tax years since inception remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

As of December 31, 2021, the Company had no uncertain tax positions. The Company has elected to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2021 and 2020.

11. STOCKHOLDERS' EQUITY

Common Stock—Voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Voting—Each holder of outstanding shares of common stock are entitled to one vote in respect of each share. The holders of outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

Dividends—Subject to the payment in full of any preferential dividends to which the holders of preferred stock are entitled, the holders of common stock shall be entitled to receive dividends out of funds legally available therefore at such times and in such amounts as the Board of Directors may determine in its sole discretion.

Liquidation Rights—In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, after the payment or provision for payment of all debts and liabilities of the Company and any preferential amounts to which the holders of preferred stock are entitled with respect to the distribution of assets in liquidation, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

There were 57,150,274 and 50,265,575 shares of common stock outstanding at December 31, 2021 and 2020, respectively.

Preferred Stock—As of December 31, 2021 and 2020, there were no shares of preferred stock issued and outstanding.

12. STOCK INCENTIVE PLANS

2015 Stock Incentive Plan

In December 2015, the Company's Board of Directors adopted the 2015 Stock Incentive Plan (the "2015 Plan"), which provided for the grant of qualified incentive and nonqualified stock options or restricted stock awards to the Company's employees, officers, directors, advisors, and outside consultants. Stock options generally vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2015 Plan. At December 31, 2021, there were no additional shares available for future grant under the 2015 Plan.

2018 Incentive Award Plan

In March 2018, the Company's Board of Directors adopted and the Company's stockholders approved the Homology Medicines, Inc. 2018 Incentive Award Plan (the "2018 Plan" and, together with the 2015 Plan, the "Plans"), which became effective on the day prior to the first public trading date of the Company's common stock. Upon effectiveness of the 2018 Plan, the Company ceased granting new awards under the 2015 Plan.

The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock or cash-based awards to employees and consultants of the Company and certain affiliates and directors of the Company. The number of shares of common stock initially available for issuance under the 2018 Plan was 3,186,205 shares of common stock plus the number of shares subject to awards outstanding under the 2015 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company on or after the effective date of the 2018 Plan. In addition, the number of shares of common stock available for issuance under the 2018 Plan is subject to an annual increase on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028 equal to the lesser of (i) 4% of the Company's outstanding shares of common stock on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Company's Board of Directors, provided that not more than 20,887,347 shares of common stock may be issued under the 2018 Plan upon the exercise of incentive stock options (the "Evergreen Provision"). As of December 31, 2021, there were 2,257,623 shares available for future grant under the 2018 Plan. On January 1, 2022, pursuant to the Evergreen Provision, an additional 2,286,010 shares were added to the 2018 Plan, representing 4% of total common shares outstanding at December 31, 2021.

2018 Employee Stock Purchase Plan

In March 2018, the Company's Board of Directors adopted, and the Company's stockholders approved, the Homology Medicines, Inc. 2018 Employee Stock Purchase Plan (the "2018 ESPP"). The 2018 ESPP allows employees to buy Company stock through after-tax payroll deductions at a discount from market value. The 2018 ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code. The number of shares of common stock initially available for issuance under the 2018 ESPP was 353,980 shares of common stock plus an annual increase on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028 equal to the lesser of (i) 1% of the Company's outstanding shares of common stock on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Company's Board of Directors, provided that not more than 4,778,738 shares of common stock may be issued under the 2018 ESPP (the "ESPP Evergreen Provision"). At December 31, 2021, there were 1,431,382 shares available for future issuance under the 2018 ESPP. On January 1, 2022, pursuant to the ESPP Evergreen Provision, an additional 571,502 shares were added to the 2018 ESPP, representing 1% of total common shares outstanding at December 31, 2021.

Under the 2018 ESPP, employees may purchase common stock through after-tax payroll deductions at a price equal to 85% of the lower of the fair market value on the first trading day of an offering period or the last trading day of an offering period. The 2018 ESPP generally provides for offering periods of six months in duration that end on the final trading day of each February and August. In accordance with the Internal Revenue Code, no employee will be permitted to accrue the right to purchase stock under the 2018 ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of the Company's common stock as of the first day of the offering period).

During the year ended December 31, 2021, 110,923 shares were issued under the 2018 ESPP for aggregate proceeds to the Company of $0.8 million. During the year ended December 31, 2020, 83,848 shares were issued under the 2018 ESPP for aggregate proceeds to the Company of $0.9 million. Pursuant to the 2018 ESPP, the Company recorded stock-based compensation of $0.1 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

Stock Options

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model, with the assumptions noted in the table below. Expected volatility for the Company's common stock was determined based on an average of the historical volatility of a peer group of publicly traded companies that are similar to the Company. The expected term of options was calculated using the simplified method, which represents the average of the contractual term of the option and the weighted-average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods commensurate with the expected term of the award. The Company recognizes forfeitures as they occur.

The assumptions used in the Black-Scholes option pricing model are as follows:

	For the Year Ended December 31,	
	2021	2020
Expected volatility	64.6% - 71.7%	63.2% — 66.3%
Weighted-average risk-free interest rate	0.50% - 1.33%	0.31% — 1.73%
Expected dividend yield	— %	— %
Expected term (in years)	5.5 - 6.25	5.5 - 6.25
Underlying common stock fair value	$4.85 - $13.91	$9.82 - $21.75

A summary of option activity under the Plans during the year ended December 31, 2021 is as follows:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2021	5,840,824	$ 15.18	7.8	$ 12,278
Granted	2,202,325	$ 11.97		
Exercised	(59,465)	$ 2.29		
Cancelled/Forfeited	(359,378)	$ 17.50		
Outstanding at December 31, 2021	7,624,306	$ 14.25	7.5	$ 2,069
Vested and expected to vest at December 31, 2021	7,624,306	$ 14.25	7.5	$ 2,069
Exercisable at December 31, 2021	4,434,630	$ 13.66	6.7	$ 2,069

The total intrinsic value of options exercised during the year ended December 31, 2021 and 2020 was $0.6 million and $0.6 million, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2021 and 2020 was $7.26 and $10.39, respectively.

Stock options granted pursuant to the 2015 Plan permit option holders to elect to exercise unvested options in exchange for unvested common stock. Options granted under the 2015 Plan that are exercised prior to vesting will continue to vest according to the respective option agreement, and such unvested shares are subject to repurchase by the Company at the optionee's original exercise price in the event the optionee's service with the Company voluntarily or involuntarily terminates.

A summary of the Company's unvested common stock from early exercises that is subject to repurchase by the Company is as follows:

	Shares
Unvested shares—January 1, 2021	3,091
Vested	(3,091)
Unvested shares—December 31, 2021	—

As of December 31, 2021 and 2020, no shares and 3,091 shares, respectively, remained subject to a repurchase right by the Company, with a related liability included in accrued expenses and other liabilities in the consolidated balance sheets of less than $0.1 million as of each date.

Restricted Stock Units

The fair values of restricted stock units ("RSUs") are based on the fair market value of the Company's common stock on the date of grant. Each RSU represents a contingent right to receive one share of the Company's common stock upon vesting. In general, RSUs vest annually in three equal installments on January 1st of each year after the grant date. The following table summarizes the Company's RSU activity for the year ended December 31, 2021:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2021	—	$ —
Granted	321,300	$ 12.79
Vested	—	$ —
Forfeited	(13,700)	$ 13.63
Outstanding at December 31, 2021	307,600	$ 12.75

Stock-based Compensation Expense

The Company recognizes compensation expense for awards to employees based on the grant date fair value of stock-based awards on a straight-line basis over the period during which an award holder provides service in exchange for the award,

which is generally the vesting period. The Company recorded stock-based compensation expense related to stock options, shares purchased under the 2018 ESPP and restricted stock units as follows:

	For the Year Ended December 31,	
	2021	2020
	(in thousands)	
Research and development	$ 8,795	$ 6,390
General and administrative	8,450	6,858
	$ 17,245	$ 13,248

As of December 31, 2021, there was $29.8 million of unrecognized compensation expense related to unvested employee and non-employee share-based compensation arrangements granted under the Plans. The unrecognized compensation expense is estimated to be recognized over a period of 2.4 years at December 31, 2021.

13. NET LOSS PER SHARE

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at December 31, 2021 and 2020, from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	As of December 31,	
	2021	2020
Unvested common stock from early exercise of options	—	3,091
Stock options to purchase common stock	7,624,306	5,840,824
Restricted stock units	307,600	—
Total	7,931,906	5,843,915

14. DEFINED CONTRIBUTION PLAN

The Company has a 401(k) defined contribution plan (the "401(k) Plan") for all of its employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits, while the Company contributes to the plan at the discretion of the Board of Directors. The Company's discretionary match made under the 401(k) Plan for the years ended December 31, 2021 and 2020 was $0.8 million and $0.7 million, respectively.

15. COLLABORATION AND LICENSE AGREEMENT

In November 2017, the Company entered into a collaboration and license agreement with Novartis (as amended, the "Collaboration Agreement") for the research, development, manufacturing and commercialization of products using the Company's gene-editing technology for the treatment of certain ophthalmic targets and sickle cell disease. On February 26, 2021, Homology received notice from Novartis that they had elected to terminate the Collaboration Agreement with the Company with respect to the remaining ophthalmic target under the Collaboration Agreement and as a result, the Company regained worldwide exclusive rights to this target. Accordingly, the notice served as notice of Novartis' termination of the Collaboration Agreement in its entirety, which became effective on August 26, 2021. Under the terms of the Collaboration Agreement, Novartis was obligated to continue to reimburse the Company for certain research and development costs through August 26, 2021. Upon effectiveness of the termination, such reimbursements ceased.

The Company recognized revenue under the Collaboration Agreement over time using a cost-to-cost method, which it believed best depicted the transfer of control to the customer. The delivery of the termination notice caused a change in the estimate of total costs to satisfy the single performance obligation under the Collaboration Agreement. The cumulative effect of revisions to the total estimated costs to complete the Company's single performance obligation was recorded in the current period when the changes were identified and amounts could be reasonably estimated. As such, the Company recognized a cumulative effect adjustment of approximately $26.9 million in collaboration revenue during the year ended December 31, 2021.

During the years ended December 31, 2021 and 2020, the Company recognized revenue under the Collaboration Agreement of $30.8 million and $2.3 million, respectively, of which $30.2 million and $0.8 million was included in deferred revenue at the beginning of each such period, respectively. As of December 31, 2021 and 2020, there was no deferred revenue and approximately $30.2 million of deferred revenue related to the Collaboration Agreement, respectively. In addition, as of December 31, 2021 and 2020, the Company recorded no accounts receivable and $0.4 million, respectively, related to reimbursable research and development costs under the Collaboration Agreement, which are included in prepaid expenses and other current assets on the consolidated balance sheets.

As of December 31, 2021, all deferred revenue under the Collaboration Agreement has been recognized and there are no further obligations due to Novartis.

16. PFIZER STOCK PURCHASE AGREEMENT

On November 9, 2020, the Company entered into a common stock purchase agreement (the "Stock Purchase Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which the Company agreed to issue and sell to Pfizer 5,000,000 shares of the Company's common stock through a private placement transaction (the "Private Placement") at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million. The shares of common stock sold to Pfizer are subject to a one-year lock-up from closing, during which time Pfizer is prohibited from selling or otherwise disposing of such shares.

Under the Stock Purchase Agreement, Pfizer was granted an exclusive right of first refusal (the "ROFR") for a 30-month period (the "ROFR Period") beginning on the date of the closing of the Private Placement (collectively, the "ROFR Provision"), to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103. Pfizer may exercise its right of first refusal under the ROFR Provision one time for each of HMI-102 and HMI-103 during the ROFR period. In addition to the ROFR, the Stock Purchase Agreement provides for an information sharing committee (the "Information Committee"), comprised of representatives of each company which will serve as a forum for sharing information regarding the development of HMI-102 and HMI-103 during the ROFR Period.

The Company recorded the issuance of common stock at its estimated fair value of $52.0 million, which reflects a discount for the lack of marketability of the shares. The remaining $8.0 million of aggregate purchase price was allocated to the other elements of the Stock Purchase Agreement, which represent a contract with a customer. The Company concluded that the Information Committee represents the only performance obligation under the contract. The ROFR does not provide Pfizer with a material right and is therefore not a performance obligation. As such, the Company allocated the $8.0 million to the Information Committee obligation.

The Company will recognize revenue over time as the measure of progress which it believes best depicts the transfer of control to Pfizer. The Information Committee will meet regularly over the ROFR Period to share information which results in recognition of the transaction price over the 30-month ROFR Period.

During the year ended December 31, 2021 and 2020, the Company recognized collaboration revenue of $3.2 million and $0.4 million, respectively. As of December 31, 2021 and 2020, there was approximately $4.4 million and $7.6 million of deferred revenue related to the Company's obligation to Pfizer, respectively.

17. ASSETS HELD FOR SALE

As part of the OXB Solutions Transaction (as defined in Note 18), the Company transferred certain manufacturing and other equipment to the newly formed manufacturing company. The fixed assets transferred to the new company as part of this transaction met the assets held for sale criteria and were reclassified to assets held for sale as of December 31, 2021. The Company determined that the carrying value of the assets held for sale did not exceed fair value less costs to sell, which resulted in no impairment charge for the year ended December 31, 2021. As of December 31, 2021, the Company has presented $28.9 million of fixed assets to be transferred to the new company as a current asset under the caption of "assets held for sale" in the accompanying consolidated balance sheets.

Pursuant to the OXB Solutions Transaction, the Company also assigned all of its right, title and interest in, to and under its facility lease to the new company. However, as the Company remains jointly and severally liable for the payment of rent under the facility lease, the Company has not been released from being the primary obligor under such lease and therefore the related right-of-use asset and lease liability are not derecognized and will remain on the Company's balance sheet.

The Company determined that the expected disposal of the fixed assets does not qualify for reporting as a discontinued operation since it does not represent a strategic shift that has or will have a major effect on the Company's operations and financial results.

18. SUBSEQUENT EVENT

On March 10, 2022, the Company closed its previously announced transaction with Oxford Biomedica Solutions LLC (f/k/a Roadrunner Solutions LLC), ("OXB Solutions"), Oxford Biomedica (US), Inc., ("OXB"), and Oxford Biomedica plc, ("OXB Parent" and collectively with OXB, "Oxford"), pursuant to the Equity Securities Purchase Agreement, or the Purchase Agreement, dated as of January 28, 2022, by and among Homology, OXB Solutions and Oxford, whereby, among other things, Homology and Oxford have agreed to collaborate to operate OXB Solutions, which will provide AAV vector process development and manufacturing to pharmaceutical and biotechnology companies (the "OXB Solutions Transaction").

Pursuant to the terms of the Purchase Agreement and a contribution agreement (the "Contribution Agreement") entered into between Homology and OXB Solutions prior to the closing of the OXB Solutions Transaction (the "Closing"), Homology has agreed to assign and transfer to OXB Solutions all of its assets that are primarily used in the manufacturing of AAV vectors for use in gene therapy or gene editing products, but excluding certain assets related to manufacturing or testing of Homology's proprietary AAV vectors (collectively, the "Transferred Assets"), in exchange for 175,000 common equity units in OXB Solutions ("Units"), and OXB Solutions assumed from us, and agreed to pay, perform and discharge when due, all of our duties, obligations, liabilities, interests and commitments of any kind under, arising out of or relating to the Transferred Assets.

Effective as of the Closing, Homology sold to OXB, and OXB purchased from Homology, 130,000 Units, (the "Transferred Units") in exchange for $130.0 million. In connection with the Closing, OXB contributed $50.0 million in cash to OXB Solutions in exchange for an additional 50,000 Units. Immediately following the Closing, (i) OXB owned 180,000 Units, representing 80 percent (80%) of the fully diluted equity interests in OXB Solutions, and (ii) Homology owned 45,000 Units, representing 20 percent (20%) of the fully diluted equity interests in OXB Solutions.

Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB Solutions (the "OXB Solutions Operating Agreement") which was executed in connection with the Closing, at any time following the three-year anniversary of the Closing, (i) OXB will have an option to cause Homology to sell and transfer to OXB, and (ii) Homology will have an option to cause OXB to purchase from Homology, in each case all of Homology's equity ownership interest in OXB Solutions at a price equal to 5.5 times the revenue for the immediately preceding 12-month period, subject to a specified maximum amount. Pursuant to the terms of the OXB Solutions Operating Agreement, Homology will be entitled to designate one director on the Board of Directors of OXB Solutions, which shall initially be Arthur Tzianabos, Homology's President and Chief Executive Officer. Further, Tim Kelly, Homology's former Chief Operating Officer, now serves as the Chief Executive Officer and Chairman of the Board of OXB Solutions.

Concurrently with the Closing and as described in Note 18, the Company and OXB Solutions entered into a lease assignment and assumption agreement pursuant to which Homology assigned all of its right, title and interest in, to and under its facility lease to OXB Solutions and a sublease agreement whereby OXB Solutions subleased certain premises in its facility to Homology. The Company also entered into certain ancillary agreements with OXB Solutions, including a license and patent management agreement whereby OXB Solutions granted certain licenses to the Company, a supply agreement for a term of three years that includes certain annual minimum purchase commitments, a transitional services agreement pursuant to which Homology will perform certain services for the benefit of OXB Solutions and OXB Solutions will perform certain services for the benefit of Homology, as well as several additional ancillary agreements.

* * * * *

ASSIGNMENT AND ASSUMPTION AGREEMENT

This ASSIGNMENT AND ASSUMPTION AGREEMENT (this "Assignment"), is made effective as of March 10, 2022 (the "Effective Date"), by and between HOMOLOGY MEDICINES, INC., a Delaware corporation ("Assignor"), with an address of One Patriots Park, Bedford, Massachusetts 01730, and ROADRUNNER SOLUTIONS LLC, a Delaware limited liability company ("Assignee"), with an address of One Patriots Park, Bedford, Massachusetts 01730. All capitalized terms used herein and not otherwise defined shall have the meaning set forth in the Lease (as defined below).

RECITALS

A. As of the Effective Date, Assignor has transferred its manufacturing business to Assignee (the "Transaction").

B. Patriots Park Owner, LLC ("Landlord"), as successor-in-interest to Bedford Patriots Park, LLC, and Assignor are parties to that certain Lease Agreement dated as of December 21, 2017 (the "Original Lease"), as amended by that First Amendment to Lease dated as of February 8, 2019 (the "First Amendment"), as amended by that Second Amendment to Lease dated as of March 15, 2019 (the "Second Amendment"), and as amended by that Third Amendment to Lease dated as of November 9, 2021 (the "Third Amendment" and together with the Original Lease, the First Amendment, and the Second Amendment, collectively, the "Lease"), for the lease of certain premises being comprised of approximately 91,529 rentable square feet of space (the "Premises") located on the first (1st) and second (2nd) floors of the building located at One Patriots Park, Bedford, Massachusetts 01730 (the "Building").

C. In connection with the Transaction and as of the Effective Date, Assignor desires to assign all of its rights under the Lease to Assignee, and Assignee desires to accept such assignment and to assume all of Assignor's obligations and liabilities under the Lease, subject to the terms and conditions set forth in this Assignment.

D. As of the Effective Date, Assignor and Assignee are entering into that certain Sublease Agreement by and between Assignee, as sublandlord, and Assignor, as subtenant (the "Sublease") pursuant to which Assignor will sublease from Assignee a portion of the Premises located on the first (1st) floor of the Building.

AGREEMENT

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein and other good and valuable consideration, the mutual receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, Assignor and Assignee hereto agrees as follows:

1. Assignment and Assumption. As of the Effective Date, (i) Assignor hereby assigns,

transfers, releases and sets over unto Assignee and its successors and permitted assigns, all of Assignor's right, title and interest in and to the Lease, and (ii) subject to the provisions of this Assignment, Assignee, effective as of the Effective Date, hereby accepts the foregoing assignment and assumes and agrees to perform and comply with all of the terms, covenants, conditions and agreements set forth in the Lease on the part of the "Tenant" therein to be fulfilled, kept, observed and performed, including any renewal, extension or modification thereof, accruing from and after the Effective Date.

2. Lease. Assignor represents and warrants as of the Effective Date to Assignee that (a) the Lease is valid, binding and in full force and effect and enforceable in accordance with its terms by Assignor and, to Assignor's knowledge, Landlord, (b) a true, complete and accurate copy of the Lease is attached hereto as Exhibit A and the Lease has not been amended or modified, except as set forth in Exhibit A, or terminated or cancelled, (c) neither Assignor nor, to Assignor's knowledge, Landlord is in breach or default under the Lease (whether monetary or otherwise) and has not given or received any written notice of breach or default or termination under the Lease, (d) Assignor has not made any assignment, sublease, transfer, conveyance or other disposition of the Lease or any interest therein, or granted any sublease, license, occupancy agreement or other use or occupancy right to any other person or entity, and (e) there are no parties in possession of the Premises other than Assignor. Assignee and Assignor each covenant and warrant to the other that, as of the Effective Date, it has, the full power, good right and lawful authority to execute this Assignment and to perform the obligations contained herein.

3. Assignor and Assignee Indemnities. Assignor hereby indemnifies, protects, defends and saves Assignee, Oxford Biomedica plc and any director, manager, officer, employee, agent or other representative of Assignee or Oxford Biomedica plc ("Assignee Parties") harmless from and against any and all losses, costs, damages and expenses, including reasonable attorneys' fees, liabilities or obligations ("Claims") arising out of, by virtue of or in any way related to any alleged obligation, including without limitation any environmental obligation or requirement to remove or restore any Alterations (as defined in the Lease) constructed by Assignor, or undertaking of the "Tenant" to perform or discharge any of the terms of the Lease which obligation or undertaking shall have arisen prior to the Effective Date. Assignor hereby releases, remises, acquits and forever discharges Assignee and the Assignee Parties from and against any and all Claims arising out of or in any way relating to the obligations imposed on the "Tenant" under the Lease, which obligations accrued as of or prior to the Effective Date, or arising from the actions of any of the Assignor Parties with respect to the Lease or the Premises as of or prior to the Effective Date. Assignee hereby protects, defends and saves Assignor and any director, manager, officer, employee, agent or other representative of Assignor ("Assignor Parties") harmless from and against all Claims which Assignor may sustain, suffer, expend or incur in connection with any alleged obligation or undertaking of the "Tenant" to perform or discharge any of the terms of the Lease which obligation or undertaking shall have arisen subsequent to the Effective Date. Assignee hereby releases, remises, acquits and forever discharges Assignor and the Assignor Parties from and against any and all Claims arising out of or in any way relating to the obligations imposed on the "Tenant" under the Lease, which obligations first accrued from and after the Effective Date, except any Claim arising out of or relating to (i) the condition of the Premises on or before the Effective Date to the extent the Claim arises as a result of a failure by Assignor to comply with its obligations under the Lease prior to the Effective Date, (ii) Assignor's obligations under this Assignment, (iii) Assignor's obligations under the Sublease (including, without

limitation, to comply with the terms, conditions and covenants of the Lease), or (iv) the Transaction. In no event shall either party be liable to the other to the extent of such other party's negligence or willful misconduct, or for any consequential, punitive, exemplary or similar damages. Assignor's and Assignee's obligations under this Section 3 shall survive any assignment of the Lease.

4. Premises Condition. On the Effective Date, Assignor shall surrender and deliver the Premises to Assignee (a) in the condition required to be maintained by the "Tenant" under the Lease, (b) vacant, other than furniture, fixtures and equipment set forth on Exhibit B, and (c) in broom clean condition; provided, however, that the foregoing shall not relieve Assignor of any of its obligations under the Lease arising on or before the Effective Date or its indemnity obligations under Section 3 above or its reimbursement, remediation or indemnity obligations under Section 5 below. Assignor shall have no obligation to remove any Alterations (as such term is defined in Section 8.1 of the Original Lease) in the Premises, make any Alterations in the Premises or otherwise prepare the Premises for Assignee's use in connection with such surrender unless such removal, additional Alterations or other preparations are required as a result of Assignor's failure to comply with any term or condition of the Lease arising on or before the Effective Date. Notwithstanding its rights under Section 24 of the Lease, Assignor represents and warrants that Assignor has not deferred and is not currently deferring any maintenance or compliance with Applicable Laws (as such term is defined in Section 24 of the Original Lease) to the Premises pursuant to Section 24 of the Lease or as otherwise may be permitted under the Lease. Assignor's obligations under this Section 4 shall survive the assignment of the Lease pursuant to this Assignment.

5. Environmental. Assignee may, at its sole cost and expense, engage a reputable licensed environmental engineer or industrial hygienist to conduct a non-invasive environmental assessment that does not constitute an Alteration (as defined in the Lease) ("Environmental Assessment"), which such Environmental Assessment is to be performed pursuant to and in compliance with all terms and conditions of the Lease. So long as such Environmental Assessment is completed within sixty (60) days after the Effective Date ("ESA Delivery Date"), Assignor shall cause (or, if so elected in writing by Assignee in Assignee's sole discretion, reimburse Assignee for Assignee's performance of) the remediation of any recognized environmental conditions in the Environmental Assessment to the extent required under the Lease (including, without limitation, any removal of Hazardous Materials required by the Lease or cleanup required by the Lease) to the extent existing in, on or under the Premises. If the Environmental Assessment is delivered to Assignor on or before the ESA Delivery Date and discloses the existence of recognized environmental conditions in, on or under the Premises for which the estimated cost of remediation in accordance with the Lease, individually or in the aggregate, is equal to or exceeds $75,000.00, then Assignor shall reimburse Assignee for the full cost and expense of the Environmental Assessment within thirty (30) days after invoice therefor. To the extent the Environmental Assessment is delivered to Assignor on or before the ESA Delivery Date, Assignor hereby acknowledges and agrees that the contents of the Environmental Assessment will be definitive as between the parties and that any recognized environmental conditions in the Environmental Assessment will be deemed to have been caused by Assignor. Assignor hereby indemnifies Landlord, Landlord Parties, Assignee and any Assignee Parties for any Claims related to any recognized environmental conditions disclosed in the Environmental Assessment (other than with respect to Existing Hazardous Materials unless exacerbated by Assignor's construction activities

or other acts or omissions by Assignor) and Assignor's entry into the Premises and performance of remediation of, or any failure to remediate, any such matters in accordance with this Section 5. Assignor's obligations under this Section 5 shall survive the assignment of the Lease pursuant to this Assignment.

6. Security Deposit. Assignee acknowledges that Landlord holds a letter of credit in the amount of $1,676,549.33 as the Total Lease Security Deposit (as defined in Section 17 of the Third Amendment) under the Lease and such Total Lease Security Deposit is not being assigned to Assignee under this Assignment. Within thirty (30) calendar days after the Effective Date, Assignee shall deliver to Landlord a replacement letter of credit pursuant to and in accordance with all terms and conditions of the Lease in the amount of $1,676,549.33 to replace the existing Total Lease Security Deposit held by Landlord as of the Effective Date; provided, however, that Assignor and Assignee hereby acknowledge and agree that the existing letter of credit held by Landlord as of the Effective Date hereof in the amount of the Total Lease Security Deposit as delivered by Assignor shall remain in full force and effect until Assignee has provided Landlord with such replacement letter of credit pursuant to and in accordance with all terms and conditions contained herein and in the Lease, as applicable.

7. Further Assurances. Each party hereto agrees to furnish to the other party all such resolutions, certificates, other documents and access to non-proprietary and non-confidential information as the other party may from time to time reasonably request to evidence, confirm and fully implement the assignment of assets and assumption of liabilities made hereby.

8. Successors and Assigns. This Assignment shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.

9. Counterparts; Effectiveness. This Assignment may be signed in any number of counterparts, and any signatures delivered by e-mail or portable document format (.pdf), each of which shall be an original, shall have the same effect as if the signatures were upon the same instrument and delivered in person.

10. Brokers. Each party hereto represents and warrants to the other and to Landlord that it has had no dealings with any real estate broker, finder or agent in connection with this Assignment or the transactions contemplated hereby, and that it knows of no real estate broker, finder or agent who is entitled to a commission in connection with this Assignment. Each of the parties agrees to indemnify, protect, defend and hold harmless the other and Landlord from and against any and all losses, liabilities, damages, claims, demands, costs and expenses (including, without limitation, reasonable attorneys' fees) suffered or incurred by the other in connection with any commissions or equivalent compensation alleged to be owing on account of the indemnifying party's dealings with any real estate broker, finder or agent in connection with this Assignment or the transactions contemplated hereby.

11. Amendments. Any amendment or waiver of this Assignment must be in writing and signed by the party against whom it is to be effective. No failure or delay in exercising any right, power or privilege hereunder shall constitute a waiver thereof, nor shall any single or partial exercise or waiver thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

12. Severability. If any provision of this Assignment, or the application thereof to any Person, place or circumstance, shall be held by a court of competent jurisdiction to be invalid, unenforceable or void, the remainder of this Assignment and such provisions as applied to other persons, places and circumstances shall remain in full force and effect, for so long as the economic or legal substance of the transactions contemplated by this Assignment is not affected in any manner materially adverse to any party.

13. Governing Law, Entire Agreement, etc. This Assignment shall be construed in accordance with and governed by the laws of the Commonwealth of Massachusetts (without reference to its principles of choice or conflict of laws or any other laws that would make the laws of any other jurisdiction other than the Commonwealth of Massachusetts applicable hereto).

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties hereto has executed and delivered this Assignment and Assumption Agreement as of the Effective Date.

ASSIGNEE:

ROADRUNNER SOLUTIONS LLC,
a Delaware limited liability company

By: /s/ Tim Kelly
Name: Tim Kelly
Title: Chief Executive Officer

ASSIGNOR:

HOMOLOGY MEDICINES, INC.
a Delaware corporation

By: /s/ Arthur O. Tzianabos
Name: Arthur O. Tzianabos
Title: President and Chief Executive Officer

EXHIBIT A

LEASE

EXHIBIT B

FF&E

SUBLEASE AGREEMENT

This SUBLEASE AGREEMENT (this "***Sublease***") is dated as of March 10, 2022 (the "***Effective Date***"), by and between ROADRUNNER SOLUTIONS LLC, a Delaware limited liability company ("***Sublandlord***"), with an address of One Patriots Park, Bedford, Massachusetts 01730, and HOMOLOGY MEDICINES, INC., a Delaware corporation ("***Subtenant***"), with an address of One Patriots Park, Bedford, Massachusetts 01730. All capitalized terms used in this Sublease and not otherwise defined herein shall have the meaning set forth in the Master Lease (as defined below).

RECITALS

A. Patriots Park Owner, LLC ("***Master Landlord***"), as successor-in-interest to Bedford Patriots Park, LLC, as landlord, and Sublandlord, as successor-in-interest to Subtenant, as tenant, are parties to that certain Lease Agreement dated December 21, 2017 (the "***Original Lease***"), as amended by that certain First Amendment to Lease dated as of February 8, 2019 (the "***First Amendment***"), as amended by that certain Second Amendment to Lease dated as of March 15, 2019 (the "***Second Amendment***"), as amended by that certain Third Amendment to Lease dated as of November 9, 2021 (the "***Third Amendment***"), and as amended by that certain Fourth Amendment to Lease dated as of even date herewith (the "***Fourth Amendment***", and together with the Original Lease, the First Amendment, the Second Amendment, and the Third Amendment, the "***Master Lease***"), pursuant to which Sublandlord leases from Master Landlord approximately 91,529 rentable square feet of space (the "***Premises***") located on the first (1st) and second (2nd) floors of the building located at One Patriots Park, Bedford, Massachusetts 01730 (the "***Building***").

B. Sublandlord desires to sublease a portion of the Premises to Subtenant, and Subtenant desires to sublease a portion of the Premises from Sublandlord, pursuant to the terms and conditions of this Sublease.

AGREEMENT

Now, Therefore, for good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, Sublandlord and Subtenant hereby agree as follows:

1. Subleased Premises.

1.1 Subleased Premises. Sublandlord hereby subleases to Subtenant that portion of the Premises set forth on Exhibit A attached hereto and incorporated herein by this reference consisting of approximately 26,850 rentable square feet of space on the first (1st) floor of the Building comprised of: (a) approximately 19,400 rentable square feet of space for Subtenant's exclusive use outlined on Exhibit A attached hereto (the "***Exclusive Subleased Premises***"), and (b) approximately 7,450 rentable square feet of space representing Subtenant's allocated portion of the "***Shared Space***" outlined on Exhibit A attached hereto (being Rooms 1100, 1101, 1135, 1136, 1136A, 1137, 1145, 1146) for Subtenant's non-exclusive use together with Sublandlord and any other subtenants or licensees of Sublandlord (collectively, the "***Subleased Premises***"), and

Subtenant hereby subleases the Subleased Premises from Sublandlord, pursuant to the terms and conditions of this Sublease, the Master Lease, and the Consent (as hereinafter defined), as applicable. On the Effective Date, Sublandlord shall deliver possession of the Subleased Premises to Subtenant in accordance with this Sublease unless delayed as a result of any cause beyond the reasonable control of Sublandlord.

1.2 Delivery. Subtenant acknowledges and agrees that Sublandlord is not obligated to separately demise the Subleased Premises from the remainder of the Premises; provided that effective as of the Sublease Commencement Date (as hereinafter defined), access into the Subleased Premises, other than the Shared Space, shall be limited exclusively to Subtenant and its employees and agents (subject to Sublandlord and Master Landlord's access rights pursuant to all terms and conditions of the Master Lease, including, without limitation, Article 27 of the Master Lease, as incorporated into this Sublease, and pursuant to Sections 1.1 above and 7.1(m) below) by way of electronic access cards provided to Subtenant. Notwithstanding the foregoing, Sublandlord shall have the right, subject to (i) Subtenant's approval not to be unreasonably withheld, conditioned, delayed or denied, (ii) all terms and conditions of the Master Lease, and (iii) Master Landlord's approval, to separately demise the Subleased Premises at any time during the Sublease Term ("***Demising Work***"). Sublandlord and Subtenant shall negotiate in good faith regarding the scope, schedule and budget for the Demising Work, and shall keep Master Landlord reasonably apprised of the same; provided, however, that if the parties cannot reach an agreement within fifteen (15) days of Sublandlord providing notice to Subtenant that it intends to perform the Demising Work, then Sublandlord's reasonable determinations regarding the scope, schedule and budget for the Demising Work will prevail. To the extent the Demising Work is undertaken, the Demising Work shall be performed in compliance with this Sublease and the Master Lease, and the cost for such Demising Work shall be paid equally by Sublandlord and Subtenant. Subtenant shall reimburse Sublandlord for Subtenant's fifty percent (50%) portion of the costs of the Demising Work within thirty (30) days of receiving an invoice therefor; provided that if Sublandlord and Subtenant do not agree on the budget under the prior sentence, Subtenant's fifty percent (50%) portion of the costs of the Demising Work will not exceed $150,000.00. Subtenant acknowledges and agrees that any Demising Work at any time shall not entitle Subtenant to any abatement of rent, constitute an eviction of Subtenant, constructive or otherwise, or impose upon Sublandlord any liability whatsoever, including but not limited to liability for consequential damages or loss of business by Subtenant; provided that such Demising Work, if any, shall be undertaken in compliance with the terms and conditions set forth in the Master Lease and shall not materially interfere with Subtenant's business in the Subleased Premises or its use of or access to the Subleased Premises; provided further that Subtenant acknowledges and agrees that such Demising Work will and may cause dust and noise and require Subtenant to move its personal property to allow for such Demising Work and Sublandlord will not be required to perform the Demising Work outside of normal business hours unless requested by Subtenant and Subtenant pays any additional cost related to such after-hours work.

1.3 Subtenant's Access. Subject to any supervening events of force majeure, emergencies, casualty or condemnation, and to the rights of the Master Landlord under the Master Lease, Sublandlord will provide Subtenant, its employees and invitees access, on a non-exclusive basis, to the Subleased Premises through the main entrance (Suite 1100), the employee entrance (Suite 1108), the collaboration/laboratory entrance (Suite 1207), the laboratory corridor (suite 1161A), the egress corridor (Suite 1005) and the loading dock twenty-four (24) hours each day,

seven (7) days per week. Access shall be provided in the form of an electronic card key or badge system for the Building. All such access shall be subject to such reasonable rules and regulations as Sublandlord and Master Landlord shall impose from time to time and all terms and conditions of the Master Lease. Except to the extent of Sublandlord's gross negligence or willful misconduct, Sublandlord shall have no liability to Subtenant, its employees, agents, invitees or licensees for losses due to theft or burglary, or for damages done by unauthorized persons on the Subleased Premises or the Building, and Sublandlord shall not be required to insure against any such losses. Prior to the substantial completion of the Demising Work, except to the extent of its gross negligence or willful misconduct, Subtenant shall have no liability to Sublandlord or the Sublandlord Parties (as defined below) for losses due to theft or burglary, or for damages done by unauthorized persons on the Subleased Premises or the Building, and Subtenant shall not be required to insure against any such losses. Sublandlord shall provide Subtenant, at Sublandlord's sole cost and expense, with one access card for each of Subtenant's initial employees working in the Subleased Premises as of the Sublease Commencement Date, totaling one hundred fifteen (115) cards. For each additional or replacement key/card, Subtenant shall pay to Sublandlord as Other Charges the amount set forth on Schedule A attached hereto and incorporated herein.

1.4 Cooperate. Sublandlord and Subtenant covenant and agree to reasonably cooperate with each other, and Subtenant further covenants and agrees to reasonably cooperate with any other subtenant or occupant to which Sublandlord subleases or otherwise permits occupancy of the Premises, in connection with the scheduling and use of the Shared Space.

1.5 Sublandlord's Data and Telecommunications. Provided it does not materially interfere with Subtenant's business, access to or quiet enjoyment of the Subleased Premises (however, subtenant acknowledges that such work may result in levels of noise, dust, obstruction of access, etc. which are in excess of that present currently in the Subleased Premises), Sublandlord reserves the right to extend utility or other similar wiring or cabling through the Subleased Premises to support other areas of the Premises, in a mutually agreeable location or locations within the Subleased Premises; provided that such wiring and/or cabling shall be placed behind walls, above drop ceilings or in such other locations that do not reduce the useable square footage of the Exclusive Subleased Premises and Sublandlord shall repair any damage done in and to the Exclusive Subleased Premises in connection with such installation. In connection with the exercise of Sublandlord's rights under this Section 1.5, Sublandlord shall use commercially reasonable efforts to minimize any interference with Subtenant's use of or access to the Subleased Premises, and any such exercise of Sublandlord's rights under this Section 1.5 shall be subject to Master Landlord's prior consent to the extent required by the Master Lease and all terms and conditions of the Master Lease.

1.6 Subtenant's Data and Telecommunications.

(a) The Premises are currently equipped with Subtenant's information technology ("***IT***") systems, switches and switching equipment, racks, wiring, cabling, telecommunications, antenna, communication equipment, and like equipment or systems. Sublandlord and Subtenant acknowledge and agree that Sublandlord shall have the right to use certain of Subtenant's IT pursuant to all terms and conditions of the Master Lease and a separate agreement while Sublandlord develops and installs its own IT systems, switches and switching

equipment, racks, wiring, cabling, telecommunications, antenna communication equipment, and like equipment or systems.

(b) Notwithstanding anything to the contrary set forth in this Sublease or in any other agreement between Sublandlord and Subtenant, and subject to all terms and conditions of the Master Lease, Sublandlord and Subtenant shall have equal rights to use and access the existing server room located in Room 1145 of the Building ("***Server Room***") in the Premises for wiring and the storage of such party's IT server rack and cabinet. Neither Sublandlord nor Subtenant makes any warranty or representation to the other as to whether the existing Server Room (including its existing HVAC, if any) and conduit is capable of supporting such party's current, planned or future IT server rack, cabinet and equipment. If any modifications to the Server Room and/or Subtenant's IT equipment, conduit or systems are needed to accommodate Sublandlord's planned, existing or future IT equipment (including but not limited to additional HVAC), any such modification shall be made pursuant to and in accordance with all terms and conditions of the Master Lease and at the sole cost and expense of Sublandlord, with the prior reasonable consent of Subtenant and, to the extent required by the Master Lease, Master Landlord.

(c) Sublandlord and Subtenant and each of their designated employees shall have access to the Server Room at all reasonable times.

2. Term. The term of this Sublease (the "***Sublease Term***") shall commence on the Effective Date (the "***Sublease Commencement Date***"), and shall expire on December 31, 2024 ("***Sublease Expiration Date***"), unless earlier terminated pursuant to the terms of this Sublease.

3. Use. Subtenant shall use and occupy the Subleased Premises in compliance with the Master Lease, and solely for conducting Subtenant's business in accordance with the Permitted Use (provided that Subtenant shall not have the right to use the Subleased Premises for biomanufacturing uses under the Master Lease unless consented to by Sublandlord, such consent not to be unreasonably withheld, provided that it will not be unreasonable for Sublandlord to withhold such consent if Sublandlord is currently using or planning to use the all or most of the square footage of the Premises permitted to be allocated to biomanufacturing under the Master Lease), and for no other purpose unless Master Landlord and Sublandlord, each in their sole and absolute discretion, otherwise consents in writing. Notwithstanding the foregoing, Sublandlord acknowledges that Subtenant shall have the right to engage in biomanufacturing to the extent that Sublandlord does not require additional square footage for biomanufacturing under the allocation in the Master Lease and does not cause Sublandlord to be in default under the Master Lease. Sublandlord makes no representation or warranty regarding the compliance of the Subleased Premises with Applicable Laws, including without limitation the Americans with Disabilities Act of 1990, as amended (the "***ADA***"). As between Sublandlord and Subtenant, Sublandlord shall have no responsibility for compliance with Applicable Laws, including without limitation the ADA, with respect to the Subleased Premises except to the extent arising from any Alterations (as such term is defined in Section 8 of the Lease) made by Sublandlord after the Effective Date (including, without limitation, the Demising Work).

4. Rent. Sublandlord shall be responsible for the timely payment of Base Rent and Additional Rent under the Master Lease and otherwise complying with the obligations of

Sublandlord under the Master Lease before and during the Sublease Term. Subtenant shall pay to Sublandlord the following as Sublease Rent hereunder:

4.1 Sublease Term Rent; Rent Commencement Date. Beginning on the Sublease Commencement Date, and continuing during the Sublease Term, Subtenant shall pay to Sublandlord, as sublease rent ("***Monthly Rent***") and in lieu of the Base Rent set forth in the Master Lease, in lawful money of the United States of America, without any deduction, offset, prior notice or demand, in advance on the first date of each month of the Sublease Term from the Sublease Rent Commencement Date through the Sublease Expiration Date, an amount equal Subtenant's Share of the Monthly Base Rent payable by Sublandlord with respect to the Premises, plus Subtenant's Share of Additional Rent (as defined in the Master Lease) to be paid by Sublandlord with respect to the entire Premises under the Master Lease in and for the Sublease Term, excluding any late fees, damages or penalties arising from Sublandlord's breach of the Master Lease (other than those, if any, resulting from Subtenant's failure to comply with this Sublease). As used herein, "***Subtenant's Share***" means: 30.15% (calculated by dividing the square footage of the Subleased Premises by the total square footage of the Premises), which shall be adjusted if the Premises leased by Sublandlord under the Master Lease is adjusted. Notwithstanding anything to the contrary contained herein, during any free rent period for the Expansion Premises under Section 7(a) of the Third Amendment, Subtenant shall pay Monthly Rent as though Sublandlord were required to pay Monthly Rent under the Master Lease in full for such period and Subtenant shall have no right to any abatement of Monthly Rent on account of Sublandlord receiving an abatement of Monthly Rent under the Third Amendment.

4.2 Direct Expenses. In addition to the Monthly Rent, commencing on the Sublease Commencement Date and continuing during the Sublease Term, Subtenant shall pay to Sublandlord, as Additional Rent, in advance on the first day of each and every calendar month during the Sublease Term, an amount equal to Subtenant's Share of Tenant's Share (as defined in the Master Lease) of Master Landlord's estimate of the Direct Expenses that Sublandlord is charged by Master Landlord pursuant to Article 4 of the Master Lease (the "***Direct Expense Rent***"), which shall be subject to change by written notice from Sublandlord to Subtenant from time to time as and when Master Landlord changes the estimated monthly payments due by Sublandlord for Tenant's pro rata share of Direct Expenses under the Master Lease. Sublandlord shall promptly provide to Subtenant copies of (i) any changes delivered in writing by Master Landlord in the estimated monthly payments due by Sublandlord for Tenant's Share of Direct Expenses under the Master Lease and (ii) Direct Expense statements that Sublandlord receives from Master Landlord. If Master Landlord changes the estimated monthly payments due by Sublandlord for Tenant's Share of Direct Expenses under the Master Lease in writing or if Sublandlord reconciles the actual Tenant's Share of Direct Expenses due by Sublandlord under the Master Lease with Master Landlord for any calendar year during the Sublease Term, Sublandlord shall provide such change and/or reconciliation in an estimate of Direct Expenses or Direct Expense statement to Subtenant and shall also reconcile the Direct Expense Rent with Subtenant in accordance with Subtenant's Share. Sublandlord shall credit any overpayments to Subtenant against the next Monthly Rent payment due by Subtenant, provided that Sublandlord has received a refund or credit of such overpayment from Master Landlord, and Subtenant shall pay any shortfall in the estimate of actual costs within thirty (30) days following delivery of the change in any estimates of Direct Expenses or Direct Expense statement to Subtenant.

4.3 Other Charges. In addition to Monthly Rent and (without duplication of) Direct Expenses Rent under Section 4.2 above, commencing on the Sublease Commencement Date and continuing during the Sublease Term, Subtenant shall pay Sublandlord, as "***Sublease Additional Rent***", (i) Subtenant's Share of (x) all costs charged to Sublandlord by Master Landlord or utility or service provider for any service or utility furnished to the extent such utility or service is provided to and utilized by the Subleased Premises, and (y) any and all other amounts of Additional Rent (as defined in the Master Lease) that are charged to Sublandlord by Master Landlord or payable by Sublandlord to any third party pursuant to the provisions of the Master Lease or otherwise, and in the case of each of subsections (x) and (y), to the extent such cost arise out of utilities and/or services provided to and utilized by the Subleased Premises, including, without limitation, all utilities paid by Sublandlord under Article 6 of the Master Lease, whether to Master Landlord or a third party provider; (ii) any and all charges incurred by Sublandlord that are specifically attributable exclusively to Subtenant, the Subleased Premises, or Subtenant's operations therein or Subtenant's Alterations made to the Subleased Premises, and not shared with any other portion of the Premises or Sublandlord; and (iii) any and all charges, actually incurred for services requested by Subtenant that Sublandlord is liable to Master Landlord or any third party provider or which relate to services that Master Landlord is not obligated to provide at no additional cost under the Master Lease (each being, and collectively, "***Other Charges***"). Such Other Charges, if not paid directly to the Master Landlord by Subtenant (which payment shall be made on or before the due date), shall be paid to Sublandlord for remittance to Master Landlord within thirty (30) days of being billed to Subtenant by Sublandlord. If Subtenant pays such Other Charges directly to Master Landlord, Subtenant shall provide documentation of such payment within five (5) days after such payment is made. Sublandlord shall deliver to Subtenant a copy of any statement received by Sublandlord from the Master Landlord reflecting all such Sublease Additional Rent including those attributable 100% to Subtenant. Additionally, if Sublandlord shall be charged by reason of Subtenant's acts or defaults under this Sublease for any sums pursuant to the provisions of the Master Lease, then Subtenant shall be liable for such sums with respect to the Subleased Premises, and such sums shall be deemed Sublease Additional Rent and collectible as such and shall be payable by Subtenant within thirty (30) days' written notice from Sublandlord.

4.4 "Sublease Rent" Defined. All Monthly Rent, Direct Expense Rent, Sublease Additional Rent and other monetary obligations of Subtenant to Sublandlord under the terms of this Sublease are deemed to be rent ("***Sublease Rent***"). Sublease Rent shall be paid promptly when due, and without deduction, abatement, counterclaim or setoff of any amount or for any reason whatsoever. Sublandlord shall have the same remedies for default in payment of Direct Expense Rent and Other Charges as Sublandlord has for default in payment of Monthly Rent. Except Direct Expense Rent or as otherwise expressly stated herein, Sublease Additional Rent will become due thirty (30) days after the date of Subtenant's receipt of Sublandlord's invoice therefor. Sublease Rent shall be payable in lawful money of the United States to Sublandlord by ACH or wire transfer to an account that Sublandlord may designate in writing. Sublease Rent payable for any partial month during the Sublease Term shall be prorated on a daily basis based on the actual number of days in such month. No payment by Subtenant or receipt or acceptance by Sublandlord of any lesser amount than the amount stipulated to be paid hereunder shall be deemed other than on account of the earliest stipulated Sublease Rent; nor shall any endorsement or statement on any check or letter be deemed an accord and satisfaction, and Sublandlord may accept any check or payment without prejudice to Sublandlord's right to recover the balance due or to pursue any other remedy available to Sublandlord in this Sublease or at law.

5. Condition of Subleased Premises. Subtenant is subleasing the Subleased Premises in its "as is" condition existing as of the Sublease Commencement Date, and Sublandlord shall have no obligation to furnish, render or supply any allowance, work, labor, services, material, fixtures, equipment or decorations to make the Subleased Premises ready for Subtenant's occupancy. The taking of possession of each portion of the Subleased Premises by Subtenant shall be conclusive evidence as against Subtenant that such portion of the Subleased Premises was in satisfactory condition at the time possession was taken. In making and executing this Sublease, Subtenant has relied solely on such investigations, examinations and inspections as Subtenant has chosen to make or has made. Subtenant acknowledges that no representations have been made to it by Sublandlord with respect to the condition of the Subleased Premises. Other than as set forth in this Sublease, all maintenance (including all routine maintenance contracts), repair and, as necessary, replacement to maintain the Exclusive Subleased Premises in the condition required under the Master Lease shall be the responsibility of Subtenant at Subtenant's sole cost and expense during the Sublease Term.

6. Subtenant's Alterations; Sublandlord's Consent.

6.1 Subtenant's Proposed Alterations. Notwithstanding anything to the contrary in the Master Lease or this Sublease, provided that Sublandlord has granted its prior written consent for Subtenant to make Alterations ("***Subtenant's Proposed Alterations***") to the Subleased Premises in accordance with Section 6.2 below, Subtenant shall be permitted to seek Master Landlord's consent for Subtenant to make Subtenant's Proposed Alterations to the Subleased Premises and Subtenant shall have the use of the Sublease Allowance for such purposes. Except for the Sublease Allowance, Subtenant shall provide a copy of all correspondence with Master Landlord regarding Subtenant's Proposed Alterations to Sublandlord within three (3) business days after Subtenant giving or receiving such correspondence, as applicable. Subtenant shall be solely responsible for any and all costs relating to approval and performance of the construction of Subtenant's Proposed Alterations, including, without limitation, architectural plans, inspections, alterations, legal fees, permits, and compliance with laws and regulations, and thereafter for any and all costs relating to maintenance, repair, replacement and removal of the Subtenant's Proposed Alterations. Subtenant shall be solely responsible for obtaining and paying for all necessary permits in connection with the construction of any Subtenant's Proposed Alterations.

6.2 Sublandlord's Consent to Subtenant's Proposed Alterations. Subtenant shall not make or cause, suffer or permit the making of any Alterations in or to the Subleased Premises, without in each instance, first (i) obtaining the prior written consent of Master Landlord and of Sublandlord, which, if Master Landlord has granted consent, will be granted in Sublandlord's reasonable discretion (provided that denial of such consent by Sublandlord will not be deemed unreasonable with respect to any Alterations that, without limitation, (w) are for expanding the square footage of the Subleased Premises used as a vivarium beyond the existing vivarium in a the Subleased Premises or otherwise require a change in the Permitted Use, (x) would reasonably be expected to materially adversely affect or interfere with Sublandlord's or any other tenant's business operations in the Premises, (y) would reasonably be expected to materially adversely affect the Building structure or systems or materially increase Sublandlord's costs of operating the Premises or (z) would be visible from the exterior of the Subleased Premises), to install such proposed Alterations; and (ii) complying with this Sublease and the Master Lease. If

any Subtenant's Proposed Alterations are made without Master Landlord's or Sublandlord's consent as required under this Section 6, Master Landlord or Sublandlord may remove the same, and may correct, repair and restore the Subleased Premises and any damage arising from such removal, and Subtenant shall be liable for all costs and expenses incurred by Sublandlord and all costs and expenses incurred by Master Landlord in the performance of such removal and restoration work. Subtenant acknowledges and agrees that Sublandlord shall bear no cost or expense relating to any Subtenant's Proposed Alterations, including the review thereof or the installation, maintenance and repair of any approved Alterations. Any and all of Subtenant's Proposed Alterations shall be performed by Subtenant pursuant to and in accordance with all terms and conditions of the Master Lease.

6.3 Removal of Alterations. At the expiration or earlier termination of this Sublease, and without limitation of Subtenant's other surrender obligations below, Subtenant shall remove all Alterations then in the Subleased Premises: (a) if such Alterations existed in the Subleased Premises as of the Effective Date, to the extent that Master Landlord notified Subtenant that such Alterations would be required to be removed at the expiration or earlier termination of the Lease Term or Master Landlord preserved its right to require removal and/or restoration of such Alterations in accordance with Section 8.3 of the Master Lease, the presumption being, as between Sublandlord and Subtenant, that, absent Master Landlord delivering written evidence to the contrary, no removal is required or Master Landlord did not reserve the right to so require, except that Sublandlord and Subtenant hereby acknowledge there is a removal requirement for the generator pad previously constructed by Subtenant, and (b) if such Alterations are constructed by Subtenant after the Effective Date, to the extent that Master Landlord and/or Sublandlord notify Subtenant in writing, at the time Subtenant specifically requests consent to such Alterations, that such Alterations will be required to be removed at the expiration or earlier termination of the Sublease Term in accordance with Section 8.3 of the Master Lease, provided further that it is hereby acknowledged that Master Landlord may preserve its right to require removal and/or restoration of such Alterations in accordance with Section 8.3 of the Master Lease, and, in each case, repair all damage resulting from such removal. Subtenant shall indemnify Sublandlord and Master Landlord from and against any costs, fees or liabilities incurred by Sublandlord or Master Landlord (including, without limitation, under the Master Lease) by reason of any of Alterations made by Subtenant to the Subleased Premises, including, without limitation, all costs and expenses incurred by Master Landlord or Sublandlord with respect to Subtenant's failure to remove any Alterations made by Subtenant in or to the Subleased Premises as required under this Section 6. Subtenant's obligations under this Section 6 shall survive the termination of this Sublease. Except to the extent provided in Section 7(b) below or pursuant to the terms and conditions of the Master Lease, Subtenant shall not place, inscribe, paint or affix or otherwise display any sign, advertisement, picture, lettering or notice of any kind on any part of the Shared Space, Premises or exterior or interior common areas of the Building (including windows and doors) or on any part of the interior of Subleased Premises which can be seen from outside the Subleased Premises.

7. Master Lease.

7.1 Sublease Subordinate to Master Lease; Subtenant's Covenants. This Sublease is in all respects subject and subordinate to all of the terms, provisions, covenants, stipulations, conditions and agreements of the Master Lease and to the matters to which the Master Lease is or shall be subject and subordinate. A copy of the Master Lease has been furnished to,

and examined by, Subtenant. Subtenant agrees as follows: except as otherwise provided in this Sublease, all references in such incorporated provision to the word "Tenant" shall be deemed to refer to Subtenant, all references to the word "Premises" shall be deemed to refer to the Subleased Premises, all references to the term "Lease" shall be deemed to refer to this Sublease, all references to the word "Term" shall be deemed to refer to the Sublease Term, all references to the term "Landlord" shall be deemed to refer to the Sublandlord, and all references to the term "indemnitees" shall be deemed to include reference to the Sublandlord, each unless expressly stated, or the context would imply, otherwise):

(a) **Basic Lease Provisions**. The provisions of the Master Lease are hereby incorporated herein by reference, except to the extent that they are inapplicable or modified by the provisions of this Section 7 hereof or otherwise by this Sublease for the purpose of incorporation by reference, each and every term, covenant and condition of the Master Lease binding upon or inuring to the benefit of Master Landlord shall, in respect of this Sublease, bind or inure to the benefit of Sublandlord, and each and every term, covenant and condition of the Master Lease binding upon or inuring to the benefit of the Tenant thereunder shall, in respect of this Sublease, bind or inure to the benefit of Subtenant, with the same force and effect as if such terms, covenants and conditions were completely set forth in this Sublease, except for Sections 1, 2.2, 3, 4, 5, 7, 9, 10, 11, 12, and 14 of the Summary of Basic Lease Information, Sections 1.1.1, 1.2, 1.4, 2.1, 2.2, 3, 7, 8.1, 10.7, 14 (except to the extent referenced in Section 7.1(g) below), 23, 29.4, 29.6 (but only the last three sentences), 29.14, 29.15, 29.24 (but only references to "Brokers" and the last sentence) 29.32, 29.33, 29.34 of the Original Lease, Exhibit 1.1.1-1, Exhibit 1.1.1-2, Exhibit 1.4.2, Exhibit 14.1, Exhibit 18 and Exhibit 29.32.1 thereof, the First Amendment (other than subsection 4(b)(iii) and Section 5), the Second Amendment, and Sections 4, 5, 6, 7, 8, 9, 12, 13), 14, 15, 17, 18(b) and (c), 19 (other than the first sentence of the amended to Section 14.2), 21, 23, 25, and Exhibits A, B and C of the Third Amendment. In no event shall Subtenant have any extension, expansion, contraction, termination, signage (other under Section 7.1(b) below), improvement allowance, roof, parking (other than under Section 7.1(g) below), assignment or subletting, passenger or freight elevator usage to any floor above the first floor or other similar options and rights set forth in the Master Lease. Notwithstanding anything in the foregoing or elsewhere in this Sublease, nothing in this Sublease shall abridge, diminish or negate any rights of Master Landlord under the Master Lease.

Neither party shall take any action or do, omit to do, or permit to be done anything (i) in violation of or default under any of the terms, covenants, conditions or provisions of the Master Lease or any other instrument to which this Sublease is subordinate (and Sublandlord shall comply with all of the terms of the Master Lease to the extent Sublandlord remains obligated thereunder or to the extent that Subtenant cannot directly comply with such obligations); or (ii) which could result in any additional cost or other liability to Sublandlord unless Subtenant assumes and pays such cost or liability.

Subtenant expressly agrees that, if the Master Lease or Sublandlord's tenancy, control or right to possession of the Premises shall terminate by expiration or any other cause, including, without limitation, a termination caused by Sublandlord's exercise of any right of Sublandlord under the Master Lease to terminate the Master Lease by reason of fire, casualty or condemnation, this Sublease shall thereupon immediately cease and terminate and Subtenant shall give immediate possession to Sublandlord; provided, however, that the liability of the Subtenant to the Sublandlord

or the liability of the Sublandlord to the Subtenant for termination caused by the applicable party's default under this Sublease shall not be discharged by reason of such termination.

(b) **Signage**. Subtenant's right to install signage for the Subleased Premises shall be limited to the Exclusive Subleased Premises and shall be subject to Sublandlord's and Master Landlord's prior approval as to location, size, design and composition (in Sublandlord's reasonable discretion and Master Landlord's sole and absolute discretion) and otherwise governed by all terms and conditions of the Master Lease, including, without limitation, Article 23 of the Master Lease. Subtenant shall have the right to install Exterior Building Signage to the extent approved by Master Landlord, provided that such signage does not diminish Sublandlord's right to Exterior Building Signage or visually interfere with or obstruct Sublandlord's Exterior Signage. The parties shall cooperate, in good faith, to install signage in the shared reception area for each of Sublandlord and Subtenant subject to Sublandlord's and, to the extent required pursuant to the Master Lease, Master Landlord's prior approval, as to location, size, design and composition (in Sublandlord's reasonable discretion and, if applicable, Master Landlord's sole and absolute discretion).

(c) **Utilities and Services**. Subtenant's consumption of utilities shall be subject to all terms and conditions of the Master Lease, including, without limitation, Article 6 of the Master Lease, which is incorporated herein by this reference. Subtenant and Sublandlord hereby agree that Subtenant shall pay Subtenant's Share of the cost of such utilities in accordance with Section 4.3 above; provided that if Subtenant's use of or Alterations to the Subleased Premises causes material increases to the cost of utilities, Subtenant shall pay such additional costs. Sublandlord shall provide pest control, janitorial and char service for the Shared Space to the extent required by the Master Lease and Subtenant shall pay Subtenant's Share for such services as Additional Rent in the amount set forth on Schedule A. All utilities which are separately metered for the Subleased Premises shall be at Subtenant's sole cost and expense and shall be paid directly to such utility provider. Any services not furnished through systems or facilities provided or maintained by Master Landlord under the Master Lease shall be the responsibility of Subtenant to obtain, at Subtenant's sole cost and expense, subject to the terms and conditions of the Master Lease; provided that Sublandlord shall maintain the HVAC, hot water boilers, steam boiler system for the Shared Space, to the extent the same are the responsibility of the tenant under the Master Lease, and Subtenant shall reimburse Sublandlord for Subtenant's Share of such costs and expenses as Additional Rent in the amount set forth on Schedule A. In addition, if Subtenant shall require utilities or services in excess of those usually furnished or supplied for tenants in similar spaces in the Building by reason of Subtenant's equipment or extended hours of business operations, then Subtenant shall first procure Sublandlord's and, to the extent required under the Master Lease, Master Landlord's consent for the use thereof, which consent Sublandlord and, to the extent permitted under the Master Lease, Master Landlord may condition upon the availability of such excess utilities or services, and Subtenant shall pay as Sublease Additional Rent an amount equal to the cost of providing such excess utilities and services. Sublandlord shall provide management, cleaning and restocking of the reception area, café, breakroom, and restrooms in the Shared Space and Subtenant shall reimburse Sublandlord there for as Additional Rent the amount set forth in Schedule A. Unless expressly set forth in this Sublease, Sublandlord shall not be responsible for the maintenance and repair obligations of the tenant under 6.2.1 of the Master Lease with respect to the Subleased Premises.

(d) **Time Limits**. The time limits contained in the Master Lease for the giving of notices, making of demands or performing of any act, condition or covenant on the part of tenant thereunder, for the occurrence of an event of default thereunder or for the exercise by the tenant thereunder of any right, remedy or option required to be performed by the tenant under the Master Lease, are changed for the purposes of incorporation herein by reference by shortening the same in each instance by two (2) business days, so that in each instance Subtenant shall have two (2) business days less time to observe or perform hereunder than Sublandlord has as the tenant under the Master Lease, unless Sublandlord has as tenant under the Master Lease three (3) or fewer days in which event Subtenant shall have the time Sublandlord has as tenant under the Master Lease.

(e) **Insurance**. On or before the Sublease Commencement Date, and for the duration of the Sublease Term, Subtenant, at Subtenant's sole expense, shall obtain and maintain for the benefit of Sublandlord and Master Landlord, the insurance types and coverages (and in such form) as are required by Article 10 of the Master Lease to be obtained and maintained by Sublandlord as tenant, which are incorporated herein by this reference, in amounts not less than those specified in the Master Lease, including, without limitation Section 10.3 of the Master Lease, which policies shall be in form and content reasonably satisfactory to Sublandlord. Each policy of liability insurance shall name Sublandlord and Master Landlord as an additional insured and the waiver of subrogation requirements of property policies shall operate between Sublandlord and Subtenant, in the same manner as between Master Landlord and Sublandlord. Subtenant will cause its insurance carriers to include any clauses or endorsements in favor of Master Landlord and Sublandlord which Sublandlord is required to provide pursuant to the provisions of the Master Lease. Subtenant's insurance shall be primary over Master Landlord's and Sublandlord's insurance. Without limitation of the foregoing, such insurance shall not be canceled or modified unless thirty (30) days prior written notice shall have been given to Sublandlord by Subtenant.

(f) **Parking**. During the Sublease Term, Subtenant shall have the right to use Subtenant's Share of the net total number of parking spaces available to Sublandlord under the Master Lease to park standard size automobiles and small utility vehicles in the parking facilities that serve the Project in accordance with the terms and subject to the conditions set forth in Article 28 of the Master Lease (i.e., Subtenant's Share shall be calculated after deduction of any parking space reductions for Exterior Equipment and/or Special Systems installations).

(g) **Assignment and Subletting**. Subtenant shall not assign, mortgage, pledge, hypothecate, encumber or permit any lien to attach to, or otherwise transfer, this Sublease or any of its interest in this Sublease, permit any assignment, or other transfer of this Sublease or any interest hereunder by operation of law, or sub-sublet, license or otherwise permit the use or occupancy of the Subleased Premises or any portion thereof by anyone other than Subtenant (each a "***Transfer***") without the prior written consent of (i) Master Landlord and (ii) Sublandlord, which consent may be granted, each in their sole discretion. Any agreement in breach of the preceding provision shall be void. In connection with any Transfer requiring Sublandlord's and/or Master Landlord's consent under this Sublease and/or Master Landlord's consent under the Master Lease, the form of sublease or assignment to be used, as applicable, shall be subject to approval by Sublandlord and Master Landlord each in their sole discretion, and Subtenant shall pay Master Landlord's review and processing fees, as well as professional fees under the Master Lease, and Sublandlord's reasonable review and processing fees, as well as reasonable professional fees

(including, without limitation, attorneys' accountants' architects' engineers and consulting fees), in any case, whether or not such consent is granted. Provided that Subtenant does not trigger Section 14.4 of the Master Lease, Subtenant may engage in a Transfer that is a Change in Control (as defined below) or an assignment of the entire Sublease without Sublandlord's consent, and without Master Landlord's consent if such Transfer is a "Permitted Transfer" under Section 14.8 of the Master Lease. If Subtenant is a corporation, partnership or trust, any transfer or transfers of or change or changes within any twelve (12) month period in the number of the outstanding voting shares of the corporation, the general partnership interests in the partnership or the identity of the persons or entities controlling the activities of such partnership or trust resulting in the persons or entities owning or controlling a majority of such shares, partnership interests or activities of such partnership or trust at the beginning of such period no longer having such ownership or control (each a "*Change in Control*") shall be regarded as a Transfer of this Sublease to the persons or entities acquiring such ownership or control and shall be subject to all the provisions of this Section 7(g) with respect to an assignment of this Sublease to the same extent and for all intents and purposes as though such were an assignment. Notwithstanding anything to the contrary herein, a Change of Control or an assignment of the Sublease that would otherwise be a Permitted Transfer under the Master Lease shall require Sublandlord's consent, in its sole discretion, if the persons or entities acquiring such ownership or control are engaged in the business of viral vector process development or manufacturing. In no event shall any provision of this Sublease limit or modify any right of Master Landlord under Article 14 of the Master Lease. Notwithstanding the foregoing, any Transfer shall be expressly conditioned upon the prior written consent of Master Landlord, and shall, in all instances, comply with all terms and conditions of the Master Lease. No Transfer by Subtenant approved by Sublandlord and Master Landlord under this Section 7(g) shall release Subtenant of Subtenant's obligations under this Sublease. Any Transferee, whether by a Change of Control or otherwise, shall assume all Subtenant indemnity obligations hereunder as of the Effective Date.

(h) **Surrender**. Subtenant shall surrender the Subleased Premises upon the expiration or earlier termination of this Sublease in the condition required under all terms and conditions of the Master Lease, including, without limitation, Article 15 of the Master Lease, and Section 6.3 of this Sublease. Notwithstanding the foregoing, at Sublandlord's written request given prior to the expiration or earlier termination of the Sublease Term, Subtenant shall surrender the Subleased Premises with those items of Subtenant's standard office furniture ("***Retained Furniture***"), an itemized list of which shall be as agreed upon by Sublandlord and Subtenant, and in consideration of Ten Dollars ($10.00) paid by Sublandlord to Subtenant as of such date and such other consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, then Subtenant agrees to sell to Sublandlord all of its right, title and interest in the Retained Furniture on the day immediately preceding the expiration date of the Sublease Term.

(i) **Casualty; Condemnation**. The restoration obligations of "Landlord" under Articles 11 and 13 of the Master Lease shall be the responsibility solely of Master Landlord and shall not be the responsibility of Sublandlord. In the event of casualty or condemnation, if the Master Lease is terminated with respect to all or a portion of the Subleased Premises pursuant to the provisions of the Master Lease, this Sublease shall automatically terminate at the same time and Subtenant shall have no claim against Sublandlord or Master Landlord for the loss of its interest hereunder or any of Subtenant's property. Any election right or option in the Master Lease with respect to restoration of the Premises or the Building or termination of the Master Lease is

expressly reserved to Sublandlord to exercise in its reasonable discretion, and Subtenant shall have a proportional right to abatement (as set forth in this Section) in connection with any casualty or condemnation of the Subleased Premises or the Building other than by reason of damage resulting from Subtenant's misuse, negligence, or willful misconduct. In the event that a certain number of days of Sublandlord's rental obligations are actually abated by Master Landlord pursuant to Articles 11 or 13 of the Master Lease with regard to the Subleased Premises other than by reason of damage resulting from Subtenant's misuse, negligence, or willful misconduct, a similar number of days of Subtenant's rental obligations shall be abated under this Sublease in the same and any such abatement received by Sublandlord shall be proportionately shared with Subtenant based upon the amount of Sublandlord's rent obligations under the Master Lease relative to the amount of Subtenant's rental obligations under this Sublease. In the event the Building (including, without limitation, any part of the Subleased Premises) or any other Common Areas of the Project are damaged or destroyed in whole or in part in circumstances resulting from Subtenant's misuse, negligence, or willful misconduct, Subtenant shall be solely responsible for, at Subtenant's sole cost and expense, all repair and restoration as may be required to restore the affected portions of the Project to a condition comparable to that existing immediately prior to the occurrence and for any and all other costs, expenses, claims, liabilities and losses incurred, whether directly or indirectly, by Sublandlord and Master Landlord as a result thereof.

(j) **Estoppel Certificate**. Any statement delivered by Subtenant to Sublandlord pursuant to Article 17 of the Master Lease that has been incorporated herein by reference, may be relied upon by Master Landlord or any mortgagee of Master Landlord or any existing or prospective purchaser, transferee or mortgagee of any or all of the Subleased Premises) and by any prospective assignee or transferee of the leasehold estate under the Master Lease. Unless otherwise agreed by Master Landlord, in no event shall Master Landlord be obligated to deliver an estoppel certificate to Subtenant.

(k) **Hazardous Materials**. Subtenant expressly acknowledges and agrees that it shall perform all removal, decontamination, compliance, reporting and remediation obligations in respect of the Subleased Premises to the extent required by Section 5.3 of the Master Lease, which has been incorporated herein by reference. If any written report, including any report containing results of any Environmental Assessment (as defined in the Master Lease) (an "***Environmental Report***") shall indicate (i) the presence of any Hazardous Materials as to which Subtenant has a removal or remediation obligation under Section 5.3 of the Master Lease, and (ii) that as a result of same, the investigation, characterization, monitoring, assessment, repair, closure, remediation, removal, or other clean-up (the "***Clean-up***") of any Hazardous Materials is required pursuant to Section 5.3 of the Master Lease, Subtenant shall immediately prepare and submit to Sublandlord and Master Landlord within thirty (30) days after receipt of the Environmental Report a comprehensive plan, subject to Sublandlord's and Master Landlord's written approval, specifying the actions to be taken by Subtenant to perform the Clean-up so that the Subleased Premises are restored to the conditions required by Section 5.3 of the Master Lease. Upon Sublandlord's and Master Landlord's approval of the Clean-up plan, Subtenant shall, at Subtenant's sole cost and expense, without limitation of any rights and remedies of Sublandlord or Master Landlord under this Sublease, immediately implement such plan with a consultant reasonably acceptable to Sublandlord and Master Landlord and proceed to Clean-Up Hazardous Materials in accordance with all Applicable Laws and as required by such plan and this Sublease. If, within thirty (30) days after receiving a copy of such Environmental Report, Subtenant fails

either (a) to complete such Clean-up, or (b) with respect to any Clean-up that cannot be completed within such thirty (30) day period, fails to proceed with diligence to prepare the Clean-up plan and complete the Clean-up as promptly as practicable, then Sublandlord shall have the right, but not the obligation, and without waiving any other rights under this Sublease, to carry out any Clean-up recommended by the Environmental Report or required by any governmental authority having jurisdiction over the Subleased Premises, and recover all of the costs and expenses thereof from Subtenant as Additional Rent, payable within ten (10) days after receipt of written demand therefor.

8. Sublandlord Not Responsible for Representations and Covenants of Master Landlord under Master Lease. Except as expressly permitted under this Sublease, Subtenant agrees not to contact Master Landlord directly, including, without limitation, concerning the Subleased Premises, Shared Space or any Master Lease or Sublease provision or obligation (e.g., the provisions of any utilities and services under the Master Lease and/or the making of any repairs or restorations). Sublandlord shall not be deemed to have made any representation made by Master Landlord in the Master Lease in its capacity as the lessor of the Building. Moreover, during the Sublease Term, Subtenant acknowledges and agrees that Sublandlord shall not be responsible for Master Landlord's breach of its covenants and obligations under the Master Lease. Without limiting the generality of the foregoing, Sublandlord shall not be obligated (i) to provide any of the services or utilities that Master Landlord has expressly agreed in the Master Lease to provide, (ii) to make any of the repairs or restorations that Master Landlord has expressly agreed in the Master Lease to make, (iii) to comply with any laws or requirements of public authorities with which Master Landlord has expressly agreed in the Master Lease to comply, or (iv) to make any payment or take any action with respect to the operation, administration or control of the Project, the Premises, the Subleased Premises or any of the Common Areas that the Master Landlord has expressly agreed in the Master Lease to take, and Sublandlord shall have no liability to Subtenant on account of any failure of Master Landlord to do so, or on account of any failure by Master Landlord to observe or perform any of the terms, covenants or conditions of the Master Lease required to be observed or performed by Master Landlord, provided that in the event that Subtenant determines in good faith that Master Landlord has not performed its obligations as expressly set forth under the Master Lease, then upon receipt of written notice from Subtenant, Sublandlord shall be obligated to use reasonable best efforts to cause Master Landlord to resolve such breaches, defaults or failures of Master Landlord under the Master Lease by promptly requesting and pursuing until response of Master Landlord, (i) additional services and/or the making of any repairs or restorations as requested by Subtenant pursuant to the terms and provisions of the Master Lease as incorporated herein and (ii) Master Landlord's consent for any action to which Sublandlord has consented and, pursuant to the terms and provisions of this Sublease and/or the Master Lease, for which Master Landlord's consent is required; provided, further however, Sublandlord shall not be required to incur any expense or expend any sums in connection with performing its obligations under the immediately preceding sentence, unless Subtenant prepays such expense and only to the extent of such prepayment, or have any obligation to commence litigation or other dispute resolution proceedings to cause Master Landlord to comply with the Master Lease. Subtenant shall not in any event have any rights in respect of the Subleased Premises greater than Sublandlord's rights under the Master Lease, and, notwithstanding any provision to the contrary, as to obligations contained in this Sublease by the incorporation by reference of the provisions of the Master Lease or as to any obligation of Master Landlord, Sublandlord shall not be required to make any payment, provide any services or perform any obligation of Master Landlord under the Lease, and

Sublandlord shall have no liability to Subtenant for any matter whatsoever, except for Sublandlord's obligation to pay the rent and other sums due under the Master Lease and otherwise to perform its obligations under the Master Lease and under this Sublease (other than any such obligations of Sublandlord under the Master Lease to be performed by Subtenant under the express terms of this Sublease), and for Sublandlord's obligation to make a written demand upon Master Landlord to fulfill its obligations as expressly set forth under the Master Lease, upon request of Subtenant and at Subtenant's sole cost and expense. Sublandlord shall have no liability to Subtenant, nor shall Subtenant's obligations under this Sublease be reduced or abated in any manner, by reason of any inconvenience, annoyance, interruption or injury to Subtenant's business arising from Master Landlord's making repairs or changes which Master Landlord is required or permitted to make under the Master Lease. Sublandlord shall not be responsible for any failure or interruption, for any reason whatsoever, of the services or facilities that may be appurtenant to or supplied at the Building by Master Landlord, including, without limitation, heat, air conditioning, water and elevator service; and no failure to furnish, or interruption of, any such services or facilities shall give rise to any (a) abatement, diminution or reduction of Subtenant's obligations under this Sublease, (b) right to terminate this Sublease or (c) liability on the part of Sublandlord; provided, however, to the extent that a certain number of days of Sublandlord's rental obligations are abated pursuant to the Master Lease with respect to the Subleased Premises, then a similar number of days of Subtenant's rental obligations shall be abated under this Sublease other than by reason of damage resulting from Subtenant's misuse, negligence, or willful misconduct and any such abatement actually received by Sublandlord shall be proportionately shared with Subtenant based upon the amount of Sublandlord's rent obligations under the Master Lease relative to the amount of Subtenant's rental obligations under this Sublease. Nothing contained in this Sublease shall be construed to create privity of estate or of contract between Subtenant and Master Landlord.

9. Indemnification.

9.1 Indemnity by Subtenant. Any applicable non-liability, waiver, release, defense, indemnification or hold harmless provision of the Master Lease for the benefit of Master Landlord under the Master Lease that is incorporated herein by reference, shall be deemed to inure to the benefit of Sublandlord (except to the extent of Sublandlord's indemnification obligations under Section 9.2 below), Master Landlord, and any other person specifically named to be benefited by said provision, for the purpose of incorporation by reference in this Sublease and shall apply to this Sublease as if each of Master Landlord and Sublandlord was the "Landlord" and Subtenant was the "Tenant" described in the Master Lease (except to the extent of Sublandlord's indemnification obligations under Section 9.2 below). Except to the extent caused by the gross negligence or willful misconduct of Sublandlord or the Sublandlord Parties (as defined below) and except for Sublandlord's indemnification obligations set forth in Section 9.2 below, to the maximum extent permitted pursuant to Applicable Laws, Subtenant hereby assumes all risk of damage to property or injury to persons in, upon or about the Exclusive Subleased Premises from any cause whatsoever (including, but not limited to, any personal injuries resulting from a slip and fall in, upon or about the Exclusive Subleased Premises) and agrees that, to the extent permitted pursuant to Applicable Laws, Sublandlord, the Guarantor (as defined in the Master Lease) its lenders, partners, subpartners and their respective officers, agents, servants, employees, and independent contractors (collectively, "***Sublandlord Parties***"; provided that for purposes of this Sublease, Subtenant shall be deemed not to be a Sublandlord Party) shall not be liable for, and are hereby released from any responsibility for, any damage either to person or property or resulting

from the loss of use thereof, which damage is sustained by Subtenant or by other persons claiming through Subtenant. Subtenant shall indemnify, defend, protect, and hold harmless the Sublandlord Parties from any and all loss, cost, damage, injury, expense and liability (including without limitation court costs and reasonable attorneys' fees) ("***Claims***") during the Sublease Term or any period of Subtenant's occupancy of the Subleased Premises incurred in connection with or arising from (a) any cause in, on or about the Subleased Premises (including, but not limited to, a slip and fall) provided that the terms of the foregoing indemnity shall not apply to the extent of any gross negligence or willful misconduct of Sublandlord or to any Claims for which Sublandlord has an indemnity obligation pursuant to Section 9.2 below, (b) any negligent acts or omissions of Subtenant or of any person claiming by, through or under Subtenant, or of the contractors, agents, servants, employees, invitees, guests or licensees of Subtenant or any such person, in, on or about the Project, (c) any breach of the terms of this Sublease by Subtenant, either prior to, during, or after the expiration of the Sublease Term, or (d) any dispute between Sublandlord and Master Landlord regarding the requirement to remove Alterations that would be subject to Section 6.3 above regardless of the result of the final determination and the costs of removal and restoration of such Alterations in the event of a final determination that removal thereof is required. Should Sublandlord be named as a defendant in any suit brought against Subtenant in connection with any matter for which Subtenant is required to indemnify Sublandlord under this Section 9.1, Subtenant shall pay to Sublandlord its reasonable costs and expenses incurred in such suit, including without limitation, its actual professional fees such as reasonable appraisers', accountants' and attorneys' fees. The provisions of this Section 9.1 shall survive the expiration or sooner termination of this Sublease.

9.2 Indemnity by Sublandlord. Except to the extent arising from the gross negligence or willful misconduct of Subtenant, Sublandlord shall indemnify Subtenant against all Claims (a) directly caused by the gross negligence or willful misconduct of Sublandlord in the Exclusive Subleased Premises during the Sublease Term, or (b) directly caused by the conduct of the Sublandlord Parties in the Shared Space or of any business of the Sublandlord Parties therein. The provisions of this Section 9.2 shall survive the expiration or sooner termination of this Sublease.

10. Notices. All notices, consents, approvals, demands and requests (collectively "***Notices***") which are required or desired to be given by either party to the other hereunder shall be given in accordance with Section 29.18 of the Master Lease that has been incorporated herein by reference, except that if addressed to: (i) Sublandlord then addressed to Roadrunner Solutions LLC, One Patriots Park, Bedford, Massachusetts 01730, Attention: Tim Kelly, Chief Executive Officer, Email: tim.kelly@homologymedicines.com, and (ii) Subtenant then addressed to Homology Medicines, Inc., One Patriots Park, Bedford, Massachusetts 01730, Attention: Paul Alloway, General Counsel, Email: palloway@homologymedicines.com and with a copy to Latham & Watkins LLP, 200 Clarendon Street, 27th Floor, Boston, Massachusetts 02116, Attention: Peter N. Handrinos and Matthew W. Goulding, Email: Peter.Handrinos@lw.com, except that any notice sent by U.S. mail shall be deemed delivered upon receipt. Each party hereto may from time to time change the names and/or addresses to which Notices given to it shall be addressed and sent as aforesaid, by designating such other names and/or addresses in a Notice given in accordance with the provisions of this Section. Further, Subtenant shall promptly, but in all events, not later than three (3) business days after receipt thereof, each furnish to Sublandlord

a copy of each notice, demand or other written communication sent to or received from Master Landlord.

11. Consents and Approvals. In any instance when Sublandlord's consent or approval is required under this Sublease and Sublandlord has agreed not to unreasonably withhold or delay such consent or approval, Sublandlord's refusal to consent to or approve any matter or thing shall be deemed reasonable if the consent or approval of Master Landlord has not been obtained despite Sublandlord's repeated requests therefor in accordance with Section 8 above. Sublandlord and Subtenant hereby acknowledge and agree that this Sublease is subject to Sublandlord obtaining the written consent (the "***Consent***") of Master Landlord as provided in the Master Lease. It is expressly understood and agreed that notwithstanding anything to the contrary contained herein, the Sublease Term shall not commence, nor shall Subtenant take possession of the Subleased Premises or any part thereof, until the Consent has been obtained.

12. Sublandlord's Covenants. Sublandlord covenants to do the following:

12.1 Sublandlord shall not (1) voluntarily agree with the Master Landlord to, or, pursuant to the terms of the Master Lease, unilaterally, surrender or terminate the Master Lease prior to its scheduled expiration date during the Sublease Term without the consent of Subtenant, provided that Sublandlord shall be permitted without Subtenant's consent to otherwise terminate the Master Lease pursuant to its terms and conditions (including a termination caused by Sublandlord's exercise of any right of Sublandlord under the Master Lease to terminate the Master Lease by reason of fire, casualty or condemnation), or (2) amend or modify the Master Lease, the result of which would materially and adversely affect Subtenant's rights or obligations under this Sublease or the Subleased Premises;

12.2 Sublandlord shall comply with all the terms and provisions of the Master Lease, except to the extent Subtenant has assumed the same or cause Sublandlord's non-compliance with any term or provision of the Master Lease, and

12.3 Sublandlord shall, promptly following receipt thereof, deliver to Subtenant a copy of any and all notices received by Sublandlord from Master Landlord which would have any material effect upon the Subleased Premises or this Sublease.

13. Sublandlord's Right to Cure Subtenant Default/Subtenant's Right to Cure Sublandlord Default. Upon a breach or default by Subtenant under this Sublease, Sublandlord may, after providing prior written notice to Subtenant and without waiving or releasing any obligation of Subtenant hereunder and without waiving any rights or remedies at law or otherwise, make such payment or perform such act. In the event that Sublandlord provides such payment hereunder, Subtenant shall reimburse Sublandlord for such payments on demand. In the event of Sublandlord's failure to pay Rent under the Master Lease by the date due (other than a failure, if any, resulting from Subtenant's failure to comply with this Sublease) and such failure continues for three (3) business days after notice of such failure is given to Sublandlord by Master Landlord, Subtenant shall have the right (but not the obligation, unless so required by the Master Landlord) on written notice, to provide such payments to Master Landlord unless Sublandlord, at its sole election, within two (2) business days after such written notice from Subtenant (a) provides Subtenant with reasonable assurances that such failure will not cause Sublandlord to be in default

under the Master Lease, or (b) establishes an escrow account to hold such unpaid Rent pending resolution of such failure by Sublandlord and Master Landlord. In the event that Subtenant provides such payment hereunder, Sublandlord shall reimburse Subtenant for such payments on demand.

14. Entire Agreement; Modification of Sublease. It is understood and acknowledged that there are no oral agreements between the parties hereto affecting this Sublease and this Sublease constitutes the parties' entire agreement with respect to the subleasing of the Subleased Premises by Subtenant and supersedes and cancels any and all previous negotiations, arrangements, brochures, agreements and understandings, if any, between the parties hereto or displayed by Sublandlord to Subtenant with respect to the subject matter thereof, and none thereof shall be used to interpret or construe this Sublease, except as by mutual agreement of the parties. None of the terms, covenants, conditions or provisions of this Sublease can be modified, deleted or added to except in writing signed by the parties hereto. Should any current or prospective mortgagee or ground lessor for the Building or Project require a modification of this Sublease, which modification will not cause an increased cost or expense to Subtenant or in any other way materially and adversely change the rights and obligations of Subtenant hereunder, then and in such event, Subtenant agrees that this Sublease may be so modified and agrees to execute whatever documents are reasonably required therefor and to deliver the same to Sublandlord and/or Master Landlord within eight (8) business days following a request therefor.

15. CONFIDENTIALITY. For purposes of this Sublease, "***Confidential Information***" shall mean any information disclosed by one party to the other party in the performance hereunder or encountered by either party in connection with the use of the shared space, including, without limitation, methods of operation, customers, customer lists, products, prices, fees, costs, technology, inventions, trade secrets, know-how, software, marketing methods, plans, personnel, suppliers, competitors, markets or other specialized information or proprietary matters; provided, however, "***Confidential Information***" does not include, and there shall be no obligation hereunder with respect to, information that (a) is generally available to the public on the Effective Date, (b) becomes generally available to the public after the Effective Date other than as a result of a disclosure not otherwise permissible hereunder, (c) is acquired by the receiving party from third party sources not in breach of any confidentiality obligation of which the receiving party is aware and having the legal right to disclose same, or (d) is independently developed by the receiving party without use of or any reference to the confidential information of the disclosing party or other information obtained in dealings with the disclosing party; provided that none of the foregoing exclusions shall apply to Personally Identifiable Information which shall remain Confidential Information. Each party shall and shall cause their respective affiliates and representatives to keep confidential this Sublease and all Confidential Information provided to it by or on behalf of the other party or otherwise obtained by it in connection with this Sublease and/or any of the transactions contemplated by it. Notwithstanding the foregoing, neither party and its respective officers, directors, employees or affiliates shall have any obligation to keep confidential any Confidential Information if and to the extent disclosure thereof is specifically required by Applicable Laws; provided, however, that in the event disclosure is required by judicial or administrative process or by other requirements of Applicable Law, a party shall, to the extent reasonably possible and legally permissible, (x) provide the other party with prompt written notice of such requirement prior to making any disclosure so that such other party may seek an appropriate protective order and (y) disclose only that information that is required to be furnished.

Upon written request of the disclosing party, the other party will promptly return to such disclosing party all of the written Confidential Information of such disclosing party, as well as all written material which incorporates any Confidential Information of such disclosing party, except that one (1) copy of the Confidential Information may be retained by the other party for archival purposes. Each party acknowledges that the disclosure of Confidential Information without the disclosing party's express written permission may cause such disclosing party irreparable harm and that the breach or threatened breach of this Section may entitle such disclosing party to injunctive relief, in addition to any other legal remedies that may be available to it. All obligations of confidentiality and non-disclosure set forth in this Section 15 will survive the expiration or earlier termination of this Sublease for a period of five years. As used herein, "***Personally Identifiable Information***" means any information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular natural person or household (including any information related to the health of a person) and any information derived from the foregoing.

16. Brokerage. Subtenant warrants that it has not employed or dealt with any broker, agent or other finder that would be due any payment or commission in connection with the execution of this Sublease or occupancy of the Subleased Premises. Sublandlord warrants that it has not employed or dealt with any broker, agent or other finder that would be due any payment or commission in connection with the execution of this Sublease or occupancy of the Subleased Premises. Sublandlord and Subtenant shall indemnify and hold each other and Master Landlord harmless from any loss, claim or damage relating to the breach of the foregoing representation and warranty. The provisions of this Section 16 shall survive the termination of this Sublease.

17. Security Deposit. On or before the date that is thirty (30) days after the Effective Date, Subtenant shall provide a security deposit (the "***Security Deposit***") in the form of a letter of credit in the amount of Six Hundred Seventy Thousand Six Hundred Nineteen and 73/100 Dollars ($670,619.73). The Security Deposit shall be subject to all of the same terms and conditions of the Total Premises Security Deposit in the Master Lease, except that Sublandlord shall be the beneficiary of the letter of credit and there shall be no reduction during the Sublease Term. There shall be no notice or cure period for failure to timely deliver the Security Deposit prior to such failure being a default of this Sublease.

[signature page follows]

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this Sublease as of the Effective Date.

SUBLANDLORD:

ROADRUNNER SOLUTIONS LLC,
a Delaware limited liability company

By: /s/ Tim Kelly
Name: Tim Kelly
Title: Chief Executive Officer

SUBTENANT:

HOMOLOGY MEDICINES, INC.,
a Delaware corporation

By: /s/ Arthur O. Tzianabos
Name: Arthur O. Tzianabos
Title: President and Chief Executive Officer

[Schedule A]

EXHIBIT A

SUBLEASED PREMISES

SCHEDULE A

Payment for Services

Exhibit 10.13

Employment Agreement

This Employment Agreement (this "Agreement"), dated as of March 18, 2020, is made by and between Homology Medicines, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and Paul Alloway, PhD, J.D. ("Executive") (collectively referred to herein as the "Parties" or individually referred to as a "Party"), and effective as of May 4, 2020 (the "Effective Date").

RECITALS

A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement.

B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1.Employment.

(a) General. Effective on the Effective Date, the Company shall employ Executive, and Executive shall be employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law, and that Executive's employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This "at-will" nature of Executive's employment shall remain unchanged during Executive's tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the "Term") shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as General Counsel of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the Chief Executive Officer of the Company (the "Supervisor"). Executive shall devote substantially all of Executive's working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board"), provided that Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this

Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

2.Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of $360,000.00 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Annual Cash Bonus Opportunity. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be increased by the Board from time to time, the "Target Annual Bonus"), provided that any Annual Bonus awarded to you for 2020 performance will be pro-rated based on the length of your employment during 2020. The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Signing Bonus. The Company agrees to pay you a one-time signing bonus of $35,000 (the "Signing Bonus"), payable upon the Company's second regular payroll date following the Start Date and subject to all applicable tax reporting and withholding requirements. In the event you resign from the Company for any reason other than Good Reason (as defined below) or you are terminated by the Company for Cause (as defined below), in either case, within twelve (12) months after your Start Date, you will be responsible for reimbursing the Company the entire gross amount of the Signing Bonus. By signing this Agreement, you authorize the Company to withhold the amount of the Signing Bonus from any final pay, on an after-tax basis, that may be owed to you upon the termination of your employment in the event you are responsible for such reimbursement.

(d) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(e) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(f) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(g) Key Person Insurance. At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall

have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death*. Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability*. If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause*. The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause*. The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason.* Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason*. Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4.Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(iv) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation with Good Reason, then, subject to Executive signing on or before the 21st day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 0.75 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the 9-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company's group medical, dental or vision plans pursuant to the Consolidated

Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans, less the amount Executive would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on the Date of Termination, during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), less the amount Executive would have had to pay to receive group health coverage as an active employee for Executive and his or her covered dependents based on the cost sharing levels in effect on the Date of Termination, which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation with Good Reason, in either case, on or within twelve (12) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive's Separation from Service, and not revoking, the Release, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to the sum of (A) the Annual Base Salary plus (B) the Target Annual Bonus, payable in equal installments over the 12-month period following the date of Executive's Separation from Service (the "CIC Severance Period") in accordance with the Company's normal payroll practices;

(ii) the payment set forth in Section 4(b)(ii);

(iii) the benefits set forth in Section 4(b)(iii), provided that the "Severance Period" will mean the CIC Severance Period; and

(iv) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5.Restrictive Covenants. As a condition to the effectiveness of this Agreement, Executive will have executed and delivered to the Company no later than contemporaneously herewith the Employee Proprietary Information and Inventions Assignment Agreement attached as Exhibit B (the "Restrictive Covenant Agreement"). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

6.Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personnel and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7.Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) The Board's reasonable, good faith determination that Executive has refused to (A) substantially perform the duties associated with Executive's position with the Company or (B) carry out the reasonable and lawful instructions of the Board concerning duties or actions consistent with the Executive's position with the Company;

(ii) Executive's breach of a material provision of this Agreement that, to the extent capable of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(v) Executive's commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the Homology Medicines, Inc. 2018 Incentive Award Plan.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be with "Good Reason" if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a reduction in Executive's Annual Base Salary or Target Annual Bonus, (ii) a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or position with the Company, (iii) the relocation of Executive's primary office to a location more than twenty-five (25) miles from the Executive's primary office as of the date of this Agreement or (iv) the Company's breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within sixty (60) days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided the Company with an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of

Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

(i) If to the Company, to the Chief Executive Officer of the Company at the Company's headquarters,

(ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or

(iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Restrictive Covenant Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including, any prior employment offer letter or employment agreement between Executive and the Company. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided*, *however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) "and" and "or" are each used both conjunctively and disjunctively; (iii) "any," "all," "each," or "every" means "any and all," and "each and every"; (iv) "includes" and "including" are each "without limitation"; (v) "herein," "hereof," "hereunder" and other similar compounds of the word "here" refer to the entire Agreement and not to any particular

paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney's fees and expenses; provided that the arbitrator may assess the prevailing Party's fees and costs against the non-prevailing Party as part of the arbitrator's award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; provided, however, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or the Restrictive Covenant Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association ("AAA") shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(k) Section 409A.

(i) *General.* The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service.* Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred; provided that Executive submits Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10.Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

HOMOLOGY MEDICINES, INC.

By: /s/ Paul Alloway
Name: Paul Alloway
Title: General Counsel

EXECUTIVE

/s/ Arthur Tzianabos
Arthur Tzianabos, President and CEO

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between _____("Executive") and Homology Medicines, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2019 (the "Employment Agreement") and that certain Employee Proprietary Information and Inventions Assignment Agreement, dated as of _____, 2020 (the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 2020, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section [4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts,

facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the

Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation and any right to receive an award for information provided thereunder, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company for discrimination (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from the Company or any Releasee for any alleged discriminatory treatment), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law and any Retained Claims. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has 7 days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Restrictive Covenant Agreement), non-solicitation, cooperation, and return of property, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law, except that the Parties expressly agree to modify the Restrictive Covenant Agreement by removing Section 6.1, and each subpart thereto, of the Restrictive Covenant Agreement, which shall be of no further force or effect upon the Effective Date (as defined below). Executive represents and warrants that Executive has complied with all provisions of the Restrictive Covenant Agreement at all times through the Effective Date.

(b) In consideration for the severance payments and benefits set forth in Section 1 of this Agreement, Executive agrees for a period of one year after the Effective Date (the "Non-Competition Restricted Period") to not, directly or indirectly, on Executive's own behalf or for the benefit of any other individual or entity other than the Company: (i) operate, conduct, or engage in, or prepare to operate, conduct, or engage in the Business (as defined below); (ii) own, finance, or invest in (except as the holder of not more than one percent of the outstanding stock of a publicly-held company) any Business; or (iii) participate in, render services to, or assist any person or entity that engages in or is preparing to engage in the Business in any capacity (whether as an employee, consultant, contractor, partner, officer, director, or otherwise) (x) which involves the same or similar types of services Executive performed for the Company at any time during the last two years of Executive's employment with the Company or (y) in which Executive could reasonably be expected to use or disclose Proprietary Information, in each case (i), (ii) or (iii) in the Restricted Territory (as defined below). Without limiting the Company's ability to seek other remedies available in law or equity, if Executive violates this Section 4(b), the Non-Competition Restricted Period shall be extended by one day for each day that Executive is in violation of such provisions, up to a maximum extension equal to the length of the Non-Competition Restricted Period, so as to give the Company the full benefit of the bargained-for length of forbearance.

(c) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) and the noncompetition obligations set forth in Section 4(b) above (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Restrictive Covenant Agreement, the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

(d) If any provision of the Restrictive Covenants shall be determined to be unenforceable by any court of competent jurisdiction or arbitrator by reason of its extending for too great a period of time or over too large a geographic area or over too great a range of activities, it shall be interpreted to extend only over the maximum period of time, geographic area or range of activities as to which it may be enforceable.

(e) As used in this Agreement:

(i) The term "Business" means any business or part thereof that develops, manufactures, markets, licenses, sells or provides any product or service that competes with any product or service developed, manufactured, marketed, licensed, sold or provided, or planned to be developed, manufactured, marketed, licensed, sold or provided, by the Company, in each case at any time during Executive's employment or engagement with the Company.

(ii) The term "Restricted Territory" means each city, county, state, territory and country in which (i) Executive provided services or had a material presence or influence at any time during the last two years of Executive's employment or engagement with the Company or (ii) the Company is engaged in or has plans to engage in the Business as of the termination of Executive's employment or engagement with the Company.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Notices; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. If Executive has attained or is over the age of 40 as of the date of Executive's termination of employment, then each Party has seven days after that Party signs this Agreement to revoke it and this Agreement will become effective on the eighth day after Executive signed this Agreement (the "Effective Date"), so long as it has been signed by the Parties and has not been revoked by either Party before that date. If Executive has not attained the age of 40 as of the date of Executive's termination of employment, then the "Effective Date" shall be the date on which Executive signs this Agreement. For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Restrictive Covenant Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 6.1(a) of the Restrictive Covenant Agreement as provided in Section 6.6 of the Restrictive Covenant Agreement, the Restrictive Covenant Agreement, including without limitation Section 6.1 of the Restrictive Covenant Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: _____

[ ]

HOMOLOGY MEDICINES, INC.

Dated: By:_____

Name:

Title:

Exhibit 10.14

Employment Agreement

This Employment Agreement (this "Agreement"), dated as of September 1, 2021 (the "Effective Date"), is made by and between Homology Medicines, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and **Michael Blum** ("Executive") (collectively referred to herein as the "Parties" or individually referred to as a "Party").

RECITALS

A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement, which shall supersede and replace any prior employment arrangement, including, but not limited to, the [offer letter], dated as of October 19, 2017, by and between the Company and Executive (the "Prior Agreement").

B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1.Employment.

(a) General. Effective on the Effective Date, the Company shall continue to employ Executive, and Executive shall remain employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law, and that Executive's employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This "at-will" nature of Executive's employment shall remain unchanged during Executive's tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the "Term") shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Sr. Vice President, Commercial of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the Chief Executive Officer of the Company the "CEO" Arthur Tzianabos (the "Supervisor"). Executive shall devote substantially all of Executive's working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the CEO the Chief Executive Officer of the Company, provided that Executive shall be permitted to (i) manage Executive's personal, financial and

legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

2.Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of $363,900.00 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board") and such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary".

(b) Annual Cash Bonus Opportunity. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 35% of Executive's Annual Base Salary (such target, as may be increased by the CEO from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

3.Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death*. Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability*. If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause*. The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause*. The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason.* Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason*. Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or

arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(iv) due to Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation with Good Reason, then, subject to Executive signing on or before the 21st day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 0.75 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the 9-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company's group medical, dental or vision plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans, less the amount Executive would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on the Date of Termination, during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date

Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), less the amount Executive would have had to pay to receive group health coverage as an active employee for Executive and his or her covered dependents based on the cost sharing levels in effect on the Date of Termination, which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earliest of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation with Good Reason, in either case, on or within twelve (12) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive's Separation from Service, and not revoking, the Release, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the sum of (A) the Annual Base Salary plus (B) the Target Annual Bonus, payable in equal installments over the 12-month period following the date of Executive's Separation from Service (the "CIC Severance Period") in accordance with the Company's normal payroll practices;

(ii) the payment set forth in Section 4(b)(ii);

(iii) the benefits set forth in Section 4(b)(iii), provided that the "Severance Period" will mean the CIC Severance Period; and

(iv) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5.Restrictive Covenants. Executive previously executed and delivered to the Company an Employee Proprietary Information and Inventions Assignment Agreement (the "Restrictive Covenant Agreement"). Executive acknowledges and agrees that Executive continues to be bound by the terms of the Restrictive Covenant Agreement, and nothing in this Agreement affects or modifies the terms of the Restrictive Covenant Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

6.Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personnel and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7.Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) Executive's refusal to (A) substantially perform the duties associated with Executive's position with the Company or (B) carry out the reasonable and lawful instructions of the Company concerning duties or actions consistent with the Executive's position with the Company;

(ii) Executive's breach of a material provision of this Agreement that, to the extent capable of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(v) Executive's commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the Homology Medicines, Inc. 2018 Incentive Award Plan.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) Disability. "Disability" shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company's employees, "disability" as defined in such long-term disability plan for the purpose of determining a participant's eligibility for benefits, *provided*, *however*, if the long-term disability plan contains multiple definitions of disability, "Disability" shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, "Disability" shall mean Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.

(f) Good Reason. For the sole purpose of determining Executive's right to severance payments and benefits as described above, Executive's resignation will be with "Good Reason" if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a reduction in Executive's Annual Base Salary or Target Annual Bonus, (ii) [a material decrease in Executive's authority or areas of responsibility as are commensurate with Executive's title or position with the Company], (iii) the relocation of Executive's primary office to a location more than twenty-five (25) miles from the Executive's primary office as of the date of this Agreement or (iv) the Company's breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within sixty (60) days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) provided the Company with an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced

(and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

(i) If to the Company, to the Chief Executive Officer of the Company at the Company's headquarters,

(ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or

(iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Restrictive Covenant Agreement, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including, without limitation, the Prior Agreement. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided*, *however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) "and" and "or" are each used both conjunctively and disjunctively; (iii) "any," "all," "each," or "every" means "any and all," and "each and every"; (iv) "includes" and "including" are each "without limitation"; (v) "herein," "hereof," "hereunder" and other similar compounds of the word "here" refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute

in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney's fees and expenses; provided that the arbitrator may assess the prevailing Party's fees and costs against the non-prevailing Party as part of the arbitrator's award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; provided, however, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement or the Restrictive Covenant Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a court to enforce this arbitration provision or an award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association ("AAA") shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by court action instead of arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(k) Section 409A.

(i) *General.* The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service.* Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section shall not be paid, or, in the case of installments, shall not commence

payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee*. Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (A) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred (B) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (C) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (D) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10.Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

HOMOLOGY MEDICINES, INC.

By: /s/ Michael Blum
Name: **Michael Blum**
Title: **Sr. Vice President, Commercial**

EXECUTIVE

/s/ Arthur Tzianabos
Arthur Tzianabos, Chief Executive Officer

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between _____ ("Executive") and Homology Medicines, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2021 (the "Employment Agreement") and that certain Employee Proprietary Information and Inventions Assignment Agreement, dated as of _____, 20[__](the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section [4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts,

facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the

Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation and any right to receive an award for information provided thereunder, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company for discrimination (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from the Company or any Releasee for any alleged discriminatory treatment), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law and any Retained Claims. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has 7 days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Restrictive Covenant Agreement), non-solicitation, cooperation, and return of property, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law, except that the Parties expressly agree to modify the Restrictive Covenant Agreement by removing Section 6.1, and each subpart thereto, of the Restrictive Covenant Agreement, which shall be of no further force or effect upon the Effective Date (as defined below). Executive represents and warrants that Executive has complied with all provisions of the Restrictive Covenant Agreement at all times through the Effective Date.

(b) In consideration for the severance payments and benefits set forth in Section 1 of this Agreement, Executive agrees for a period of one year after the Effective Date (the "Non-Competition Restricted Period") to not, directly or indirectly, on Executive's own behalf or for the benefit of any other individual or entity other than the Company: (i) operate, conduct, or engage in, or prepare to operate, conduct, or engage in the Business (as defined below); (ii) own, finance, or invest in (except as the holder of not more than one percent of the outstanding stock of a publicly-held company) any Business; or (iii) participate in, render services to, or assist any person or entity that engages in or is preparing to engage in the Business in any capacity (whether as an employee, consultant, contractor, partner, officer, director, or otherwise) (x) which involves the same or similar types of services Executive performed for the Company at any time during the last two years of Executive's employment with the Company or (y) in which Executive could reasonably be expected to use or disclose Proprietary Information, in each case (i), (ii) or (iii) in the Restricted Territory (as defined below). Without limiting the Company's ability to seek other remedies available in law or equity, if Executive violates this Section 4(b), the Non-Competition Restricted Period shall be extended by one day for each day that Executive is in violation of such provisions, up to a maximum extension equal to the length of the Non-Competition Restricted Period, so as to give the Company the full benefit of the bargained-for length of forbearance.

(c) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) and the noncompetition obligations set forth in Section 4(b) above (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Restrictive Covenant Agreement, the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

(d) If any provision of the Restrictive Covenants shall be determined to be unenforceable by any court of competent jurisdiction or arbitrator by reason of its extending for too great a period of time or over too large a geographic area or over too great a range of activities, it shall be interpreted to extend only over the maximum period of time, geographic area or range of activities as to which it may be enforceable.

(e) As used in this Agreement:

(i) The term "Business" means any business or part thereof that develops, manufactures, markets, licenses, sells or provides any product or service that competes with any product or service developed, manufactured, marketed, licensed, sold or provided, or planned to be developed, manufactured, marketed, licensed, sold or provided, by the Company, in each case at any time during Executive's employment or engagement with the Company.

(ii) The term "Restricted Territory" means each city, county, state, territory and country in which (i) Executive provided services or had a material presence or influence at any time during the last two years of Executive's employment or engagement with the Company or (ii) the Company is engaged in or has plans to engage in the Business as of the termination of Executive's employment or engagement with the Company.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Notices; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period (the "Effective Date"), so long as it has been signed by the Parties and has not been revoked by Executive before that date. For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Restrictive Covenant Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 6.1(a) of the Restrictive Covenant Agreement as provided in Section 6.6 of the Restrictive Covenant Agreement, the Restrictive Covenant Agreement, including without limitation Section 6.1 of the Restrictive Covenant Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: _____
[_____]

HOMOLOGY MEDICINES, INC.

Dated: By:_____
Name:
Title:

EQUITY SECURITIES PURCHASE AGREEMENT

by and among

HOMOLOGY MEDICINES, INC.,

ROADRUNNER SOLUTIONS LLC,

OXFORD BIOMEDICA (US), INC.

and, solely for the purposes of Article IX hereof,

OXFORD BIOMEDICA PLC

Dated as of January 28, 2022

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EXHIBITS

SCHEDULES

EQUITY SECURITIES PURCHASE AGREEMENT

This EQUITY SECURITIES PURCHASE AGREEMENT, dated as of January 28, 2022 (this "Agreement"), is made and entered into by and among Homology Medicines, Inc., a Delaware corporation ("Seller"), Roadrunner Solutions LLC, a Delaware limited liability company (the "Company"), Oxford Biomedica (US), Inc., a Delaware corporation ("Purchaser"), and, solely for the purposes of Article IX, Oxford Biomedica plc, a public company organized under the laws of England and Wales ("Parent Guarantor"). Each of Seller, the Company, Purchaser and Parent Guarantor (solely for purposes of Article IX) is sometimes individually referred to herein as a "Party," and all of them are sometimes collectively referred to herein as the "Parties." Certain terms used in this Agreement have the respective meanings ascribed to them in Section 10.10.

RECITALS

WHEREAS, as of the date hereof, Seller is engaged in part in the business of the manufacturing of adeno-associated virus vectors for use in gene therapy or gene editing products (the "Business");

WHEREAS, Seller conducts the Business primarily at a certain facility located at One Patriots Park, Bedford, Massachusetts 01730 (the "Facility"), which Seller leases pursuant to the Facility Lease;

WHEREAS, prior to the Closing, Seller and the Company will enter into a contribution agreement substantially in the form attached hereto as Exhibit A (the "Contribution Agreement"), pursuant to which, among other things, on the terms and subject to the conditions set forth therein, and effective as of the Closing, (a) Seller will assign and transfer to the Company the Transferred Assets, and the Company will assume from Seller, and agree to pay, perform and discharge when due, the Transferred Liabilities and (b) in exchange therefor, the Company will issue to Seller 175,000 of the Company's units of limited liability company interest ("Units," and the transactions described in this recital, the "Contribution");

WHEREAS, in connection with the Contribution, and prior to the Closing, Seller and the Company will enter into (a) a license and patent management agreement substantially in the form attached hereto as Exhibit B (the "License and Patent Management Agreement"), pursuant to which the Company will grant licenses under certain intellectual property to Seller and Seller and the Company will cooperate in the management of the Transferred Patents, (b) a manufacturing and supply agreement substantially in the form attached hereto as Exhibit C (the "Supply Agreement"), pursuant to which the Company will manufacture and supply Products (as defined in the Supply Agreement) to Seller, (c) a transitional services agreement substantially in the form attached hereto as Exhibit D (the "Transitional Services Agreement"), pursuant to which (i) Seller will perform certain Services (as defined in the Transitional Services Agreement) and (ii) the Company will perform certain services for the benefit of Seller, (d) a lease assignment in the form attached hereto as Exhibit E (the "Lease Assignment"), pursuant to which Seller will assign all of its right, title and interest in, to and under the Facility Lease to the Company, (e) a sublease agreement in the form attached hereto as Exhibit F (the "Sublease Agreement"), pursuant to which the Company will sublease certain premises of the Facility to Seller as further described therein, (f) an employee matters agreement substantially in the form attached hereto as Exhibit G (the "Employee Matters Agreement"), pursuant to which the Parties will agree to allocate certain liabilities and obligations relating to employees associated with the Business, (g) a patent assignment agreement substantially in the form attached hereto as Exhibit H (the "Patent Assignment Agreement"), evidencing the recorded transfer of certain Patent rights from Seller to the Company as set forth therein, and (h) a quality agreement substantially in the form attached hereto as Exhibit I (the "Quality Agreement"), pursuant to which the Company will comply with certain quality requirements in connection with the manufacturing activities to be performed under the Supply Agreement;

WHEREAS, on the terms and subject to the conditions set forth herein, and effective as of the Closing, Seller will sell to Purchaser, and Purchaser will purchase from Seller, 130,000 Units (the "Transferred Units") in exchange for a cash payment by Purchaser to Seller at the Closing in the amount of $130,000,000 (the "Transfer Price");

WHEREAS, on the terms and subject to the conditions set forth herein, and effective as of the Closing, the Company will issue to Purchaser, and Purchaser will purchase from the Company 50,000 Units (the "Subscribed Units" and together with the Transferred Units, the "Purchased Units") in exchange for a cash contribution by Purchaser to the Company at the Closing of $50,000,000 (the "Subscription Price" and, together with the Transfer Price, the "Purchase Price");

WHEREAS, immediately following the consummation of the Contribution, the Equity Transfer (as defined below) and the Equity Issuance (as defined below), (a) Purchaser will own, in the aggregate, 180,000 Units, collectively representing 80% of the outstanding Units as of such time, and (b) Seller will own, in the aggregate, 45,000 Units, collectively representing 20% of the outstanding Units as of such time; and

WHEREAS, at the Closing, the Company, Purchaser and Seller will enter into an amended and restated limited liability company agreement, in substantially the form attached hereto as Exhibit J (the "LLC Agreement"), which shall, among other things, set forth ongoing rights and obligations of the Parties with respect to the governance of the Company.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual representations, warranties and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I
TRANSACTIONS

1.1 **Purchase and Sale of the Transferred Units; Issuance and Sale of the Subscribed Units.**

(a) On the terms and subject to the conditions set forth herein, at the Closing, Seller shall sell and convey to Purchaser, and Purchaser shall purchase and acquire from Seller, the Transferred Units (free and clear of all Liens, other than restrictions on the transfer thereof under applicable securities Laws and under the LLC Agreement), in exchange for the Transfer Price, paid by Purchaser on the Closing Date by wire transfer of immediately available funds to an account designated in writing by Seller at least two (2) Business Days prior to the Closing Date (the transactions described in this Section 1.1(a), the "Equity Transfer").

(b) On the terms and subject to the conditions set forth herein, at the Closing, the Company shall issue and convey to Purchaser, and Purchaser shall purchase and acquire from the Company, the Subscribed Units (free and clear of all Liens, other than restrictions on the transfer thereof under applicable securities Laws and under the LLC Agreement), in exchange for the Subscription Price, paid by Purchaser on the Closing Date by wire transfer of immediately available funds to an account designated in writing by the Company at least two (2) Business Days prior to the Closing Date (the transactions described in this Section 1.1(b), the "Equity Issuance").

1.2 **Closing.** The closings of the Equity Transfer and the Equity Issuance (collectively, the "Closing") shall occur simultaneously and shall take place remotely (by e-mail, teleconference or

videoconference and wire transfer, as applicable) at 10:00 a.m., New York, New York local time, on the date that is three (3) Business Days after the first day on which all of the conditions set forth in Article VI have been satisfied or, to the extent permitted by applicable Law, waived by the applicable Party or Parties entitled to the benefit thereof (other than those conditions that, by their nature or terms, are to be satisfied at the Closing, but subject to the satisfaction or waiver thereof) or at such other time and place as the Parties shall otherwise mutually agree. The date on which the Closing actually occurs is referred to herein as the "Closing Date." Each of the Equity Transfer and the Equity Issuance shall be effective, and Purchaser shall be deemed the beneficial owner and owner of record of the Transferred Units or the Subscribed Units, as applicable, at such time at or after the Closing at which the Transfer Price or the Subscription Price, as applicable, has actually been received by Seller or the Company, as applicable.

1.3 **Closing Actions and Deliveries.**

(a) *Contribution*. Immediately prior to the Closing, the Company and Seller shall consummate the Contribution pursuant to the terms of the Contribution Agreement.

(b) *Deliveries by Seller*. At the Closing, Seller shall deliver (or cause to be delivered):

(i) to Purchaser, certificates representing the Transferred Units duly endorsed or accompanied by transfer powers or an assignment of the Transferred Units duly executed by Seller (or such other documents evidencing the Transferred Units and transfer or assignment thereof as Seller and Purchaser may mutually agree);

(ii) to Purchaser, a certificate, dated as of the Closing Date, duly executed on behalf of Seller by an officer of Seller, certifying the resolutions (or action taken by unanimous written consent in lieu thereof) of the board of directors of Seller approving the execution, delivery and performance of this Agreement and each of the Transaction Documents to which Seller is a party and the consummation of each of the transactions contemplated hereby and thereby;

(iii) to Purchaser, the certificate required to be delivered pursuant to Section 6.2(f);

(iv) to the Company, a duly executed counterpart of the Contribution Agreement;

(v) to Purchaser and the Company, duly executed counterparts of each of (A) this Agreement, (B) the LLC Agreement, (C) the Supply Agreement, (D) the License and Patent Management Agreement, (E) the Transitional Services Agreement, (F) the Lease Assignment, (G) the Sublease Agreement, (H) the Employee Matters Agreement, (I) the Patent Assignment Agreement and (J) the Quality Agreement;

(vi) to Purchaser, a duly executed IRS Form W-9; and

(vii) to Purchaser, the Landlord Consent executed by the landlord under the Facility Lease as required by Section 5.6(c).

(c) *Deliveries by the Company*. At the Closing, the Company shall deliver (or cause to be delivered):

(i) to Purchaser, certificates representing the Subscribed Units duly endorsed (or such other documents evidencing the Subscribed Units as the Company and Purchaser may mutually agree);

(ii) to Purchaser, the certificate required to be delivered pursuant to Section 6.2(e);

(iii) to Purchaser, a certificate, dated as of the Closing Date, duly executed on behalf of the Company by an officer of the Company, certifying (A) the organizational documents of the Company and (B) resolutions (or action taken by unanimous written consent in lieu thereof) of the board of directors of the Company approving the execution, delivery and performance of this Agreement and each of the Transaction Documents to which the Company is a party and the consummation of each of the transactions contemplated hereby and thereby;

(iv) to Seller, a duly executed counterpart of the Contribution Agreement; and

(v) to Seller and Purchaser, duly executed counterparts of each of (A) this Agreement, (B) the LLC Agreement, (C) the Supply Agreement, (D) the License and Patent Management Agreement, (E) the Transitional Services Agreement, (F) the Lease Assignment, (G) the Sublease Agreement, (H) the Employee Matters Agreement, (I) the Patent Assignment Agreement and (J) the Quality Agreement.

(d) *Deliveries by Purchaser*. At the Closing, Purchaser shall deliver (or cause to be delivered):

(i) to Seller, the Transfer Price, in the manner prescribed in Section 1.1(a);

(ii) to the Company, the Subscription Price, in the manner prescribed in Section 1.1(a);

(iii) to Seller, resolutions (or action taken by unanimous written consent in lieu thereof) of the board of directors of Purchaser approving the execution, delivery and performance of this Agreement and each of the Transaction Documents to which Purchaser is a party and the consummation of each of the transactions contemplated hereby and thereby;

(iv) to Seller, the certificate required to be delivered pursuant to Section 6.3(c); and

(v) to Seller and the Company, duly executed counterparts of each of (A) this Agreement, (B) the LLC Agreement and (C) the Supply Agreement.

1.4 **Transfer Taxes.** Seller, on the one hand, and Purchaser, on the other hand, shall each pay fifty percent (50%) of any transfer, recording, filing, stamp, documentary, sales, use, registration, value-added or similar Tax which may be payable in connection with this Agreement and the transactions contemplated hereby (including, for the avoidance of doubt, the Contribution) ("Transfer Taxes").

1.5 **Withholding.** Purchaser shall be entitled to deduct or withhold from any payment required to be made to Seller under this Agreement any Taxes required to be deducted or withheld; provided, however, that the Parties shall use commercially reasonable efforts to minimize or reduce any such Taxes to the extent permitted by applicable Law. Purchaser shall remit the amount of Taxes so deducted or withheld to the appropriate Taxing Authority, and any amount of Taxes so withheld and remitted shall be treated as paid to Seller for all purposes of this Agreement.

ARTICLE II
REPRESENTATIONS AND WARRANTIES OF THE COMPANY AND SELLER

Each of the Company and Seller hereby represents and warrants to Purchaser as follows (except to the extent set forth in the disclosure schedules delivered to Purchaser by the Company concurrently with the Parties' execution and delivery of this Agreement (the "Disclosure Schedules"), it being understood that any information, item or matter set forth in a particular section or subsection of the Disclosure Schedules shall be deemed disclosure with respect to, and shall be deemed to apply to and qualify, the Section or subsection of this Agreement to which such section or subsection of the Disclosure Schedules corresponds

in number and each other Section or subsection of this Agreement to the extent that it is reasonably apparent from the face of such disclosure that such information, item or matter is relevant to such other Section or subsection):

2.1 **Organization and Authorization.**

(a) The Company is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. The Company has full power and authority to enter into each of the Transaction Documents to which it is or is specified to be a party (collectively, the "Company Transaction Documents") and to carry out the transactions contemplated hereby and thereby and perform its other obligations hereunder and thereunder. The execution, delivery and performance of each of the Company Transaction Documents (including the Equity Issuance contemplated hereby) have been duly authorized by all necessary limited liability company or other action of the Company. This Agreement and the other Company Transaction Documents that are contemplated by the terms hereof or thereof to be executed and delivered as of the date hereof have been duly and validly executed and delivered by the Company, and the Company Transaction Documents that are contemplated by the terms hereof or thereof to be executed and delivered after the date hereof will be duly and validly executed and delivered by the Company on or before the respective dates on which such Company Transaction Documents are so contemplated to be executed and delivered. Each of the Company Transaction Documents constitutes (or, in the case of any Company Transaction Document that is contemplated by the terms hereof or thereof to be executed and delivered after the date hereof, will constitute, when executed and delivered) a valid and legally binding obligation of the Company, enforceable in accordance with its terms, subject to the Enforceability Exceptions. The Company has made available to Purchaser or its advisors true and complete copies of the Company's organizational documents.

(b) The Company has all requisite limited liability company power and authority to own the Transferred Assets and to carry on the Business immediately following the Closing as such Business is currently conducted.

(c) The Company is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the character of its property, or the nature of the activities conducted by it, makes such license or qualification necessary, except where the failure to be so licensed or qualified has not had and would not reasonably be expected to be material to the Company.

2.2 **Non-Contravention.** The execution, delivery and performance of the Company Transaction Documents by the Company, and the consummation by the Company of the transactions contemplated hereby and thereby, and compliance with the terms and provisions hereof and thereof, do not and will not: (a) violate, conflict with, result in a breach of any provision of, or constitute a default (with or without notice, lapse of time or both) under, any provision of the Company's governing documents; (b) violate, conflict with, result in the breach of, constitute a default (with or without notice, lapse of time or both) under, give rise to any right to change in terms or acceleration, modification, cancelation or termination (as distinct from any right to terminate, modify or cancel at will without cause pursuant to the terms thereof) of any material right or obligation of the Company under, or require any notice, consent, approval, authorization, waiver or action or filing pursuant to, any agreement, obligation or other instrument to which the Company is a party or by which the Company or any of its properties or assets, including the Transferred Assets, are bound, or cause the creation of any Lien (other than Permitted Liens and Liens arising from acts of Purchaser or any of its Affiliates other than the Closing of the transactions contemplated hereby) upon any of the assets of the Company; (c) violate, conflict with or result in a breach or default (whether after the giving of notice, lapse of time or both) under, any provision of any Laws applicable to the Company or any of its properties or assets, including the Transferred Assets; (d) require the Company give any notice to, or make any declaration or filing with, or obtain any consent, waiver or approval of, any

Governmental Authority or other Person other than pursuant to applicable securities Laws or the rules or regulations of any applicable securities exchange or listing authority; or (e) accelerate any obligation under, or give rise to a right of termination of, any permit, license or authorization issued by any Governmental Authority that is applicable to the Company or any of its assets, except, in the case of the foregoing clauses (b) through (e), as would not, individually or in the aggregate, reasonably be expected to be material to the Business or the Company.

2.3 **Capitalization; Subsidiaries.**

(a) The authorized share capital of the Company consists of 500,000 Units. As of the date hereof, there are issued and outstanding a total of 175,000 Units, all of which are owned beneficially and of record by Seller. Immediately following the consummation of the Contribution, the Equity Transfer and the Equity Issuance, there will be issued and outstanding a total of 225,000 Units, 180,000 of which will be owned of record by Purchaser and 45,000 of which will be owned of record by Seller.

(b) Except for the securities described in Section 2.3(a) and the transactions contemplated by the Transaction Documents, there are no outstanding (i) Capital Interests of the Company, (ii) subscriptions, calls, options, warrants, rights (including preemptive rights), puts or other securities convertible into or exchangeable or exercisable for Capital Interests of the Company or any other Contracts to which the Company is a party or by which the Company is bound obligating the Company to issue or sell any Capital Interests of the Company, (iii) equity equivalents, stock appreciation rights, phantom stock ownership interests or similar rights in the Company, (iv) Contracts to which the Company is a party or by which the Company is bound obligating the Company to repurchase, redeem or otherwise acquire any Capital Interests of the Company or (v) bonds, debentures, notes or other indebtedness for borrowed money (or indebtedness issued or incurred in substitution or exchange for borrowed money) of the Company having the right to vote (or convertible into, or exchangeable for, Capital Interests of the Company having the right to vote) on any matter on which the Company's equityholders may vote.

(c) The Company does not have any subsidiaries or own any Capital Interests in any other Person.

2.4 **Equity Issuance.**

(a) The Equity Issuance (i) does not require any further action by the Company, its board of directors, Seller (as the Company's sole equityholder) or Seller's board of directors or shareholders, (ii) is not subject to any preemptive rights, rights of first refusal or similar rights of any present or future holders of Capital Interests of the Company or Seller and (iii) does not conflict with any provision of any Contract to which the Company or Seller is a party or by which either is bound.

(b) Each of the Subscribed Units, when issued, sold and delivered in accordance with the terms and conditions set forth in this Agreement, will be validly issued and free of preemptive rights, rights of first refusal, rights of first offer and similar rights and restrictions on transfer (other than restrictions arising under the Transaction Documents and restrictions on transfer arising under applicable securities Laws).

2.5 **[Reserved].**

2.6 **No Operations, Assets or Liabilities.** As of immediately prior to the consummation of the transactions contemplated by the Transaction Documents, other than in connection with any action taken in accordance with Section 5.1, (a) the Company has not conducted any business or operations other than in connection with the transactions contemplated by the Transaction Documents and (b) the Company

has no assets or liabilities. Immediately following the Contribution, the Company will not have any liabilities or obligations, other than the Transferred Liabilities.

2.7 **Absence of Certain Developments.** Except as disclosed in Schedule 2.7, since September 30, 2021, (a) Seller has operated the Business in the ordinary course of business, (b) there has not been any Material Adverse Effect, and (c) no event has occurred, and no action has been taken by Seller or any of its Subsidiaries related to the Business for which consent of Purchaser would be required pursuant to Section 5.1 had such action been taken by Seller following the date of this Agreement.

2.8 **Tax Matters.**

(a) All material Tax Returns that were required to be filed by the Company or with respect to the Business or the Transferred Assets have been timely filed (taking into account any extensions of time for such filings). All material Tax Returns filed by the Company or with respect to the Business or the Transferred Assets are complete and accurate in all material respects. All material Taxes owed by the Company or with respect to the Business or the Transferred Assets (whether or not shown on any Tax Return) have been timely paid. No claim has ever been made by an authority in a jurisdiction in which the Company and Seller do not file a Tax Return that Seller or the Company is or may be subject to taxation by that jurisdiction in respect of Taxes of the Business or the Transferred Assets.

(b) There are no Liens for Taxes (other than statutory Liens for Taxes not yet due and payable) on any of the Transferred Assets.

(c) There are no pending or threatened audits, investigations, disputes, notices of deficiency, claims or other Actions for or relating to any material liability for Taxes of the Company or with respect to the Business or the Transferred Assets. No statute of limitations in respect of material Taxes of the Company or with respect to the Business or the Transferred Assets has been waived.

(d) There are no material Tax indemnification or Tax sharing agreements under which the Company would reasonably be expected to be liable after the Closing Date for any Tax liability of any other Person, other than customary agreements with customers, vendors, lessors, or lenders or other agreements that do not relate primarily to Taxes.

(e) The Company has not entered into a "reportable transaction" that has given rise to a disclosure obligation under Section 6011 of the Code and the Treasury Regulations promulgated thereunder.

(f) The Company has been treated as a disregarded entity for United States federal income tax purposes at all times since its formation. Seller is not treated as a disregarded entity for United States federal income tax purposes.

2.9 **Title to and Condition of Transferred Assets; Sufficiency of Transferred Assets.**

(a) Seller has good and valid title, free and clear of all Liens (other than Permitted Liens), to, or a valid leasehold interest in, or a valid license or other right to use, all of the real or tangible property included in the Transferred Assets. Upon the consummation of the Contribution, good and valid title, free and clear of all Liens (other than Permitted Liens), to, or a valid leasehold interest in, or a valid license or other right to use, all of the real or tangible property included in the Transferred Assets shall pass to the Company.

(b) All of the real or tangible property included in the Transferred Assets is in good condition and repair in all material respects (ordinary wear and tear excepted).

(c) The Transferred Assets, will, together with any assets of Seller to which the Company will have a license, right to use, or right to receive services pursuant to the Transaction Documents and the transactions contemplated thereby, constitute all of the assets, rights and properties necessary and sufficient for the conduct of the Business as currently conducted.

2.10 **Real Property.**

(a) Seller does not own any real property that is used in connection with the Business.

(b) The Facility Lease is legal, valid, binding, enforceable and in full force and effect, subject to the Enforceability Exceptions; and neither Seller nor, to the knowledge of Seller, any other party to the Facility Lease is in breach of or default under the Facility Lease, Seller has no present expectation or intention of not fully performing on a timely basis all obligations required to be performed by Seller under the Facility Lease, and, to the knowledge of Seller, no event has occurred or circumstance exists that, with the delivery of notice, the passage of time or both, would constitute such a breach or default or permit the termination, modification or acceleration of rent under the Facility Lease by any of Seller or the other party thereto. Seller has not received notice, and Seller has no knowledge, in either case to the effect that any other party intends to cancel, terminate, breach or attempt to alter the terms of the Facility Lease, or not exercise any option to renew thereunder. Seller has not received any notice from any Governmental Authority alleging a violation of any Laws with respect to the Facility and Seller has no knowledge that the Facility is in violation of any Laws.

(c) Except for the Facility Lease, there are no leases, subleases, licenses, concessions or other Contracts granting to any Person the right to use or occupy the Facility or any part thereof, and other than Seller, there are no Persons in possession of the Facility.

(d) Except as disclosed on Schedule 2.10(d), (i) Seller's current uses of the Facility do not, to the knowledge of Seller, violate any restrictive covenant or zoning ordinance that affects the Facility; (ii) Seller's possession and quiet enjoyment of the Facility has not been disturbed and to the knowledge of Seller there are no disputes with respect to the Facility or Actions between Seller and the landlord under the Facility Lease with respect to the Facility Lease and the rights and/or obligations of the tenant and/or the landlord thereunder; (iii) no security deposit or portion thereof with respect to the Facility Lease has been applied which has not been re-deposited in full; (iv) to Seller's knowledge there are no condemnation, expropriation or other Actions in eminent domain, zoning, building code, or other moratorium proceeding pending or threatened affecting all or any portion of the Facility; and (v) to Seller's knowledge, there are no special assessments filed or proposed against the Facility or any portion thereof.

(e) No portion of the Facility has been damaged or destroyed by fire or other casualty that has not been restored. The Facility is supplied with the utilities necessary for the operation thereof as the same is currently operated, to the extent necessary for the conduct of the Business. Seller has complied with all of its current obligations under the Facility Lease to be fulfilled, kept, observed and performed.

2.11 **Intellectual Property.**

(a) Schedule 2.11(a) sets forth, as of the date hereof, (i) a complete and accurate list of all issued and unexpired Patents and pending Patent applications included in the Company Intellectual Property (the "Transferred Patents"), indicating for each item: (1) the issued patent number and/or patent application number and the applicable filing jurisdiction, and (2) all filing, maintenance and other deadlines occurring

within 120 days of the date hereof, and (ii) a complete and accurate list of all Know-How within the Company Intellectual Property that is owned by the Company ("Transferred Know-How"). The Transferred Patents are subsisting and are valid. Seller is the sole and exclusive legal and beneficial owner of all right, title and interest in and to (x) the Transferred Patents and (y) the Transferred Know-How, in each case, free and clear of all Liens, other than Permitted Liens. Seller is the sole and exclusive legal and beneficial owner or licensee of all right, title and interest in and to the other Company Intellectual Property and has the valid right to use all of such other Company Intellectual Property (including Transferred Patent and Transferred Know-How), in each case, free and clear of all Liens, other than Permitted Liens.

(b) All necessary registration, maintenance, renewal and other material fees for each of Transferred Patents have been timely paid and all necessary documents, recordations and certificates in connection with such Transferred Patents have been timely filed with the relevant Governmental Authority or authorized private registrar for the purposes of maintaining or perfecting such Transferred Patents (taking into account any permitted extensions).

(c) All prior art and information known to the Seller and material to the patentability of the Transferred Patents has been disclosed to the relevant Governmental Authority during the prosecution of the Transferred Patents to the extent required by the Seller's duty of candor to such Governmental Authority.

(d) Except as set forth on Schedule 2.11(d), the consummation of the transactions contemplated hereby will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other Person in respect of, the Company's right to own, use or hold for use any Intellectual Property rights as owned, used or held for use that are material in the conduct or operation of the Business as currently conducted.

(e) To the knowledge of Seller, (i) the conduct of the Business as currently conducted does not infringe, misappropriate, or violate, and the conduct of the Business, during the past three (3) year period, has not infringed, misappropriated, or violated any Intellectual Property owned by a third party, and (ii) no third party is infringing, misappropriating or violating, and has not infringed, misappropriated or violated during the past three (3) year period, any Company Intellectual Property.

(f) There are no Actions (including any administrative proceedings) settled in the past three (3) years, pending or to the knowledge of Seller, threatened (including in the form of offers to obtain a license): (i) alleging any infringement, misappropriation or violation of the Intellectual Property rights of any Person by Seller in the conduct or operation of the Business; (ii) challenging the validity, scope, enforceability, registrability or ownership of any Company Intellectual Property or Seller's rights with respect to any Company Intellectual Property that is not owned by Company; or (iii) by Seller alleging any infringement, misappropriation or violation by any Person of any Company Intellectual Property. To the knowledge of Seller, there are no facts or circumstances that would reasonably be likely to provide a basis for an Action challenging the enforceability or ownership of Transferred Know-How, or an Action challenging the registrability or ownership of Transferred Patents.

(g) Except as disclosed on Schedule 2.11(g), and except for any commercial off-the-shelf software or other agreement that is made available for a total cost of less than $150,000, neither Seller nor the Company has any obligations pursuant to any agreement to compensate any Person for the use of any Company Intellectual Property.

(h) Except as set forth on Schedule 2.11(h), all current and former employees, consultants and contractors of Seller or the Company, as applicable, that have developed or created any portion of any material Company Intellectual Property owned or purported to be owned by Seller or the Company have

executed valid and enforceable written instruments with Seller and the Company that assign to Seller and the Company all rights, title and interest in and to any and all such Intellectual Property (except, in each case, (i) to the extent ownership of any such Intellectual Property vests *ab initio* with Seller or the Company under applicable Law, or (ii) with respect to consultants, and contractors from which Seller and the Company have obtained a license or other right to use any such Intellectual Property). To the knowledge of Seller, no current or former employee of Seller or the Company has excluded any Intellectual Property from any written assignment executed by any such Person in connection with work performed for or on behalf of Seller or the Company.

(i) Each of Seller and the Company has taken commercially reasonable steps to protect the confidentiality of any Trade Secrets included in the Company Intellectual Property. Each of Seller and the Company has taken reasonable steps in accordance with Seller's and the Company's reasonable business judgment to protect the confidentiality of all specific inventions disclosed in filed patent applications prior to the filing of patent applications therefor, including by requiring all persons having access to any of such subject matter to execute binding, written confidentiality agreements providing customary confidentiality and restriction on use and publication terms sufficient to maintain the confidential status and limit the use and publication of such subject matter. To the knowledge of Seller, there has not been any printed publication, sale, offer for sale, or public use by Seller or the Company of the specific invention disclosed in filed patent applications prior to the filing of a patent application therefor.

(j) The inventions in the Company Intellectual Property (a) were not conceived, discovered, developed, generated or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e), and (c) are not otherwise subject to the provisions of the Bayh-Dole Act.

(k) The representations and warranties set forth in this Section 2.11 and Sections 2.7, 2.9 (provided that Section 2.9 shall not be construed as a representation of non-infringement of the Intellectual Property rights of any Person) and 2.12 are the sole and exclusive representations and warranties regarding Intellectual Property rights or other intellectual property matters set forth in this Agreement.

2.12 **Material Contracts.**

(a) Schedule 2.12(a) sets forth, as of the date hereof, each Contract (w) to which either Seller or the Company is a party, (x) which is not an Excluded Asset (as defined under the Contribution Agreement), (y) under which there are continuing rights or obligations and (z) to which any of the descriptions set forth below apply (collectively, the "Material Contracts"):

(i) any Contract related to the Business which is a lease or sublease of real property;

(ii) any Contract for the acquisition or sale of any material asset related to the Business (other than, in each case, purchases or sales of Inventory in the ordinary course), in each case, involving assets the aggregate annual value of which exceeds $150,000;

(iii) any Contract for the purchase of products, materials, supplies, equipment or services related to the Business (excluding purchase orders issued or executed in the ordinary course of business) with a total annual payment or financial commitment exceeding $150,000;

(iv) any Contract that provides for the sale or distribution of any product with a total annual payment or financial commitment exceeding $150,000;

(v) any Contract covering the Business that contains any non-compete provision that restricts Seller or any of its Affiliates in any material respect from engaging or competing in any line of business or in any geographic area, or from developing, manufacturing, marketing, distributing or selling any products or services, or that contains any standstill or customer non-solicitation obligations binding on Seller or the Company;

(vi) any Contract related to the Business involving aggregate consideration in excess of $250,000 that provides indemnification for or the assumption of any Tax, environmental or other material liability of any third party;

(vii) any Contract related to a capital expenditure of the Business involving aggregate consideration in excess of $250,000;

(viii) any Contract related to the Business not otherwise described in this Section 2.12(a) involving an annual aggregate consideration in excess of $150,000;

(ix) any Contract evidencing Indebtedness with respect to which Seller is an obligor and that imposes a Lien, other than a Permitted Lien, on any of the Transferred Assets;

(x) any Contract related to the Business to which any Governmental Authority is a party;

(xi) collective bargaining agreements or similar Contracts with any union, works council or other labor organization that applies to any of the Transferred Employees or independent contractors;

(xii) any partnership, joint venture, strategic alliance or similar Contract related to the Business with an aggregate value in excess of $150,000;

(xiii) any written license, sublicense or similar Contract (other than (i) any Contract granting rights with respect to any databases, licenses to off-the-shelf software or any other Intellectual Property licensed or otherwise delivered pursuant to a click-wrap, shrink-wrap or similar agreement granted by third parties in the ordinary course of business with an aggregate annual cost of less than $200,000 and (ii) any Contracts granting non-exclusive licenses in the ordinary course of business such as agreements with suppliers, advertising agencies, marketing companies, distributors and other vendors in which the license to Intellectual Property is incidental to the agreement) pursuant to which Seller (A) is granted any license, sublicense, option for a license, or similar right from a third party with respect to any Intellectual Property that is currently used in the conduct of the Business or (B) has granted any license, sublicense, option for a license or similar right to a third party with respect to any Intellectual Property that is currently used in the conduct of the Business; and

(xiv) any Contract outside the ordinary course of business that contains an express grant of any right of first refusal, right of first offer or right of first negotiation in favor of any Person in respect of the acquisition of the Business or any of the Transferred Assets.

(b) Copies of the Material Contracts (including all amendments and modifications thereto), which are true and complete, have been made available to Purchaser. All Material Contracts are valid and are in full force and effect and constitute legal, valid and binding obligations of Seller (and following the Contribution, as applicable, the Company), and, to the knowledge of the Company and Seller, of the other parties thereto, and are enforceable in accordance with their respective terms, except as enforceability may be limited by the Enforceability Exceptions. Seller has not received any written or, to the knowledge of Seller, oral notice during the past twelve (12) months from any other party to any Material Contract terminating, or threatening to terminate, such Material Contract. Except as disclosed in Schedule 2.12(b),

(i) neither Seller nor, to the knowledge of Seller, any other party to any Material Contract is in material default in complying with, or otherwise in material breach of, any provision of such Material Contract and (ii) to the knowledge of Seller, no condition or event or fact exists which, with notice, lapse of time or both, (A) would be likely to constitute a material default thereunder or material breach of any Material Contract on the part of Seller or, to the knowledge of Seller, any other party thereto or (B) would be reasonably likely to create in any other party to any Material Contract the right to terminate (whether for cause or otherwise), modify or cancel (as distinct from any right to terminate, modify or cancel at will without cause pursuant to the terms thereof) such Material Contract.

2.13 **Compliance with Laws.**

(a) The Company is, and since the date of its formation has been, in compliance in all material respects with all Laws applicable to the Business or the Transferred Assets. Since the date of its formation, the Company has not received any written, or to the knowledge of Seller, oral notice of any material violation by the Company of any Law applicable to the Business or the Transferred Assets, and no Action alleging any material violation of any Law by the Company is pending or, to the knowledge of Seller, threatened against the Company.

(b) Seller is, and during the past three (3) years has been, in compliance in all material respects with all Laws applicable to the Business or the Transferred Assets. During the past three (3) years, Seller has not received any written or, to the knowledge of Seller, oral notice of any material violation by Seller of any Law applicable to the Business or the Transferred Assets, and no Action alleging any material violation of any such Law by Seller is pending or, or to the knowledge of Seller, threatened against Seller.

(c) Seller (and following the Contribution, the Company) holds, to the extent legally required, all material Permits necessary to operate the Business as currently conducted by Seller. Such Permits are in full force and effect and no suspension, termination, nonrenewal or cancelation of any of such Permits is pending, or, to the knowledge of Seller (or the Company), threatened, and Seller and the Company are in compliance in all material respects with the terms of such Permits. The transactions contemplated in this Agreement and the Transaction Documents will not (with or without notice, lapse of time or both) result in a material default under or a material breach or violation of, any Permit, or adversely affect in any material respect the rights and benefits afforded to Seller or the Company under any such Permit.

2.14 **Litigation.**

(a) No Action is pending or, to Seller's knowledge, threatened, against the Company with respect to the Company's execution, delivery or performance of this Agreement or any other Company Transaction Document by the Company or the consummation by the Company of the transactions contemplated hereby or thereby or that challenges the validity or enforceability of this Agreement or any Company Transaction Document or any action taken or to be taken in connection herewith or therewith.

(b) No Action is pending or, to the knowledge of Seller, threatened (i) against the Company or, to the knowledge of Seller, any director, officer, manager or employee (in his, her or its capacity as such) of the Company or (ii) against Seller to the extent relating to the Business, the Transferred Assets or the Transferred Liabilities or affecting any of the Business, the Transferred Assets or the Transferred Liabilities or, to the knowledge of Seller, against any director, officer, manager or employee (in his, her or its capacity as such) of Seller to the extent relating to the Business, the Transferred Assets or the Transferred Liabilities;

(c) Except as disclosed on Schedule 2.14:

(i) no Action is pending or, to the knowledge of Seller, threatened (x) against the Company or, to the knowledge of Seller, any director, officer, manager or employee (in his, her or its capacity as such) of the Company or (y) against Seller to the extent relating to the Business, the Transferred Assets or the Transferred Liabilities or affecting any of the Business, the Transferred Assets or the Transferred Liabilities or, to the knowledge of Seller, against any director, officer, manager or employee (in his, her or its capacity as such) of Seller to the extent relating to the Business, the Transferred Assets or the Transferred Liabilities; and

(ii) no Order is imposed or, to the knowledge of Seller, threatened (x) against the Company or (y) against Seller to the extent relating to the Business, the Transferred Assets or the Transferred Liabilities or affecting any of the Business, the Transferred Assets or the Transferred Liabilities.

2.15 **Environmental Matters.**

(a) Seller is, and since December 21, 2017 has been, in compliance with all Environmental Laws applicable to the Business and Transferred Assets.

(b) Since December 21, 2017, Seller has not received any written or, to the knowledge of Seller, oral notice of any violation of any Environmental Law applicable to the Business or the Transferred Assets, and, to the knowledge of Seller, no Action alleging any violation of any such Environmental Law is pending or threatened against Seller.

(c) To the knowledge of Seller, the real properties currently, or formerly, owned, leased or operated by Seller in connection with the Business or which real properties constitute Transferred Assets (including, without limitation, soils and surface and ground waters) have any Hazardous Substance present that would reasonably be expected to give rise to any liability or remedial obligation of Seller or the Company caused by activities carried out by Seller at such properties and, to the knowledge of Seller, none of those real properties otherwise or any other real property has any Hazardous Substances present that would reasonably be expected to give rise to any liability or remedial obligation of Seller or the Company.

(d) To the knowledge of Seller, neither the execution of this Agreement nor the consummation of the transactions contemplated hereby will require any investigation or remediation by the Company pursuant to any Environmental Laws applicable to the Business or the Transferred Assets with respect to Hazardous Substances at any of the real property included in the Transferred Assets.

(e) Other than as may be included in the Transferred Assets, the Company has not assumed, whether by contract or operation of law, or provided an indemnity regarding, the liability of any other Person under any Environmental Law.

(f) Seller has made available to Purchaser true and complete copies of all material environmental, health, and safety reports, assessments, correspondence, permits, and any other material documents relating to the operations, properties or facilities of the Company, the Business, or the Transferred Assets.

2.16 **Plans.** Schedule 2.16 lists each material Business Benefit Plan. Each Business Benefit Plan has been established, operated and administrated in all material respects in compliance with its terms and applicable Law, including ERISA and the Code. For each Business Benefit Plan, Seller has made available to Purchaser a true and complete copy of the summary plan description (if required), as modified by any summaries of material modifications, or a written summary (including cost information) of any Business Benefit Plan for which no summary plan description is required. Neither the Company nor any

entity that would be deemed at any relevant time to be a single employer with the Company under Section 414(b), (c), (m) or (o) of the Code or Section 4001 of ERISA, sponsors, contributes to, maintains or has any liability with respect to any employee benefit plan, program or arrangement (a) that is or was subject to Title IV of ERISA or Section 412 of the Code or Section 302 of ERISA, (b) a "multiemployer plan" (as defined in Section 3(37) or Section 4001(a)(3) of ERISA), (c) a "multiple employer welfare arrangement" (as defined in Section 3(4) of ERISA), (d) a "multiple employer plan" (as defined in Section 4063 or Section 4064 of ERISA), (e) a "voluntary employees' beneficiary association" (as defined in Section 501(c)(9) of the Code) or any other funded arrangement for the provision of health, other welfare, or fringe benefits; or (f) any health or other welfare arrangement that is self-insured. No Business Benefit Plan provides, and neither Seller, the Company nor any of their respective affiliates has, any liability or obligation to provide to any Transferred Employee (or their dependents of beneficiaries), postretirement medical, life insurance or other welfare benefits, except (i) as otherwise required under state or federal benefits continuation laws, (ii) the full cost of which is borne by the employee or former employee (or any beneficiary of the employee or former employee) or (iii) for benefits provided during any period during which the former employee is receiving severance pay. There are no pending or, to the knowledge of Seller, threatened Actions (other than routine claims for benefits) by a Governmental Authority by or on behalf of or against any Business Benefit Plan which would reasonably be expected to result in any liability to the Company. Other than as disclosed in Schedule 2.16, neither the execution of this Agreement or the consummation of the transactions contemplated hereby will, either alone or in combination with any other event, result in any (i) severance payment or any increase in severance payments to any Transferred Employee under any Business Benefit Plan, (ii) accelerated vesting or timing of payment or material increases in the amount of any benefit payable to or in respect of any Transferred Employee under any Business Benefit Plan, or (iii) result in any "parachute payment" (within the meaning of Section 280G of the Code) or tax gross-up payment being made to any Transferred Employee.

2.17 **Employees.** Seller has made available to Purchaser, with respect to each Transferred Employee, such Transferred Employee's (i) legal name, (ii) home address, (iii) location of employment, (iv) current annual base salary or base hourly wage rate, (v) target annual incentive compensation opportunity, (vi) job title, (vii) date of hire, (viii) service date used for crediting length of service for purposes of the Business Benefit Plans, (ix) status as exempt or non-exempt under the Fair Labor Standards Act, (x) whether part-time or full-time, (xi) immigration status, and (xii) status as active or on leave and the date of expected return. Seller has made available to Purchaser, with respect to each independent contractor engaged by Seller or its Affiliate primarily to perform services for the Business, each independent contractor's name, location, consulting or contracting term, and consulting or contracting fee. Each of the Company and, except as would not reasonably be expected to result in any liability to the Company, Seller has complied in all material respects with all applicable Laws respecting labor, employment, employment practices, terms and conditions of employment, wages and hours, benefits and occupational safety and health. During the past three (3) years, (y) to the knowledge of Seller, no allegations of sexual harassment have been made against any current or former officer or employee of Seller with respect to the Business or any Transferred Employee and (z) neither Seller nor the Company has entered into any settlement agreements related to allegations of sexual harassment or misconduct by any Transferred Employee.

2.18 **Transactions with Affiliates.** Except as set forth on Schedule 2.18, and except for, and as provided in, the Transaction Documents, there are no loans, leases or other Contracts (a) between the Company, on the one hand, and any director, officer, manager, member, equityholder or other Affiliate of the Company, on the other hand, or (b) with respect to the Business, any Transferred Asset or Transferred Liability, between Seller, on the one hand, and the Company or any director, officer, manager, member, equityholder or other Affiliate of Seller or the Company, on the other hand.

2.19 **Insurance.** All insurance plans related to the Business and the Transferred Assets that are in effect as of the date hereof ("Insurance Policies") have been made available to Purchaser. None of Seller,

the Company or any of their respective Subsidiaries has received any notice of cancelation of any Insurance Policy or material premium increases with respect to any Insurance Policy. All premiums due and payable under all Insurance Policies have been paid and each of Seller and the Company is in compliance in all material respects with the terms of the Insurance Policies.

2.20 **Inventory.** Except as set forth on Schedule 2.20, (i) all Inventory is owned by Seller free and clear of all Liens (other than Permitted Liens) and (ii) no Inventory is held on a consignment basis.

2.21 **Regulatory Matters.**

(a) The Company is, and since the date of its formation has been, in compliance in all material respects with all applicable Regulatory Requirements. Since the date of its formation, the Company has not received any written notice of any material violation of Regulatory Requirements by the Company, and no Action alleging any material violation of any Regulatory Requirement is pending or, to the knowledge of Seller, threatened against the Company.

(b) Seller is, and during the past three (3) years has been, in compliance in all material respects with all Regulatory Requirements applicable to the Business or the Transferred Assets. During the past three (3) years, Seller has not received any written notice of any material violation of any Regulatory Requirement applicable to the Business or the Transferred Assets, and no Action alleging any material violation of any such Regulatory Requirement by Seller is pending or, to the knowledge of Seller, threatened against Seller.

(c) During the past three (3) years, neither Seller nor any of its Affiliates, with respect to the Business, has been subject to physical inspections or received written inspection reports from the U.S. Department of Agriculture or the U.S. Food and Drug Administration, in which such Governmental Authority has asserted or alleged in writing that the operations of the Business were or are not in compliance with any applicable Laws.

(d) During the past three (3) years, there have been no Actions or Judgments regarding the processing or transfer of personal information by Seller or its Affiliates in connection with the Business, and neither Seller nor any of its Affiliates has received any written communications from any Governmental Authority having primary jurisdiction over the enforcement of data protection Laws that would reasonably be expected to limit, in any material respect, such processing or transfers.

2.22 **Anti-Corruption.** Neither the Company, Seller with respect to the Business, nor, to Seller's knowledge, any of the Transferred Employees (a) has used any funds for any unlawful contributions, unlawful gifts, unlawful entertainment or other unlawful expenses; (b) has made any direct or indirect unlawful payments to any Government Official; (c) has violated any Anti-Corruption Laws; (d) has established or maintained any unlawful or unrecorded fund of monies or other properties; (e) has made any false or fictitious entries on its accounting books and records; (f) has made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of any nature, and has not paid, and is not paying, any fee, commission or other payment that has not been properly recorded on its accounting books and records as required by the Anti-Corruption Laws; or (g) has otherwise given or received anything of value to or from a Government Official, an intermediary for payment to any Government Officials or any political party for the purpose of obtaining or retaining business, in the case of each of the foregoing clauses (a) through (g), during the preceding five (5) years.

2.23 **Suppliers.** Schedule 2.23 sets forth a true and complete list of the ten (10) largest suppliers (by estimated total spending) for the Business (other than Affiliates of Seller and other than Persons providing construction services) for the twelve (12) month period ended December 31, 2021. Neither

Seller nor any of its Affiliates has received any notice that any such supplier has terminated or canceled, or has finally determined that it will terminate or cancel, its business relationship in respect of the Business with Seller or any of its Affiliates.

2.24 **Fees and Expenses.** Except as set forth on Schedule 2.24, none of Seller, the Company or any of their respective Affiliates has made any arrangements or taken any other action that has resulted in, or that would result in, the Company being or becoming liable for any fees or expenses payable to a third party in connection with the transactions contemplated by this Agreement or any other Transaction Document.

2.25 **TID U.S. Business.** Seller has conducted an assessment and determined that none of the Company or any of its Affiliates or the Business (a) produce, design, test, manufacture, fabricate, or develop "critical technologies" as that term is defined in 31 C.F.R. § 800.215; (b) perform the functions as set forth in column 2 of Appendix A to 31 C.F.R. part 800 with respect to covered investment critical infrastructure; or (c) maintain or collect, directly or indirectly, "sensitive personal data" as that term is defined in 31 C.F.R. § 800.241; and, therefore, in turn, is not a "TID U.S. business" within the meaning of 31 C.F.R. § 800.248.

2.26 **NO OTHER REPRESENTATIONS OR WARRANTIES.** Except for the representations and warranties of Seller and the Company expressly set forth in this Article II (the "Seller and Company Representations") or in any certificate delivered by Seller or the Company hereunder and as otherwise expressly set forth in Article III, none of the Company, any of its Representatives or any other Person is making, has made or shall be deemed to have made, any representation or warranty, express or implied, in law or in equity, with respect to Seller, the Company or any of their respective Affiliates or the transactions contemplated by this Agreement or any other Transaction Document or any other matter. Neither Seller nor any other Person will have or be subject to any liability or other obligation to Purchaser, its Affiliates or Representatives or any Person resulting from the sale of any Units to Purchaser or Purchaser's use of, or the use by any of its Affiliates or Representatives of, any such information, including information, documents, projections, forecasts or other material made available to Purchaser, its Affiliates or Representatives in any "data rooms," teaser, confidential information memorandum or management presentations in connection with the transactions contemplated by this Agreement, unless any such information is expressly and specifically included in a representation or warranty contained in this Article II or Article III. Seller and each of its Subsidiaries disclaim any and all other representations and warranties, whether express or implied.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby represents and warrants to Purchaser as follows (except to the extent set forth in the Disclosure Schedules, it being understood that any information, item or matter set forth in a particular section or subsection of the Disclosure Schedules shall be deemed disclosure with respect to, and shall be deemed to apply to and qualify, the Section or subsection of this Agreement to which such section or subsection of the Disclosure Schedules corresponds in number and each other Section or subsection of this Agreement to the extent that it is reasonably apparent from the face of such disclosure that such information, item or matter is relevant to such other Section or subsection):

3.1 **Organization and Authorization.** Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Seller has full power and authority to enter into each of the Transaction Documents to which it is or is specified to be a party (collectively, the "Seller Transaction Documents") and to carry out the transactions contemplated hereby and thereby and perform its other obligations hereunder and thereunder. The execution, delivery and performance of each of the

Seller Transaction Documents have been duly authorized by all necessary corporate or other action of Seller. This Agreement and the other Seller Transaction Documents that are contemplated by the terms hereof or thereof to be executed and delivered as of the date hereof have been duly and validly executed and delivered by Seller, and the Seller Transaction Documents that are contemplated by the terms hereof or thereof to be executed and delivered after the date hereof will be duly and validly executed and delivered by Seller on or before the respective dates on which such Seller Transaction Documents are so contemplated to be executed and delivered. Each of the Seller Transaction Documents constitutes (or, in the case of any Seller Transaction Document that is contemplated by the terms hereof or thereof to be executed and delivered after the date hereof, will constitute, when executed and delivered) a valid and legally binding obligation of Seller, enforceable in accordance with its terms, subject to the Enforceability Exceptions. Neither Seller nor any of its Affiliates has entered into any Contract with a third party (other than any nondisclosure or confidentiality agreement) to effect an Acquisition Proposal.

3.2 **Non-Contravention.** The execution, delivery and performance of the Seller Transaction Documents by Seller, and the consummation by Seller of the transactions contemplated hereby and thereby, and compliance with the terms and provisions hereof and thereof, do not and will not: (a) violate, conflict with, result in a breach of any provision of, or constitute a default (with or without notice, lapse of time or both) under, any provision of Seller's governing documents; (b) violate, conflict with, result in the breach of, constitute a default (with or without notice, lapse of time or both) under, give rise to any right to change in terms or acceleration, modification, cancelation or termination (as distinct from any right to terminate, modify or cancel at will without cause pursuant to the terms thereof) of any material right or obligation of Seller under, or require any notice, consent, approval, authorization, waiver or action or filing pursuant to, any agreement, obligation or other instrument to which Seller is a party or by which Seller or any of its properties or assets, including the Transferred Assets, are bound, or cause the creation of any Lien (other than Permitted Liens and Liens arising from acts of Purchaser or any of its Affiliates other than the Closing of the transactions contemplated hereby) upon any of the material assets of Seller; (c) violate, conflict with or result in a breach or default (whether after the giving of notice, lapse of time or both) under, any provision of any Laws applicable to Seller or any of its properties or assets, including the Transferred Assets; (d) require Seller to give any notice to, or make any declaration or filing with, or obtain any consent, waiver or approval of, any Governmental Authority or other Person other than pursuant to applicable securities Laws or the rules or regulations of any applicable securities exchange or listing authority; or (e) accelerate any obligation under, or give rise to a right of termination of, any permit, license or authorization issued by any Governmental Authority that is applicable to Seller or any of its assets, except, in the case of the foregoing clauses (b) through (e), as would not, individually or in the aggregate, reasonably be expected to be material to the Company or the Business. Seller is not currently engaged in, and is not currently contemplating engaging in, discussions or participating in negotiations with any third parties relating to any acquisition or purchase (whether by merger, consolidation, business combination, recapitalization, liquidation, dissolution or otherwise) of a majority of the equity of Seller or any material portion of Seller's business.

3.3 **Title to Transferred Units.** Seller has good and valid title to the Transferred Units, free and clear of all Liens (other than restrictions on transfer arising under applicable securities Laws), and is the sole record and beneficial owner thereof. Assuming Purchaser has the requisite power and authority to be the lawful owner of the Transferred Units, upon the consummation of the Equity Transfer, good and valid title to the Transferred Units will pass to Purchaser, free and clear of all Liens (other than restrictions arising under the Transaction Documents, Liens subsequently created or imposed by acts of Purchaser or any of its Affiliates and restrictions on transfer arising under applicable securities Laws).

3.4 **Governmental Consents.** No consent, approval or authorization of, or notice to, or registration, qualification or filing with, any Governmental Authority is required to be obtained, given or made with respect to Seller in connection with the execution, delivery or performance of this Agreement or any other Seller Transaction Document by Seller or the consummation by Seller of the transactions

contemplated hereby or thereby, except for (a) compliance with, and filings as may be required under, the HSR Act and (b) compliance with, and filings as may be required under, applicable securities Laws or the rules and regulations of any applicable securities exchange or listing authority.

3.5 **Litigation.** No Action is pending or, to Seller's knowledge, threatened, against Seller with respect to Seller's execution, delivery or performance of this Agreement or any other Seller Transaction Document by Seller or the consummation by Seller of the transactions contemplated hereby or thereby or that challenges the validity or enforceability of this Agreement or any Seller Transaction Document or any action taken or to be taken in connection herewith or therewith.

3.6 **Fees and Expenses.** Except as set forth on Schedule 3.6, neither Seller nor any of its Affiliates has made any arrangements or taken any other action that has resulted in, or that would result in, Purchaser or the Company being or becoming liable for any finder's, broker's, agent's or advisor's fee or commission or like payment payable to a third party in connection with the transactions contemplated by this Agreement or any other Transaction Document.

3.7 **ACKNOWLEDGEMENT.** Seller acknowledges and agrees that, except for the representations and warranties of Purchaser expressly set forth in Article IV (the "Purchaser Representations") or in any certificate delivered by Purchaser hereunder, (a) none of Purchaser, any of its Representatives or any other Person is making, has made or shall be deemed to have made, and Purchaser and its Representatives expressly disclaim, any representation or warranty, express or implied, in law or in equity, with respect to Purchaser or any of its Affiliates or the transactions contemplated by this Agreement or any other Transaction Document or any other matter, (b) Seller is not entitled to rely on, has not relied and will not rely on any other representations or warranties, whether made by Purchaser or any of its Representatives or any other Person, (c) Seller is an informed and sophisticated participant in the transactions contemplated by this Agreement and the other Transaction Documents and the negotiations with respect thereto and has undertaken such an investigation and reviewed and evaluated such documents, properties and information as it has deemed necessary, and, in entering into this Agreement and each other Seller Transaction Document, Seller is relying solely on its own investigation and analysis, and (d) none of Purchaser, any of its Representatives or any other Person is making, has made or shall be deemed to have made, and Purchaser and its Representatives expressly disclaim, any representation or warranty, express or implied, in law or in equity, as to the accuracy or completeness of any documents, materials or other information (including any estimates, forecasts, budgets, plans or projections (financial or otherwise)) with respect to Purchaser or any of its Affiliates or any of the transactions contemplated by this Agreement or any other Transaction Document or any other matter that are or have been made available (whether in any data room, virtual data room or otherwise) to Seller or any of its Representatives.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser hereby represents and warrants to Seller and the Company as follows:

4.1 **Organization and Authorization.** Purchaser is a corporation duly organized, validly existing and in good standing under the laws of Delaware. Purchaser has full power and authority to enter into each of the Transaction Documents to which it is or is specified to be a party (collectively, the "Purchaser Transaction Documents") and to carry out the transactions contemplated hereby and thereby and perform its other obligations hereunder and thereunder. The execution, delivery and performance of each of the Purchaser Transaction Documents have been duly authorized by all necessary corporate or other action of Purchaser. This Agreement and the other Purchaser Transaction Documents that are contemplated by the terms hereof or thereof to be executed and delivered as of the date hereof have been duly and validly executed and delivered by Purchaser, and the Purchaser Transaction Documents that are contemplated by

the terms hereof or thereof to be executed and delivered after the date hereof will be duly and validly executed and delivered by Purchaser on or before the respective dates on which such Purchaser Transaction Documents are so contemplated to be executed and delivered. Each of the Purchaser Transaction Documents constitutes (or, in the case of any Purchaser Transaction Document that is contemplated by the terms hereof or thereof to be executed and delivered after the date hereof, will constitute, when executed and delivered) a valid and legally binding obligation of Purchaser, enforceable in accordance with its terms, subject to the Enforceability Exceptions.

4.2 **Non-Contravention.** The execution and delivery by Purchaser of the Purchaser Transaction Documents, and the performance of Purchaser's obligations thereunder and the consummation by Purchaser of the transactions contemplated thereby, do not and will not (a) violate, conflict with or result in a breach of any provision of or constitute a default (with or without notice, lapse of time or both) under Purchaser's governing documents, (b) violate, conflict with or result in a breach or default (with or without notice, lapse of time or both) under, result in the acceleration of obligations under, create in any party the right to terminate, modify or cancel (as distinct from any right to terminate, modify or cancel at will without cause pursuant to the terms thereof), give rise to a change in terms of, or require any notice, consent, approval, authorization, waiver or action or filing pursuant to, any agreement, obligation or other instrument to which Purchaser is a party or by which Purchaser or any of its properties or assets are bound or cause the creation of any Lien upon any of the assets of Purchaser, (c) violate, conflict with or result in a breach or default (whether after the giving of notice, lapse of time or both) under, any provision of any Law applicable to Purchaser or any of its properties or assets, (d) require Purchaser to give any notice to, or make any declaration or filing with, or obtain any consent, waiver or approval of, any Governmental Authority or other Person other than pursuant to applicable securities Laws or the rules or regulations of any applicable securities exchange or listing authority or (e) accelerate any obligation under, or give rise to a right of termination of, any permit, license or authorization issued by any Governmental Authority that is applicable to Purchaser or any of its material assets, except, in the case of clauses (b) through (e), any such items that, individually or in the aggregate, would not reasonably be expected to prevent or materially impede or delay the consummation by Purchaser, as applicable, of the Contribution and the other transactions contemplated by this Agreement or other Transaction Documents.

4.3 **Purchase Entirely for Own Account.** Purchaser is acquiring the Purchased Units solely for Purchaser's own account (or the account or accounts of one or more of its Affiliates) and not as a nominee or agent, and solely for investment purposes and not with a view to, or for offer or sale in connection with, the resale or distribution of any part thereof in violation of any applicable Law. Purchaser has no present intention of selling, granting any participation in or otherwise distributing the Purchased Units or any part thereof to any other Person.

4.4 **Investment Experience.** Purchaser has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Purchased Units. Purchaser is able to bear the economic risk of its investment in the Purchased Units (potentially including a total loss of such investment). Purchaser has conducted an independent review and analysis of the Business, the Facility, the Transferred Assets, the Transferred Liabilities and the business and affairs of the Company that Purchaser considers sufficient and reasonable for purposes of its making its investment in the Purchased Units.

4.5 **Accredited Investor.** Purchaser is an "accredited investor" within the meaning of SEC Rule 501 of Regulation D.

4.6 **Restricted Securities.** Purchaser understands that the Purchased Units are being acquired from the Company in a transaction not involving a public offering and have not been registered under the U.S. federal securities Laws or registered or qualified under the securities Laws of any U.S. state or any

other jurisdiction and that the Purchased Units are characterized as "restricted securities" under the U.S. federal securities Laws. Purchaser understands that the Purchased Units may not be sold, offered for sale, or otherwise transferred or disposed of without registration under the U.S. federal securities Laws and registration or qualification under any applicable securities Laws of any U.S. state or any other jurisdiction, except pursuant to an exemption from the registration or qualification requirements under such securities Laws, and that, in the absence of such registration or such an exemption, the Purchased Units must be held indefinitely.

4.7 **Governmental Consents.** No consent, approval or authorization of, or notice to, or registration, qualification or filing with, any Governmental Authority is required to be obtained, given or made with respect to Purchaser in connection with the execution, delivery or performance of this Agreement or any other Purchaser Transaction Document by Purchaser or the consummation by Purchaser of the transactions contemplated hereby or thereby, except for (a) compliance with, and filings as may be required under, the HSR Act and (b) compliance with, and filings as may be required under, applicable securities Laws or the rules and regulations of any applicable securities exchange or listing authority.

4.8 **Litigation.** No Action is pending or, to Purchaser's knowledge, threatened, against Purchaser with respect to Purchaser's execution, delivery or performance of this Agreement or any other Purchaser Transaction Document by Purchaser or the consummation by Purchaser of the transactions contemplated hereby or thereby or that challenges the validity or enforceability of this Agreement or any Purchaser Transaction Document or any action taken or to be taken in connection herewith or therewith. No Action is pending or, to Purchaser's knowledge, threatened against Purchaser which, if adversely determined, would or would reasonably be expected to cause the Company to suffer or incur any material Losses.

4.9 **Available Funds.** Purchaser will have available at the Closing cash sufficient to pay the full amount of the Purchase Price and all fees, costs, expenses and other amounts required to be paid by Purchaser or any of its Affiliates at the Closing pursuant to this Agreement and the other Transaction Documents or otherwise in connection with the transactions contemplated hereby and thereby.

4.10 **Fees and Expenses.** Neither Purchaser nor any of its Affiliates has made any arrangements or taken any other action that has resulted in, or that would result in, Seller or the Company being or becoming liable for any fees or expenses payable to a third party in connection with the transactions contemplated by this Agreement or any other Transaction Document.

4.11 **ACKNOWLEDGEMENT.** Purchaser acknowledges and agrees that, except for the representations of the Company and Seller expressly set forth in Article II, the representations and warranties of Seller expressly set forth in Article III (the "Seller Representations") and any representations of the Company or Seller expressly set forth in any certificate delivered by the Company or Seller, as applicable, hereunder (a) none of Seller, the Company or any of their respective Representatives or any other Person is making, has made or shall be deemed to have made, and Seller, the Company and their respective Representatives expressly disclaim, any representation or warranty, express or implied, in law or in equity, with respect to Seller, the Company or any of their respective Affiliates, the Business, the Transferred Assets, the Transferred Liabilities or the transactions contemplated by this Agreement or any other Transaction Document or any other matter, (b) Purchaser is not entitled to rely on, has not relied and will not rely on any other representations or warranties, whether made by Seller, the Company, any of their respective Representatives or any other Person, (c) Purchaser is an informed and sophisticated participant in the transactions contemplated by this Agreement and the other Transaction Documents and the negotiations with respect thereto and has undertaken such an investigation and reviewed and evaluated such documents, properties and information as it has deemed necessary, and, in entering into this Agreement and each other Purchaser Transaction Document, Purchaser is relying solely on its own investigation and

analysis, and (d) none of Seller, the Company, any of their respective Representatives or any other Person is making, has made or shall be deemed to have made, and Seller, the Company and their respective Representatives expressly disclaim, any representation or warranty, express or implied, in law or in equity, as to (i) the accuracy or completeness of any documents, materials or other information (including any estimates, forecasts, budgets, plans or projections (financial or otherwise)) with respect to Seller, the Company or any of their respective Affiliates, the Business, the Transferred Assets, the Transferred Liabilities or any of the transactions contemplated by this Agreement or any other Transaction Document or any other matter that are or have been made available (whether in any data room, virtual data room or otherwise) to Seller or any of its Representatives and (ii) the condition, value or quality of any of the respective businesses, assets or liabilities of Seller, the Company or any of their respective Affiliates (including the Business, the Transferred Assets and the Transferred Liabilities), and Seller, the Company and their respective Representatives expressly disclaim any representation or warranty of merchantability, usage, suitability or fitness for any particular purpose with respect to such businesses, assets and liabilities (including the Business, the Transferred Assets and the Transferred Liabilities), the workmanship thereof or the absence of any defects (whether latent or patent) therein.

ARTICLE V
COVENANTS

5.1 **Conduct of Seller.** During the period from the date of this Agreement to the earlier of the Closing and the termination of this Agreement in accordance with its terms, except (w) as otherwise required by applicable Law, (x) as part of any COVID-19 Measures taken by Seller in connection with Seller's operation of the Business, (y) as disclosed on Schedule 5.1 or as otherwise expressly contemplated by this Agreement or any other Transaction Document, (z) pursuant to Section 5.6(a) or (zz) with the prior written consent of Purchaser (which consent shall not be unreasonably withheld, conditioned or delayed with respect to Sections 5.1(b)(iv), 5.1(b)(v), 5.1(b)(xi), 5.1(b)(xiii), 5.1(b)(xiv), 5.1(b)(xvi) and 5.1(b)(xvii)), each of Seller and the Company agrees that:

(a) it shall use commercially reasonable efforts to conduct the Business in the ordinary course and in compliance with applicable Laws; and

(b) without limiting the generality of the foregoing clause (a), it shall not, and shall cause its controlled Affiliates not to (in the case of Seller, solely with respect to the Company, the Business, the Transferred Assets and the Transferred Liabilities):

(i) amend, restate, supplement or otherwise modify the certificate of formation or limited liability company agreement or any other organizational documents of the Company;

(ii) issue, sell, pledge or transfer any Capital Interest in the Company;

(iii) establish or acquire any Subsidiary of the Company;

(iv) make any acquisition, directly or indirectly, of any assets or properties with a value in excess of $150,000 individually or $1,500,000 in the aggregate;

(v) sell, lease, transfer or otherwise dispose of any of the Transferred Assets having a value in excess of $50,000 individually or $100,000 in the aggregate;

(vi) initiate any new business lines that are materially different from the Business as it is conducted or contemplated to be conducted as of the date hereof;

(vii) enter into or adopt any plan or agreement of complete or partial liquidation, restructuring, recapitalization or dissolution, or file a voluntary petition in bankruptcy or commence a voluntary legal procedure for reorganization or bankruptcy or other similar applicable Law now or hereafter in effect;

(viii) split, combine or reclassify the outstanding Units nor enter into any agreement with respect to voting of any of the Units;

(ix) declare, set aside or pay any dividend or other distribution, payable in cash, stock, property, or otherwise, in respect of the Units;

(x) incur any Indebtedness or issue any debt securities or warrants or other rights to acquire debt securities of the Company or assume, guarantee or endorse, as an accommodation or otherwise the obligations of any other Person for Indebtedness or capital obligations;

(xi) (A) agree to make any capital expenditures related to the Business or in or on the Facility which would commit the Company to make any payments following the Closing or (B) spend or commit to be spent any portion of the Refurbishment Allowance (as defined in the Facility Lease) or TI Allowance (as defined in the Facility Lease);

(xii) incur, create or assume any Lien (other than Permitted Liens) with respect to any Transferred Asset, other than those Liens that will be discharged at or prior to the Closing;

(xiii) enter into, amend or otherwise modify in any material respect, waive any material term of, or voluntarily terminate any Material Contract, except for renewals, extensions and other amendments or modifications in the ordinary course of business and expirations in accordance with the terms of such Material Contract;

(xiv) terminate, cancel, amend in any material respect, waive any material term of, or voluntarily fail to maintain, renew or comply with the terms of any material Permit held by the Company that is necessary to operate the Business as currently conducted and as contemplated to be conducted immediately following the Closing;

(xv) make any material loan, advance, capital contribution to, or investment in, any Person other than loans, advances or capital contributions to, or investments in the ordinary course of business;

(xvi) (A) grant any severance or termination pay or retention bonus or change in control bonus, in each case, to any Transferred Employee who has an annual base salary in excess of $150,000, (B) enter into any collective bargaining agreement covering any Transferred Employees or independent contractors, or (C) amend any Business Benefit Plan or adopt a plan that would be a Business Benefit Plan in each case in a manner that disproportionately affects Transferred Employees;

(xvii) (A) hire or terminate (other than for cause) the employment of any Transferred Employee who has an annual base salary in excess of $150,000 or (B) adopt, enter into or materially amend any individual employment agreement for a Transferred Employee;

(xviii) make, change or revoke any Tax election; settle or compromise any claim, notice, audit report or assessment in respect of Taxes; change any annual Tax accounting period or any method of Tax accounting; file any amended Tax Return or any Tax Return with a due date (including extensions) after the Closing Date; surrender any right to claim a material Tax refund; or consent to any extension or waiver of the statute of limitations period applicable to any Tax claim or assessment;

(xix) waive, release, assign, compromise, commence, settle or agree to settle any Action directly related to the Business; or

(xx) authorize, agree or commit to do any of the foregoing.

5.2 **Access to Books and Records.** Without limiting Section 5.4, during the period from the date of this Agreement to the earlier of the Closing and the termination of this Agreement in accordance with its terms, Seller and the Company shall provide Purchaser and its authorized Representatives with reasonable access, during normal business hours and upon reasonable advance notice, to the executive officers, properties, books and records of Seller and the Company solely to the extent relating to the Business, the Transferred Assets or the Transferred Liabilities as may be reasonably requested by Purchaser solely for purposes in furtherance of the transactions contemplated by the Transaction Documents; provided that (a) such access does not interfere with the normal operations of Seller or the Company and (b) such access shall occur in such a manner as Seller reasonably determines to be appropriate to prevent the waiver or loss of any attorney-client privilege or work-product protection of Seller or the Company or any of their respective Affiliates, the violation of any applicable Law or the breach of any duty of confidentiality owed to any Person (whether arising under any Contract or under any applicable Law or otherwise). All requests for such access shall be directed to Tim Kelly and Paul Alloway or such other Person(s) as such Persons may designate in writing to Purchaser (collectively, the "Designated Contacts"). Purchaser shall comply with, and shall cause its Affiliates and Representatives to comply with, all of their obligations under the Confidentiality Agreement with respect to any information disclosed pursuant to this Section 5.2, which Confidentiality Agreement will remain in full force and effect with respect to such information until the Closing. Nothing in this Section 5.2 shall require any of Seller or the Company or any of their respective Affiliates to provide access to, or to disclose any information to, Purchaser or any of its representatives if such access or disclosure (i) would reasonably be expected to cause competitive harm to Seller or the Company if the transactions contemplated by this Agreement were not consummated, (ii) would be reasonably likely to, result in the waiver or other loss of any legal privilege or protection, (iii) would result in a breach of any duty (whether arising in Contract, under applicable Law or otherwise) of confidentiality owed to any Person or (iv) would be reasonably likely to, result in the violation of any applicable Law (including Laws relating to antitrust or competition matters) or any Contract to which Seller or the Company is party or which is binding on the respective assets of Seller or the Company.

5.3 **Efforts; Consents, Regulatory and Other Authorizations.**

(a) Each Party shall coordinate and cooperate and use its reasonable best efforts to (i) take, or cause to be taken, all appropriate action, and do, or cause to be done, all things necessary, proper or advisable under applicable Laws or otherwise to promptly consummate and make effective the transactions contemplated by this Agreement; and (ii) obtain all authorizations, consents, orders and approvals of, and give all notices to and make all filings with, any Governmental Authority and other third parties (including the consents and filings described in this Article V that may be or become necessary for the performance of its obligations under this Agreement and the consummation of the transactions contemplated by this Agreement, including those consents set forth in the Disclosure Schedules). Each Party shall cooperate fully with the other parties to this Agreement in promptly seeking to obtain all such authorizations, consents, orders and approvals, giving such notices and making such filings.

(b) In furtherance and not in limitation of the terms of Section 5.3(a), to the extent required by applicable Laws, each of the Parties (i) shall file, or cause to be filed, a Notification and Report Form pursuant to the HSR Act with respect to the transactions contemplated by this Agreement within five (5) Business Days of the date hereof, (ii) shall make, or to cause to be made, any filing or notification that may be required under any other applicable foreign antitrust laws, if applicable, as promptly as practical, (iii) shall supply promptly any additional information and documentary material that may be requested by any

Governmental Authority (including the Antitrust Division of the United States Department of Justice and the United States Federal Trade Commission) pursuant to the HSR Act and other Persons necessary to consummate the transactions contemplated hereby, and (iv) shall cooperate in connection with any filing under applicable antitrust laws and in connection with resolving any investigation or other inquiry concerning the transactions contemplated by this Agreement commenced by any Governmental Authority, including the United States Federal Trade Commission, the Antitrust Division of the United States Department of Justice or the office of any state attorney general. Any filing fees payable in connection with any filings pursuant to the HSR Act or any other Governmental Authority shall be paid by Purchaser. Each Party shall promptly (A) supply the other with any information which may be required in order to effectuate such filings and (B) supply any additional information which reasonably may be required by a Governmental Authority of any jurisdiction and which the parties may reasonably deem appropriate. No party shall independently participate in any meeting, or engage in any substantive conversation, with any Governmental Authority in respect to any such filings, investigation or other inquiry without giving the other party prior notice of the meeting or conversation and, unless prohibited by such Governmental Authority, the opportunity to attend or participate. The Parties will consult and cooperate with one another in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any party in connection with proceedings under or relating to the HSR Act or other antitrust laws. Each Party shall (x) give the other Parties prompt notice of the commencement or threat of commencement of any Action by or before any Governmental Authority with respect to the transactions contemplated by this Agreement, (y) keep the other Parties informed as to the status of any such Action or threat, and (z) promptly inform the other Parties of any communication to or from any Governmental Authority regarding the transactions contemplated by this Agreement.

(c) Nothing contained in this Section 5.3 shall be deemed to require Purchaser or any of its Affiliates to engage in any Divestiture Action.

(d) Each of Purchaser and Seller (i) shall promptly furnish to the other Party copies of any notices or written communications received by Purchaser or Seller or any of their Affiliates from any third party or any Governmental Authority with respect to the transactions contemplated by this Agreement and (ii) agrees to provide the other Party and its counsel the opportunity, on reasonable advance notice, to participate in any substantive meetings or discussions, either in person or by telephone, between Purchaser, Seller or any of their Affiliates, agents or advisors, on the one hand, and any Governmental Authority, on the other hand, concerning or in connection with the transactions contemplated hereby; provided, however, that each of Seller and Purchaser shall be permitted to designate confidential information as 'Outside Antitrust Counsel Only', and remove or redact any information or contents that are protected by legal privilege and restrict the Company's access to such materials accordingly. Neither Party shall be required to share with the other Party a copy of its filing made under the HSR Act.

(e) Purchaser shall not acquire or agree to acquire any rights, assets, business person or divisions therefore (through acquisition, license, joint venture, collaboration or otherwise), if such acquisition would reasonably be expected to delay or prevent Purchaser's ability to obtain the timely expiration or termination of the waiting periods under the HSR Act or any other antitrust law with respect to the transactions contemplated hereby.

5.4 **Contact with Business Relations.** During the period from the date of this Agreement to the earlier of the Closing and the termination of this Agreement in accordance with its terms, Purchaser shall not, and Purchaser shall not permit its Representatives to, directly or indirectly, contact or communicate outside of the ordinary course of business with any director, officer, employee, customer, supplier, distributor, licensor, lessor, lessee or lender of, or other Person having a business relationship with, Seller or the Company regarding Seller, the Company, the Business, the Transferred Assets, the Transferred Liabilities or any of the transactions contemplated by this Agreement or any other Transaction

Document without the prior written consent of Seller, other than contemplated discussions with employees of the Company and Seller or any other Transferred Employee regarding any post-Closing employment arrangements.

5.5 **Acquisition Proposals.**

(a) *No Solicitation*. The Company and Seller agree that, during the period from the date of this Agreement to the earlier of the Closing and the termination of this Agreement in accordance with its terms, neither they nor any of their officers and directors shall, and they shall not permit or direct their respective Representatives to, directly or indirectly: (i) solicit, initiate, discuss, knowingly encourage or knowingly facilitate any inquiries with respect to, or the making, submission or announcement of, any offer or proposal for an Acquisition Proposal; (ii) participate in any negotiations regarding, or furnish to any Person any nonpublic information with respect to, or take any other action intended or reasonably expected to facilitate the making of any inquiry or proposal to the Company or Seller that constitutes, or is reasonably expected to lead to, an Acquisition Proposal; (iii) engage in discussions with any Person with respect to any Acquisition Proposal, except as to the existence of the provisions of this Section 5.5; (iv) approve, endorse or recommend any Acquisition Proposal; (v) enter into any letter of intent or similar document or any Contract contemplating any Acquisition Proposal or transaction contemplated thereby; or (vi) enter into any agreement, arrangement, understanding or other Contract with any Person requiring it to abandon, terminate or fail to consummate the transactions contemplated hereby. Without limiting the foregoing, it is understood that any violation of the restrictions set forth in the preceding sentence by any Representative of the Company or Seller shall be deemed to be a breach of this Section 5.5(a) by the Company or Seller, as applicable. The Company and Seller will promptly cease any and all existing activities, discussions or negotiations with any third parties conducted heretofore with respect to any Acquisition Proposal. For purposes of this Agreement, "Acquisition Proposal" means any inquiry, proposal or offer in writing from any Person (other than Purchaser or its Affiliates or their respective representatives) relating to (A) any direct or indirect acquisition or purchase of the Business or the Transferred Assets, (B) any acquisition (whether by merger, consolidation, business combination, recapitalization, liquidation, dissolution or otherwise) involving the Business or the Transferred Assets or (C) any direct or indirect acquisition (whether by purchase, merger, consolidation, business combination, recapitalization, liquidation, dissolution or otherwise) involving the acquisition of any material portion of the Business or the Transferred Assets.

(b) *Notification of Unsolicited Acquisition Proposals.* As promptly as practicable after receipt of any written Acquisition Proposal, either the Company or Seller, as applicable, shall provide Purchaser with notice of such Acquisition Proposal.

5.6 **Third Party Consents.**

(a) Except with respect to any waiver, permit, approval, clearance or consent from any Governmental Authority, subject to the terms and conditions of this Agreement, prior to the Closing, Seller shall, and shall cause its Subsidiaries to, use commercially reasonable efforts to obtain the consents, waivers, approvals, orders and authorizations necessary to transfer and assign the Non-Assignable Assets (each a "Third Party Consent") effective as of the Closing. To the extent that any Third Party Consent has not been obtained prior to the Closing, until the date that is six (6) months after the Closing Date, Purchaser, Seller and the Company shall cooperate and use their respective commercially reasonable efforts to obtain such Third Party Consent. Notwithstanding the foregoing, no Party shall be required to incur any Liabilities, or provide any financial accommodation, in order to obtain any such Third Party Consent with respect to the transfer or assignment of any Non-Assignable Asset for the benefit of the Party to whom such Non-Assignable Asset is contemplated to be transferred under this Agreement (the "Receiving Party"). During the period from the date of this Agreement to the earlier of the Closing and the termination of this

Agreement in accordance with its terms, with respect to any Contracts (i) that are Excluded Assets (as defined in the Contribution Agreement), including those set forth on Schedule 5.6(a)(i), and (ii) that are set forth on Schedule 5.6(a)(ii), in each case that are reasonably necessary to operate the Business immediately following the Closing, Seller shall use commercially reasonable efforts, in consultation with Purchaser, to (a) negotiate in good faith reasonable alternative arrangements for such Contracts and (b) implement any such alternative arrangements as of or prior to the Closing.

(b) In addition, to the extent permitted by applicable Law and the terms of the Non-Assignable Asset, in the event any Third Party Consent has not been obtained by the Closing, the applicable other Party (the "Transferring Party") shall hold in trust for the benefit of the Receiving Party such Non-Assignable Asset and shall promptly forward to the Receiving Party, any monies or other benefits received pursuant to such Non-Assignable Asset for the period commencing after the Closing Date, in each case, until such time as the Third Party Consent is obtained, but in no event longer than six (6) months after the Closing Date. For the period beginning on the Closing Date and not to exceed six (6) months after the Closing Date, the Transferring Party shall comply with all material obligations under the Non-Assignable Assets and the Receiving Party shall promptly reimburse the Transferring Party for any reasonable and documented out-of-pocket costs, expenses or payments made by the Transferring Party in respect of such Non-Assignable Asset. Once a Third Party Consent described in this Section 5.6 is obtained from, or such other action described in this Section 5.6 is taken by, such third party, the applicable Non-Assignable Assets shall be deemed to have been automatically assigned and transferred to the Company, in each case, on the terms set forth in this Agreement, as of immediately prior to the Closing, for no additional consideration.

(c) Notwithstanding the foregoing, Seller shall obtain written consent to the Sublease Agreement from the landlord under the Facility Lease (the "Landlord Consent") prior to Closing. The Landlord Consent shall acknowledge that the Company is a "Permitted Transferee" under the Facility Lease and has all rights afforded to the tenant under the Facility Lease, including options to extend the term and expand the Facility, after the Closing notwithstanding the consummation of the Lease Assignment, the Sublease and the other transactions contemplated by this Agreement. The Landlord Consent shall not, without Purchaser's prior written consent, (x) require the Company to pay any sum to the landlord other than as is provided in the Facility Lease or (y) reduce any rights or increase any obligations of the tenant under the Facility Lease.

5.7 **Environmental Assessment.** Purchaser may, at its sole cost and expense, engage a reputable licensed environmental engineer or industrial hygienist to conduct an Environmental Assessment (as defined in the Facility Lease) that is addressed to Purchaser, the Company and the landlord under the Facility Lease and is in compliance with Section 15.3 of the Facility Lease. So long as such Environmental Assessment is completed within sixty (60) days after the Closing Date (the "ESA Delivery Date"), Seller shall cause (or, if so elected in writing by Purchaser in Purchaser's sole discretion, reimburse Purchaser for Purchaser's performance of) the remediation of any recognized environmental conditions in the Environmental Assessment to the extent required under the Facility Lease (including any removal of Hazardous Materials (as defined in the Facility Lease) required by Section 15.3 of the Facility Lease or cleanup required by Section 5.3.4 of the Facility Lease) to the extent existing in, on or under the Facility. If the Environmental Assessment is delivered to Seller on or before the ESA Delivery Date and discloses the existence of recognized environmental conditions in the Facility for which the estimated cost of remediation, individually or in the aggregate, is equal to or exceeds $75,000.00, then Seller shall reimburse Purchaser for the full cost and expense of the Environmental Assessment within thirty (30) days after invoice therefor. To the extent the Environmental Assessment is delivered to Seller on or before the ESA Delivery Date, Seller hereby acknowledges and agrees that the contents of the Environmental Assessment will be definitive as between the parties and that any recognized environmental conditions in the Environmental Assessment will be deemed to have been caused by Seller. Seller shall, upon reasonable prior written notice from Purchaser, provide Purchaser and Purchaser's Representatives access to the

Facility at such times as designated by Purchaser from the date of this Agreement and continuing until the Closing Date for the purposes of conducting the Environmental Assessment.

5.8 **Tax Matters.**

(a) *Transfer Price Allocation*. The Transfer Price shall be allocated among the Transferred Assets in accordance with Section 1060 of the Code and the Treasury Regulations promulgated thereunder (and any similar provision of state, local or foreign Law, as appropriate) (the "Allocation"). The Allocation shall be delivered by Purchaser to Seller within thirty (30) days after the Closing Date for Seller's review and comment, and Purchaser shall reflect any reasonable comments to the Allocation by Seller. Seller and Purchaser shall work in good faith to resolve any disputes relating to the Allocation. If Seller and Purchaser are unable to resolve any such dispute within thirty (30) days following the date such Allocation is delivered by Purchaser to Seller, such dispute shall be resolved promptly by a nationally recognized accounting firm acceptable to both Purchaser and Seller, the costs of which shall be borne equally by Seller, on the one hand, and Purchaser, on the other hand. No Party shall take any Tax position on or file any Tax Return that is inconsistent with such Allocation (as may be modified by this Section 5.8(a)).

(b) *Pre-Closing Tax Returns*. Seller shall prepare and timely file, or shall cause to be prepared and timely filed, all Tax Returns in respect of the Company or with respect to the Transferred Assets that relate to Pre-Closing Tax Periods (other than Straddle Periods) that are due after the Closing, and, except to the extent of Purchaser's liability for any Transfer Taxes, Seller shall be responsible for, and shall pay or cause to be paid, all Taxes due with respect to such Tax Returns. Such Tax Returns prepared by Seller shall be prepared by treating items on such Tax Returns in a manner consistent with the past practices of Seller, except as required by applicable Law. Seller shall deliver at least fifteen (15) days prior to the due date (taking into account any extension) for the filing of such Tax Returns to Purchaser a draft of such Tax Returns that show any material amount of Tax due for Purchaser's review and reasonable comment. Seller shall incorporate any reasonable comment that Purchaser submits to the Company no less than five (5) days prior to the due date of such Tax Returns.

(c) *Straddle Period Tax Returns*. The Company shall prepare and timely file, or shall cause to be prepared and timely filed, all Tax Returns in respect of the Company that relate to a Straddle Period, and Seller shall pay, or cause to be paid, all Taxes with respect to such Tax Returns that are allocable to the portion of the Straddle Period ending on the Closing Date as determined pursuant to Section 5.8(d). All such Tax Returns shall be prepared by the Company consistent with past practices of Seller or the Company, as applicable, unless otherwise required by applicable Law.

(d) *Straddle Period Allocation*. The portion of any Tax of the Company or with respect to the Transferred Assets imposed with respect to a Straddle Period that is allocable to the taxable period that is deemed to end on the Closing will be: (i) in the case of all property Taxes and other Taxes imposed on a periodic basis, deemed to be the amount of such Taxes for the entire Straddle Period *multiplied by* a fraction, the numerator of which is the number of calendar days of such Straddle Period in the Pre-Closing Tax Period and the denominator of which is the number of calendar days in the entire Straddle Period, and (ii) in the case of all other Taxes, determined as though the taxable year of the Company terminated at the close of business on the Closing Date. The Parties acknowledge and agree that any federal and state or other local income Tax Returns filed with respect to the Company for any Straddle Period shall employ the interim closing of the books method to address the differing interests of the Company's equityholders during such Straddle Period, except to the extent otherwise required by applicable Law.

(e) *Tax Contests*. The Parties shall promptly notify each other upon receipt by such Party of notice of any inquiries, claims, assessments, audits or similar proceedings by a Taxing Authority with respect to Taxes or Tax Returns of the Company or with respect to the Transferred Assets relating to a

Pre-Closing Tax Period or a Straddle Period (any such inquiry, claim, assessment, audit or similar event, a "Tax Contest"). Any failure to so notify the other Parties of any Tax Contest shall not relieve such other Parties of any liability with respect to such Tax Contest except to the extent such Parties were actually prejudiced as a result thereof. The Company shall control the conduct of any Tax Contest, including any settlement or compromise thereof; provided, however, that (i) the Company shall keep Seller reasonably informed of the progress of any Tax Contest, and (ii) the Company shall not settle or compromise any such Tax Contest without obtaining the prior written consent of Seller, which consent shall not be unreasonably withheld or delayed. Notwithstanding anything to the contrary herein, this Section 5.8(e) (and not Section 8.5) shall control the conduct of any Tax Contests.

(f) *Tax Treatment*. The Parties acknowledge and agree that, for U.S. federal income Tax purposes and applicable state and local income Tax purposes, (i) the Contribution shall be disregarded; (ii) the transfer of the Transferred Units pursuant to this Agreement in exchange for the Transfer Price shall be treated consistent with Situation 1 of Revenue Ruling 99-5; and (iii) the issuance of the Subscribed Units to Purchaser in exchange for the Subscription Price shall be treated as a contribution of the Subscription Price to the Company under Section 721 of the Code. The Parties shall not take any position on any Tax Return, in connection with any Tax Contest, or otherwise that is inconsistent with the foregoing sentence, unless required otherwise by applicable Law.

(g) *Payment of Certain Taxes*. Notwithstanding anything to the contrary in Section 8.5, any amount required to be paid by Seller pursuant to Section 5.8(b) or Section 5.8(c) shall be satisfied directly by Seller.

(h) *Survival*. Notwithstanding anything to the contrary in this Agreement, the covenants in this Section 5.8 shall survive until 60 days following the expiration of the statute limitations for the relevant Taxes.

5.9 **Employee Matters.** The Parties agree that employee matters will be governed by the Employee Matters Agreement.

5.10 **Data Room**. Promptly following the date hereof, Seller shall deliver to Purchaser a flash drive or other electronic storage device containing the true and complete contents of the Data Room as of two (2) days prior the date of this Agreement.

5.11 **Closing Balances**. Within ten (10) Business Days after the Closing Date, Seller shall deliver to Purchaser a schedule setting forth the net book value of the Transferred Assets that are fixed assets (as defined by GAAP), Inventory, prepaids and unfulfilled purchase orders, in each case as of immediately prior to the consummation of the Contribution (including, for the avoidance of doubt, any fixed assets (as defined by GAAP), Inventory, prepaids and unfulfilled purchase orders obtained, acquired or issued by the Company prior to the Closing Date in compliance with Section 5.1(b)).

5.12 **Non-Interference**. The Parties have invested significant time, costs and resources to select the employees for their proper roles with respect to certain employees who are intended to become Transferred Employees. To ensure that the Company receives the benefit of such investments and obtains skilled employees necessary to conduct the Business as conducted immediately prior to the Closing, the Seller shall instruct its employees with a title of senior vice president or higher and its employees in the human resources department not to, from the date of this Agreement until the Closing, intentionally and knowingly discourage employees associated with the Business from becoming Transferred Employees.

5.13 **Cooperation; Further Actions.** Following the Closing, the Parties shall use commercially reasonable efforts (except to the extent a higher standard is provided for herein, in which case, the applicable Party shall use efforts that meet such higher standard) to take, or cause to be taken, all such actions, to execute and deliver, or cause to be executed and deliver, all such additional agreements, instruments and other documents, to make, or cause to be made, all filings and to do, or cause to be done, all such other things as are necessary, proper or advisable, or otherwise reasonably requested by any other Party, in order to enable each Party to perform its obligations under this Agreement and each other Transaction Document, to consummate the transactions contemplated by this Agreement and each other Transaction Document and otherwise to carry out the intent and purposes of this Agreement and each other Transaction Document.

ARTICLE VI
CONDITIONS TO CLOSING

6.1 **Conditions to Obligations of Purchaser, Seller and the Company.** The respective obligations of Purchaser, Seller and the Company to consummate the Closing shall be subject to the satisfaction, as of the Closing, of each of the following conditions:

(a) *No Prohibition*. No Law enjoining or otherwise prohibiting or making illegal the consummation of the Contribution, the Equity Transfer or the Equity Issuance shall be in effect; and

(b) *Governmental Approvals*. Any waiting period (and any extension thereof) applicable to the consummation of the transactions contemplated by this Agreement under the HSR Act shall have expired or been terminated.

6.2 **Conditions to Obligation of Purchaser.** The obligation of Purchaser to consummate the Closing shall be subject to the satisfaction (or waiver by Purchaser), as of the Closing, of each of the following conditions:

(a) *Representations and Warranties.* Each of the representations and warranties of Seller or the Company, as applicable, contained in (i) Section 2.3 (*Capitalization*) shall be true and correct in all respects as of the Closing as though then made, (ii) the Company Fundamental Representations (other than Section 2.3 (*Capitalization*)) and the Seller Fundamental Representations shall be true and correct (disregarding any limitation or exception as to materiality, material adverse effect or Material Adverse Effect or similar qualification set forth therein) in all material respects as of the Closing as though then made, except to the extent that any such representation or warranty expressly speaks as of an earlier time, in which case such representation or warranty shall be true and correct (disregarding any limitation or exception as to materiality, material adverse effect or Material Adverse Effect or similar qualification set forth therein) in all material respects as of such earlier time, and (iii) Article II or Article III, as applicable, other than the representations and warranties addressed by the preceding clause (i) or (ii), shall be true and correct (disregarding any limitation or exception as to materiality, material adverse effect or Material Adverse Effect or similar qualification set forth therein) as of the Closing as though then made, except, (A) where the failure of such representations or warranties to be so true and correct, individually or in the aggregate, does not constitute a Material Adverse Effect or (B) to the extent that any such representation or warranty expressly speaks as of an earlier time, in which case such representation or warranty shall be true and correct (disregarding any limitation or exception as to materiality, material adverse effect or Material Adverse Effect or similar qualification set forth therein) as of such earlier time, except where the failure of such representations or warranties to be so true and correct, individually or in the aggregate, does not constitute a Material Adverse Effect.

(b) *Covenants.* Each of Seller and the Company shall have performed or complied with in all material respects all agreements and covenants required under this Agreement to be performed or complied with by it at or prior to the Closing.

(c) *Contribution.* The Contribution shall have been consummated in accordance with the Contribution Agreement.

(d) *No Material Adverse Effect.* No Material Adverse Effect shall have occurred since the date of this Agreement.

(e) *Company Officer Certificate*. Purchaser shall have received a certificate from an officer of the Company on behalf of the Company that, as of the Closing, each of the conditions set forth in Section 6.2(a) (as it applies to the Company) and Section 6.2(b) (as it applies to the Company) has been satisfied.

(f) *Seller Officer Certificate*. Purchaser shall have received a certificate from an officer of Seller on behalf of Seller that, as of the Closing, each of the conditions set forth in Section 6.2(a) (as it applies to Seller) and Section 6.2(b) (as it applies to Seller) have been satisfied.

(g) *Closing Deliveries*. Purchaser shall have received each of the documents and other items required to be delivered to Purchaser by Seller pursuant to Section 1.3(b) or by the Company pursuant to Section 1.3(c).

6.3 **Conditions to Obligations of Seller and the Company.** The respective obligations of Seller and the Company to consummate the Closing shall be subject to the satisfaction (or waiver by Seller), as of the Closing, of each of the following conditions:

(a) *Representations and Warranties*. Each of the representations and warranties of Purchaser contained in Article IV shall be true and correct in all respects as of the Closing as though then made (except to the extent that any such representation or warranty expressly speaks as of an earlier time, in which case such representation or warranty shall be true and correct as of such earlier time as though then made), except where the failure of any such representation or warranty to be true and correct, individually or in the aggregate, would not reasonably be expected to have a material adverse effect on Purchaser's ability to consummate the transactions contemplated hereby in accordance with the terms hereof.

(b) *Covenants*. Purchaser shall have performed or complied in all material respects all agreements and covenants required under this Agreement to be performed or complied with by it prior to the Closing.

(c) *Purchaser Officer Certificate*. The Company and Seller shall have received a certificate from an officer of Purchaser on behalf of Purchaser that, as of the Closing, each of the conditions set forth in Section 6.3(a) and Section 6.3(b) have been satisfied.

(d) *Closing Deliveries*. The Company and Seller shall have received each of the documents and other items required to be delivered by Purchaser to Seller or the Company pursuant to Section 1.3(d).

ARTICLE VII
TERMINATION

7.1 **Termination.** This Agreement may be terminated at any time prior to the Closing:

(a) by the mutual written consent of Purchaser and Seller;

(b) by either Purchaser or Seller:

(i) if any Governmental Authority of competent jurisdiction has enacted, issued, promulgated, enforced or entered any judgment, order or decree ("Judgment") which has become final and non-appealable and remains in effect and has the effect of permanently enjoining or otherwise permanently prohibiting or making illegal the consummation of the Closing; provided that the right to terminate this Agreement pursuant to this Section 7.1(b)(i) shall not be available to any Party whose failure to perform any of its obligations under this Agreement has been the cause of, or materially contributed to, the issuance of such non-appealable final Judgment; or

(ii) if the Closing has not occurred before 5:00 p.m., New York, New York local time, on April 28, 2022 (such time on such date, the "Outside Deadline"); provided that the right to terminate this Agreement pursuant to this Section 7.1(b)(ii) shall not be available to a Party if such Party's breach of any of its obligations under this Agreement is the primary cause of the failure of the Closing to have occurred before the Outside Deadline.

(c) by Purchaser, if any of the Seller Representations or the Seller and Company Representations has failed to be true and correct, or if Seller or the Company has failed to perform or comply with any covenant or agreement set forth in this Agreement, in each case, such that the condition specified in Section 6.2(a) or Section 6.2(b), as applicable, would not be satisfied at the Closing and (A) such failure, by its nature, could not be cured prior to the Outside Deadline through Seller's or the Company's exercise of its reasonable best efforts or (B) such failure has not been cured by the earlier of (x) the date that is thirty (30) days after the date on which Purchaser first notifies Seller in writing of such failure (or such earlier time after Seller's receipt of such notice as Seller and the Company have ceased to use reasonable best efforts to cure such failure) and (y) the Outside Deadline; provided that the right to terminate this Agreement pursuant to this Section 7.1(c) shall not be available to Purchaser at any time at which Seller would have the right to terminate this Agreement pursuant to Section 7.1(d); or

(d) by Seller, if any of the Purchaser Representations has failed to be true and correct, or if Purchaser has failed to perform or comply with any covenant or agreement set forth in this Agreement, in each case, such that the condition specified in Section 6.3(a) or Section 6.3(b), as applicable, would not be satisfied at the Closing and (A) such failure, by its nature, could not be cured prior to the Outside Deadline through Purchaser's exercise of its reasonable best efforts or (B) such failure has not been cured by the date that is thirty (30) days after the date on which Seller first notifies Purchaser in writing of such failure (or such earlier time after Purchaser's receipt of such notice as Purchaser has ceased to use reasonable best efforts to cure such failure) and (y) the Outside Deadline; provided that the right to terminate this Agreement pursuant to this Section 7.1(d) shall not be available to Seller at any time at which Purchaser would have the right to terminate this Agreement pursuant to Section 7.1(c).

7.2 **Manner of Termination.** The Party desiring to terminate this Agreement pursuant to Section 7.1 (other than pursuant to Section 7.1(a)) shall deliver written notice of such termination to the other Parties specifying the provision hereof pursuant to which such termination is made and the factual basis therefor.

7.3 **Effect of Termination.** In the event of the termination of this Agreement pursuant to Section 7.1, this Agreement shall forthwith become void and have no further force or effect, without any liability or obligation thereafter on the part of any Person, other than liability of Seller, the Company or Purchaser, as the case may be, for any willful and intentional breach of any covenant in this Agreement required to be performed prior to such termination, except that the provisions of this Article VII and Article X shall survive any termination of this Agreement and shall remain legal, valid, binding and enforceable obligations of the Parties in accordance with their respective terms.

ARTICLE VIII
INDEMNIFICATION

8.1 **Survival of Representations, Warranties and Covenants.** Each of the Seller and Company Representations, the Seller Representations and the Purchaser Representations (other than the Company Fundamental Representations, the Seller Fundamental Representations and the Purchaser Fundamental Representations) shall survive the Closing and continue in full force and effect until the date that is twelve (12) months after the Closing Date, on which date such representations and warranties shall terminate and be of no further force or effect. Each of the Company Fundamental Representations (other than representations made in Section 2.8 or Section 2.11), the Seller Fundamental Representations and the Purchaser Fundamental Representations shall survive the Closing and continue in full force and effect until the date that is thirty-six (36) months after the Closing Date, on which date such representations and warranties shall terminate and be of no further force or effect. All of the covenants of the Parties contained in this Agreement shall survive and remain in effect in accordance with their terms; provided that any covenants that are to be performed at or prior to the Closing shall survive the Closing and shall terminate and be of no further force or effect on the date that is twelve (12) months after the Closing Date. Notwithstanding the preceding sentences of this Section 8.1, if any Indemnified Party provides notice of a claim for indemnification to the Company and in accordance with this Article VIII prior to the date on which the applicable representation, warranty or covenant in respect of which such claim is made terminates pursuant to the foregoing provisions of this Section 8.1, such claim shall survive until it is finally resolved or judicially determined in accordance with this Article VIII. It is the express intent of the Parties that the provisions of this Section 8.1 shall modify and supersede the statute of limitations that otherwise would apply to any claim under applicable Law and that the time periods set forth in this Section 8.1 for the assertion of claims, which are the result of arms'-length negotiations of the Parties, shall be enforced as agreed herein. Notwithstanding anything to the contrary, (i) the representations contained in Section 2.8 and any indemnification obligations of Seller for Pre-Closing Taxes shall survive until the date that is sixty (60) days following the expiration of the applicable statute of limitations and (ii) the representations set forth in Section 2.11 shall survive until the three (3) year anniversary of the Closing Date.

8.2 **Indemnification for the Benefit of Purchaser.** Subject to the other provisions of this Article VIII, from and after the Closing, Seller shall indemnify and hold harmless Purchaser and its Affiliates (other than the Company and any subsidiary of the Company) and their respective directors, managers, officers, employees and agents (collectively, the "Purchaser Indemnified Parties") from and against any Losses that such Purchaser Indemnified Party suffers or incurs to the extent resulting from or arising out of any of the following:

(a) any breach or inaccuracy of any of the Seller and Company Representations or any of the Seller Representations or any representation or warranty made by Seller or the Company in any certificate or writing delivered by the Company or Seller in connection herewith (in each case, disregarding all qualifications as to materiality, the words "material," "materiality" and Material Adverse Effect);

(b) any failure by the Company or Seller to perform or comply in all material respects with their respective covenants, obligations or agreements contained in this Agreement (other than with respect to any covenants to be performed at or prior to the Closing, which, for the avoidance of doubt, shall expire and have no further force or effect as of the date that is twelve (12) months after the Closing Date);

(c) any Excluded Liability; or

(d) any Pre-Closing Taxes.

8.3 **Indemnification for the Benefit of Seller.** Subject to the other provisions of this Article VIII, from and after the Closing, Purchaser shall indemnify and hold harmless Seller and its Affiliates (other than the Company and any subsidiary of the Company) and their respective directors, managers, officers, employees and agents (collectively, the "Seller Indemnified Parties," and together with the Purchaser Indemnified Parties, the "Indemnified Parties") from and against any Losses that such Seller Indemnified Party actually incurs to the extent resulting from or arising out of any of the following:

(a) any breach or inaccuracy of any of the Purchaser Representations or any representation or warranty made by Purchaser in any certificate delivered by Purchaser in connection herewith (in each case, disregarding all qualifications as to materiality, the words "material," "materiality" and Material Adverse Effect); and

(b) any failure by Purchaser to perform or comply with its covenants, obligations or agreements contained in this Agreement.

8.4 **Certain Limitations on Indemnification.**

(a) Notwithstanding anything to the contrary in this Agreement, Seller shall not have any indemnification obligations for any Loss (i) under Section 8.2(a) (except to the extent arising (x) from Fraud of Seller or the Company in the making of any Seller and Company Representation or Seller Representation, as applicable, or any representation or warranty of Seller or the Company, as applicable, in any certificate delivered hereunder or (y) from any breach or inaccuracy of any Company Fundamental Representation or Seller Fundamental Representation) unless and until the aggregate amount of all Losses for which indemnification is available under Section 8.2(a) exceeds $250,000 (the "Deductible"), in which event Seller shall be required to pay only the amount of such Losses that exceeds the Deductible but only up to a maximum amount in respect of all such Losses in the aggregate of $15,000,000, or (ii) under Section 8.2(a) with respect to breaches or inaccuracies of any Company Fundamental Representation or Seller Fundamental Representation (except to the extent arising from Fraud of Seller or the Company) and under Section 8.2(b) through (e) (except to the extent arising from Fraud of Seller or the Company) to the extent that the cumulative indemnification obligations of Seller for any such Losses in the aggregate exceed the Transfer Price. Neither the Purchaser Indemnified Parties, on the one hand, nor the Seller Indemnified Parties, on the other hand, shall be entitled to recover more than once in respect of the same Loss.

(b) The amount of any Loss for which indemnification is provided under Section 8.2 or Section 8.3 shall be net of (i) any amounts recovered by the Seller Indemnified Parties or the Purchaser Indemnified Parties, as applicable, pursuant to any indemnification or contribution by or indemnification or contribution agreement with any third party and (ii) any insurance proceeds or other cash receipts or sources of reimbursement recovered with respect to such Loss, in each case, less the amounts expended in cash to recover such amounts (the source of any such amount referred to in the preceding clause (i) or (ii), a "Collateral Source"). If the amount to be netted hereunder from any payment required under this Article VIII is determined after payment by the Indemnifying Party of any amount otherwise required to be paid to an Indemnified Party pursuant to Article VIII, the Indemnified Party shall repay to the Indemnifying Party, promptly after such determination, any amount that the Indemnifying Party would not have had to pay pursuant to this Article VIII had such determination been made at the time of such payment.

(c) Each of Seller, Purchaser and each Indemnified Party shall take, and shall cause its Affiliates to take, all commercially reasonable steps to mitigate any Loss as may be required under applicable Law.

(d) Notwithstanding anything contained in this Agreement to the contrary, "material" or "Material Adverse Effect" or similar materiality-type qualifications contained in the representations and

warranties set forth in this Agreement (other than the word "material" in the terms "Material Contract" and "Material Contracts") or any certificate or writing delivered in connection herewith shall be ignored for purposes of determining the amount of any Losses for which indemnification may be sought pursuant to Section 8.2(a) or Section 8.3(a).

8.5 **Indemnification Procedures.**

(a) Any Indemnified Party entitled to be indemnified under this Article VIII shall promptly give written notice to the Party from which indemnification may be sought pursuant to this Article VIII (the "Indemnifying Party") of any Action pending or threatened against such Indemnified Party that has given or would reasonably be expected to give rise to such right of indemnification with respect to such Action (a "Third Party Claim"), indicating, with reasonable specificity, the nature of such Third Party Claim, the basis therefor, to the extent practicable, the amount and calculation of the Losses for which the Indemnified Party is entitled to indemnification under this Article VIII (and a good faith estimate of any such future Losses relating thereto) and the provisions of this Agreement in respect of which such Losses shall have occurred, and the Indemnified Party shall promptly make available to the Indemnifying Party any information or documentation (including copies of all court papers) related to the foregoing or otherwise reasonably requested by the Indemnifying Party. A failure by the Indemnified Party to give notice and to tender the defense of the Action in a timely manner pursuant to this Section 8.5(a) shall not limit the obligations of the Indemnifying Party under this Article VIII, except to the extent such Indemnifying Party is materially prejudiced thereby.

(b) With respect to any Third Party Claim, the Indemnifying Party under this Article VIII shall have the right, but not the obligation, to assume the control and defense, at its own expense and by counsel of its own choosing, of such Third Party Claim and any Third Party Claims related to the same or a substantially similar set of facts; provided that the Indemnifying Party shall not be entitled to assume the control and defense of such Third Party Claim, and shall pay the reasonable fees and expenses of counsel retained by the Indemnified Party, if (i) the Third Party Claim alleges criminal conduct by the Indemnified Party or any of its Affiliates, (ii) the Third Party Claim relates to Intellectual Property, (iii) the Third Party Claim seeks an injunction or non-monetary or equitable relief against the Indemnified Party or any of its Affiliates, (iv) the Losses associated with such Third Party Claim are reasonably likely to exceed the maximum amount for which the Indemnifying Party can then be liable pursuant to this Article VIII in light of the limitations on indemnification contained herein, (v) at the time of assumption or thereafter, the Indemnifying Party fails to conduct the investigation, defense or prosecution reasonably actively and reasonably diligently, (vi) any Indemnifying Party is also a party to such Third Party Claim and the Indemnified Party determines in good faith after consultation with outside counsel that joint representation would give rise to a material conflict of interest or (vii) the Indemnifying Party does not agree in writing that it is obligated (without reservation of any rights) to indemnify the Indemnified Party with respect to such Third Party Claim subject only to the limitations on indemnification contained herein. If the Indemnifying Party so undertakes to control and defend any such Third Party Claim, it shall notify the Indemnified Party of its intention to do so, and the Indemnified Party shall, and shall cause its Affiliates and its and their respective Representatives to, cooperate with the Indemnifying Party and its counsel in the defense against, and settlement of, any such Third Party Claim; provided, however, that the Indemnifying Party shall not settle any such Third Party Claim without the written consent of the Indemnified Party (not to be unreasonably withheld, conditioned or delayed) unless such settlement does not involve any injunctive relief against or any finding or admission of any violation of Law or wrongdoing by the Indemnified Party, and any money damages are borne solely by the Indemnifying Party (other than solely with respect to the Deductible, to the extent such damages would constitute Losses to which the Deductible would be applicable). Subject to the foregoing, the Indemnified Party shall have the right to employ separate legal counsel and to participate in but not control the defense of such Action at its own cost and expense; provided that, subject to the provisions of this Article VIII, the Indemnifying Party shall bear the reasonable fees of

one firm of legal counsel (and one additional firm of legal counsel in each jurisdiction implicated in such Action) representing all Indemnified Parties in such action and all related actions, if, but only if, the defendants in such Action include both an Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have reasonably concluded, based on the advice of legal counsel, that there is a material conflict of interest between the Indemnifying Party and the Indemnified Party with respect to such Action. No Indemnified Party may settle any Third Party Claim without the written consent of the Indemnifying Party (not to be unreasonably withheld, conditioned or delayed). If the Indemnifying Party does not assume the control and defense of a Third Party Claim, it shall nevertheless be entitled to participate in the defense of such Action at its own cost and expense, and the Indemnified Party shall cooperate fully with the Indemnifying Party and its counsel in the defense against, and settlement of, any such Third Party Claim.

(c) In the event that any Indemnified Party has or may have an indemnification claim against any Indemnifying Party under this Agreement that does not involve a Third Party Claim, the Indemnified Party shall promptly give written notice thereof to the Indemnifying Party indicating, with reasonable specificity, the nature of such claim, the basis therefor the amount and, to the extent practicable, the calculation of the Losses for which the Indemnified Party is entitled to indemnification under this Article VIII (and a good faith estimate of any such future Losses relating thereto) and the provisions of this Agreement or any Transaction Document in respect of which such Losses shall have occurred, and the Indemnified Party shall promptly make available to the Indemnifying Party any information or documentation related to the foregoing reasonably or otherwise requested by the Indemnifying Party. A failure by the Indemnified Party to give notice in a timely manner pursuant to this Section 8.5(c) shall not limit the obligations of the Indemnifying Party under this Article VIII, except to the extent such Indemnifying Party is prejudiced thereby. If the Indemnifying Party disputes its liability with respect to such claim, the Indemnifying Party and the Indemnified Party shall proceed in good faith to negotiate a resolution of such dispute and, if not resolved through negotiations, such dispute shall be resolved by litigation in the appropriate court of competent jurisdiction set forth in Section 10.7.

(d) In the event that a Purchaser Indemnified Party is finally determined to be entitled to indemnification pursuant to this Article VIII, such Purchaser Indemnified Party shall be entitled to payment from Seller, solely as provided in Section 8.4(b), in the amount of the Losses with respect to which such Purchaser Indemnified Party is so entitled to indemnification under this Article VIII. In the event that any Seller Indemnified Party is entitled to indemnification pursuant to this Article VIII, such Seller Indemnified Party shall be entitled to payment from Purchaser.

8.6 **Exclusive Remedy.** Other than in the case of Fraud (and notwithstanding anything in Section 2.26 to the contrary), the sole and exclusive remedy for any and all claims for monetary damages or Losses arising under, out of or in connection with, or related to, this Agreement or any of the transactions contemplated hereby shall be the rights of indemnification set forth in this Article VIII, and no Person shall have any other entitlement, remedy or recourse, whether in contract, tort or otherwise. Notwithstanding the foregoing, nothing in this Section 8.6 shall limit any Person's rights or remedies under any other Transaction Document.

ARTICLE IX
PARENT GUARANTY

9.1 **Parent Guaranty.** Parent Guarantor hereby unconditionally guarantees to Seller the due and punctual payment and performance of the obligations of Purchaser pursuant to this Agreement, the LLC Agreement and the Employee Matters Agreement (such obligations, the "Guaranteed Obligations" and the guaranty by Parent Guarantor set forth in this Section 9.1, the "Parent Guaranty"). Parent Guarantor is guaranteeing the Guaranteed Obligations as primary obligor and not merely as surety. The Parent

Guaranty is an absolute, unconditional and irrevocable guaranty of payment and performance, as applicable, and not of collection. If, for any reason whatsoever, Purchaser fails to, or is unable to, duly, punctually and fully pay or perform the Guaranteed Obligations, Parent Guarantor will forthwith pay and cause to be paid in lawful currency of the United States with respect to payment obligations, or perform or cause to be performed, with respect to performance obligations, the Guaranteed Obligations. Parent Guarantor hereby irrevocably waives diligence, presentment, demand of payment, filing objections with a court, any right to require proceeding first against any Party, any right to require the prior disposition of the assets of any Party to meet its obligations, the lack of validity or the unenforceability of Parent Guarantor's guaranty of the Guaranteed Obligations, any rights to set offs, recoupments or counterclaims, notice, protest and all demands whatsoever, except as provided for under Section 14.13 of the LLC Agreement. The Parent Guaranty shall apply regardless of any amendments, modifications, waivers or extensions to this Agreement whether or not Parent Guarantor receives notice of the same and Parent Guarantor waives all need for notice of the same.

9.2 **Parent Guarantor Representations.** Parent Guarantor is a legal entity duly organized, validly existing and in good standing under the Laws of its jurisdiction of organization. Parent Guarantor has all requisite corporate power and authority and has taken all corporate action necessary in order to execute, deliver and perform its obligations under the Parent Guaranty. This Agreement, solely in respect of this Article IX, has been duly executed and delivered by Parent Guarantor and, solely in respect of this Article IX, is a valid and binding agreement of Parent Guarantor, enforceable against it in accordance with its terms, subject to the Enforceability Exceptions.

9.3 **Additional Agreements.** The provisions of Section 10.5 (*Notices*), Section 10.7 (*Governing Law; Venue*), Section 10.8 (*Waiver of Jury Trial*), Section 10.11 (*Confidentiality; Publicity*), Section 10.12 (*Remedies*) and Section 10.13 (*Interpretation*) are hereby incorporated by reference into this Article IX and shall apply to Parent Guarantor, *mutatis mutandis*, as if fully set forth in this Article IX.

ARTICLE X
MISCELLANEOUS

10.1 **Entire Agreement.** The Transaction Documents (including the schedules and exhibits hereto and thereto) constitute the full and entire understanding and agreement among the Parties with respect to the subject matters hereof and thereof, and any and all other written or oral agreements existing prior to or contemporaneously herewith are expressly superseded and canceled.

10.2 **Amendments.** This Agreement may be amended, in whole or in part, only by an agreement in writing which makes reference to this Agreement and has been duly authorized, executed and delivered by each of the Parties. Any purported amendment of this Agreement effected in a manner that does not comply with the preceding sentence shall be void and of no effect.

10.3 **Waivers.** Any Party may (a) extend the time for the performance of the obligations or acts of any other Party to be performed hereunder, (b) waive any inaccuracy in any of the representations or warranties of any other Party that are contained in this Agreement or (c) waive compliance by any other Party with any of the agreements or conditions contained in this Agreement, but, in the case of each of the foregoing clauses (a) through (c), such extension or waiver shall be valid only if set forth in an instrument in writing duly authorized, executed and delivered by the Party granting such extension or waiver. No waiver by any Party shall operate or be construed as a waiver in respect of any failure, breach, or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any rights, remedy,

power, or privilege arising hereunder shall operate or be construed as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

10.4 **Fees and Expenses.** Except as otherwise provided herein, all costs and expenses incurred in connection with this Agreement, and the transactions contemplated hereby, and the Contribution (including the fees and expenses of its advisors, accountants and legal counsel) shall be paid by the Party incurring such expense; provided that all filing fees payable under or pursuant to the HSR Act and any foreign antitrust law shall be paid by Purchaser. Any costs and expenses of the Company incurred prior to the Closing shall be paid by Seller.

10.5 **Notices and Demands.** All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed effectively given, delivered and received upon the earlier of actual receipt or (a) personal delivery to the Party to be notified, (b) when sent, if sent by electronic mail during the normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next Business Day, (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid and (d) one (1) Business Day after deposit with a nationally recognized overnight courier, freight prepaid, specifying next business day delivery, with written verification of receipt, as follows:

if to the Company:

Roadrunner Solutions LLC

One Patriots Park

Bedford, Massachusetts 01730

Attention: Tim Kelly, Chief Executive Officer

Email: tim.kelly@homologymedicines.com

with a copy (which shall not constitute notice) to:

Homology Medicines, Inc.

One Patriots Park

Bedford, Massachusetts 01730

Attention: Paul Alloway, General Counsel

Email: palloway@homologymedicines.com

if to Purchaser or to Parent Guarantor:

Oxford Biomedica (UK) Limited

Windrush Court

Transport Way

Oxford OX4 6LT

Attention: Natalie Walter, General Counsel

Email: N.Walter@oxb.com

with a copy (which shall not constitute notice) to:

Covington & Burling LLP

22 Bishopsgate
London EC2N 4BQ

Attention: Paul Claydon

Email: PClaydon@cov.com

Covington & Burling LLP

The New York Times Building

620 Eighth Avenue
New York, NY 10018
Attention: Jack S. Bodner

Email: JBodner@cov.com

if to Seller:

Homology Medicines, Inc.
One Patriots Park
Bedford, Massachusetts 01730
Attention: Paul Alloway, General Counsel

Email: palloway@homologymedicines.com

with a copy (which shall not constitute notice) to:

contracts@homologymedicines.com; and

Latham & Watkins LLP

200 Clarendon Street, 27th Floor

Boston, Massachusetts 02116

Attention: Peter N. Handrinos and Matthew W. Goulding

Email: Peter.Handrinos@lw.com, Matthew.Goulding@lw.com

or to such other address, email address or fax number of which any Party may notify the other Parties as provided above.

10.6 **Severability.** Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable Law, but if any provision of this Agreement shall be deemed prohibited or invalid under such applicable Law, such provision shall be ineffective to the extent of such prohibition or invalidity, and such prohibition or invalidity shall not invalidate the remainder of such provision or the other provisions of this Agreement.

10.7 **Governing Law; Venue.**

(a) This Agreement, and all claims or causes of action based upon, arising out of, or related to this Agreement or the transactions contemplated hereby (whether based on contract, tort, equity or otherwise), shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to principles or rules of conflict of Laws (whether of the State of Delaware or of any other jurisdiction) to the extent such principles or rules would require or permit the application of Laws of a jurisdiction other than the State of Delaware.

(b) Any proceeding or Action based upon, arising out of or related to this Agreement or the transactions contemplated hereby must be brought in the Court of Chancery of the State of Delaware (or, to the extent such court does not have subject matter jurisdiction, the Superior Court of the State of Delaware), or, if it has or can acquire jurisdiction, in the United States District Court for the District of Delaware, and each of the Parties irrevocably (i) submits to the exclusive jurisdiction of each such court in any such proceeding or Action, (ii) waives any objection it may now or hereafter have to personal jurisdiction, venue or to convenience of forum, (iii) agrees that all claims in respect of the proceeding or Action shall be heard and determined only in any such court and (iv) agrees not to bring any proceeding or Action arising out of or relating to this Agreement or the transactions contemplated hereby in any other court. Nothing herein contained shall be deemed to affect the right of any Party to serve process in any manner permitted by Law or to commence Actions or otherwise proceed against any other party in any other jurisdiction, in each case, to enforce judgments obtained in any Action, suit or proceeding brought pursuant to this Section 10.7.

10.8 **WAIVER OF JURY TRIAL.** EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY (A) CERTIFIES THAT NO OTHER PARTY OR REPRESENTATIVE THEREOF OR OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY OR PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE OTHER TRANSACTION DOCUMENTS BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10.8.

10.9 **Successors and Assigns.** Except as otherwise provided in the Transaction Documents, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the respective successors, assigns, heirs, executors and administrators of the Parties. No Party shall assign, delegate or otherwise transfer any of its rights or obligations under this Agreement (whether by operation of law or otherwise) without the prior written consent of Seller (in the case of any proposed assignment, delegation or transfer by Purchaser) or Purchaser (in the case of any proposed assignment, delegation or transfer by Seller or the

Company). Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person other than a Party any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.10 **Certain Definitions.** Except as otherwise provided herein or as otherwise clearly required by the context, the following terms shall have the respective meanings indicated when used in this Agreement:

(a) "Acquisition Proposal" has the meaning set forth in Section 5.5(a).

(b) "Action" means any claim, demand, action, cause of action, right of recovery, right of set-off, suit, audit, arbitration, inquiry, proceeding or investigation by or before any Governmental Authority.

(c) "Affiliate" means, with respect to a specified Person, any other Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person, and without limiting the generality of the foregoing, includes, with respect to the specified Person: (i) any other Person which beneficially owns or holds 50% or more of the outstanding voting securities or other securities convertible into voting securities of such Person; (ii) any other Person of which the specified Person beneficially owns or holds 50% or more of the outstanding voting securities or other securities convertible into voting securities; or (iii) any director, manager, officer or employee of such Person; provided, however, that with respect to any individual Person, the term "Affiliate" shall also include (A) each other member of such individual's Family, (B) any Affiliate of such individual or one or more members of such individual's Family, (C) any person with respect to which such individual or one or more members of such individual's Family serves as a director, officer, partner, executor or trustee (or in any other similar capacity) and (D) any trust or estate planning vehicle for the benefit of such individual or his or her Family.

(d) "Agreement" has the meaning set forth in the preamble to this Agreement.

(e) "Allocation" has the meaning set forth in Section 5.8(a).

(f) "Anti-Corruption Laws" means the Foreign Corrupt Practices Act of 1977, as amended, the Anti-Kickback Act of 1986 or any applicable Laws of similar effect, and the related regulations thereunder.

(g) "Business" has the meaning set forth in the recitals to this Agreement.

(h) "Business Benefit Plan" means any "employee benefit plan" (as defined in Section 3(3) of ERISA), whether or not subject to ERISA, and each material compensation or benefit plan, program, arrangement or agreement providing bonus, incentive, deferred compensation, vacation, sick, stock purchase, stock option, severance, employment, consulting, change of control, fringe benefits or other compensation or benefits that is sponsored or maintained by Seller or any of its Affiliates (or pursuant to which Seller or any of its Affiliates have any liability) in which the Transferred Employees participate.

(i) "Business Day" means any day other than a Saturday, Sunday or other day on which commercial banks in New York, New York or London, United Kingdom are authorized or required by Law to close.

(j) "Capital Interests" means, with respect to any specified Person, any share of capital stock of, or other ownership, membership, partnership, joint venture or equity interest in, such specified

Person or any Indebtedness, subscription, put, call, option, warrant or other security, right (including any preemptive right) or entitlement of, or issued or granted by, such specified Person or any of its Affiliates that is convertible into, or exercisable or exchangeable for, or otherwise gives any other Person any right or entitlement to acquire, any share of capital stock of, or other ownership, partnership, joint venture or equity interest in, such specified Person, in all cases, whether vested or unvested and whether or not or subject to any other contingency.

(k) "CARES Act" means the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136) and any administrative or other guidance published with respect thereto.

(l) "Closing" has the meaning set forth in Section 1.2.

(m) "Closing Date" has the meaning set forth in Section 1.2.

(n) "Code" means the United States Internal Revenue Code of 1986.

(o) "Collateral Source" has the meaning set forth in Section 8.4(b).

(p) "Company" has the meaning set forth in the preamble to this Agreement.

(q) "Company Fundamental Representations" means, collectively, each of the representations and warranties set forth in Section 2.1 (*Organization and Authorization*), Section 2.2 (*Non-Contravention*), Section 2.3 (*Capitalization; Subsidiaries*), Section 2.6 (*No Operations, Assets or Liabilities*), Section 2.8 (*Taxes*) and Section 2.24 (*Fees and Expenses*).

(r) "Company Intellectual Property" means (i) all of the Intellectual Property rights owned by the Company or licensed to the Company, and (ii) practiced only in the conduct of the Business.

(s) "Company Transaction Documents" has the meaning set forth in Section 2.1(a).

(t) "Confidentiality Agreement" means that certain Confidentiality Agreement, dated June 21, 2021, as amended on September 27, 2021, October 21, 2021 and December 29, 2021 by and between Seller and Oxford Biomedica (UK) Limited.

(u) "Contract" means any agreement, contract, license, sublicense, lease, sublease, guarantee, purchase order, letter of credit, undertaking, letter agreement, instrument, document, note, bond, mortgage, pledge, security interest or other legally binding commitment or obligation, whether oral or written, each as amended or modified from time to time.

(v) "Contribution" has the meaning set forth in the recitals to this Agreement.

(w) "Contribution Agreement" has the meaning set forth in the recitals to this Agreement.

(x) "COVID-19" means SARS-CoV-2 or COVID-19, and any evolutions, mutations or variants thereof or related or associated epidemics, pandemic or disease outbreaks.

(y) "COVID-19 Measures" means any quarantine, "shelter in place," "stay at home," workforce reduction, social distancing, shut down, closure, sequester, in each case resulting from any Laws, orders, directives, guidelines or recommendations by any Governmental Authority, including the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), in connection with or in response to COVID-19, including the CARES Act.

(z) "Data Room" means the online data room entitled "Homology" hosted by Intralinks.

(aa) "Deductible" has the meaning set forth in Section 8.4(a).

(bb) "Disclosure Schedules" has the meaning set forth in Article II.

(cc) "Divestiture Action" means any of the following actions (i) selling or otherwise disposing of, or holding separate and agreeing to sell or otherwise dispose of, assets, categories of assets or businesses of the Company or Purchaser or their respective Subsidiaries, (ii) terminating existing relationships, contractual rights or obligations of the Company or Purchaser or their respective Subsidiaries; (iii) terminating any venture or other arrangement; (iv) creating any relationship, contractual rights or obligations of the Company or Purchaser or their respective Subsidiaries; or (v) effectuating any other change or restructuring of the Company or Purchaser or their respective Subsidiaries (and, in each case, entering into agreements or stipulating to the entry of any order or decree or filing appropriate applications with any Governmental Authority, in each case, pursuant to or under the HSR Act or other applicable antitrust laws and, in the case of actions by or with respect to the Company or its businesses or assets, consenting to such action by or with respect to the Company).

(dd) "Employee Matters Agreement" has the meaning set forth in the recitals to this Agreement.

(ee) "Enforceability Exceptions" means (i) applicable bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting creditors' rights generally and (ii) general equitable principles (whether considered in a proceeding in equity or at law).

(ff) "Environmental Law" means any judgment, decree, order, law, rule or regulation in each case, having the force and effect of law (including the common law) and pertaining to preservation or protection of the environment or natural resources, pollution, occupational health and safety, or governing the use, manufacture, generation, storage, handling, disposal, release, emission of, or exposure to, Hazardous Substances.

(gg) "Environmental Permit" means all permits, licenses and other authorizations required under any Environmental Law.

(hh) "Equity Issuance" has the meaning set forth in Section 1.1(b).

(ii) "Equity Transfer" has the meaning set forth in Section 1.1(a).

(jj) "ERISA" means the Employee Retirement Income Security Act of 1974, as amended.

(kk) "ESA Delivery Date" has the meaning set forth in Section 5.7.

(ll) "Facility" has the meaning set forth in the recitals to this Agreement.

(mm) "Facility Lease" means that certain Lease Agreement, dated as of December 21, 2017, by and between Patriots Park Owner, LLC, a Delaware limited liability company, as landlord, and Seller, as tenant, as amended by that First Amendment to Lease, dated February 8, 2019, as further amended by that Second Amendment to Lease dated March 15, 2019, and as further amended by that Third Amendment to Lease dated as of November 9, 2021.

(nn) "Family" means, with respect to an individual Person, (i) such individual's spouse and any former spouses, (ii) any other individual Person who is related to such individual or such individual's spouse (or any former spouse) within the second degree and (iii) any other individual Person who resides with such individual.

(oo) "Fraud" means a claim for Delaware common law fraud with respect to the making by a Party of any of the representations and warranties contained in Article II, Article III or Article IV; provided that "Fraud" shall not include any claim based on constructive knowledge, negligent misrepresentation, recklessness or similar theory.

(pp) "GAAP" means generally accepted accounting principles in the United States as in effect from time to time.

(qq) "Government Official" means (i) any officer or employee of any Governmental Authority, (ii) any Person acting in an official capacity on behalf of a Governmental Authority, (iii) any officer or employee of a Person that is majority or wholly owned by a Governmental Authority, (iv) any officer or employee of a public international organization, such as the World Bank or the United Nations, (v) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party or (vi) any candidate for political office.

(rr) "Governmental Authority" means any foreign, federal, state, local, county, municipal, provincial, multinational government or other governmental or quasi-governmental authority or regulatory board, court, tribunal, arbitrating body, governmental department, commission, board, body, self-regulating authority, bureau or agency, as well as any other instrumentality or entity designated to act for or on behalf of any of the foregoing.

(ss) "Guaranteed Obligations" has the meaning set forth in Section 9.1.

(tt) "Hazardous Substance" means (i) those substances defined in or regulated as hazardous or toxic (or terms of similar meaning and regulatory effect) under the following federal statutes and their state or provincial counterparts and all regulations thereunder: the Hazardous Materials Transportation Act, the Resource Conservation and Recovery Act, the Comprehensive Environmental Response, Compensation, and Liability Act, the Clean Water Act, the Safe Drinking Water Act, the Atomic Energy Act, the Federal Insecticide, Fungicide, and Rodenticide Act and the Clean Air Act; (ii) petroleum and petroleum products, including crude oil and any fractions thereof; (iii) natural gas, synthetic gas, and any mixtures thereof; (iv) polychlorinated biphenyls, asbestos and radon; (v) any other contaminant (including per- and polyflouroalkyl substances); and (vi) any substance, material or waste regulated by any federal, state, provincial, local or foreign Governmental Authority pursuant to any Environmental Laws.

(uu) "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

(vv) "Indebtedness" means, with respect to any Person, without duplication, and to the extent not paid prior to the Closing, all liabilities of such Person (i) for borrowed money or indebtedness issued or incurred in substitution or exchange for borrowed money, (ii) in respect of deferred purchase price for property (including pursuant to capitalized liability under all capital or finance leases (but not operating leases) of such Person, any earn-outs or other forms of contingent payments due for the acquisition of Capital Interests or assets), (iii) evidenced by any note, bond, debenture, mortgage or other debt instrument or debt security, (iv) by which such Person assures a creditor against loss (including contingent reimbursement obligations with respect to letters of credit), (v) secured by a Lien (other than Permitted Liens) on any assets and properties of such Person, (vi) to repay deposits or other amounts advanced by and owing to third parties, (vii) under conditional sale or other title retention agreements relating to property

acquired by such Person, (viii) owing, whether or not ultimately forgivable, under any COVID-19 legislation relief program, including the Paycheck Protection Program, (ix) for guarantees, sureties, bankers acceptances or similar obligations securing such indebtedness, with respect to any indebtedness, obligations, claim or liability of any other Person of a type described in clauses (i) through (viii) above, and (x) for all principal, accrued and unpaid interest, prepayment penalties, redemption premiums, call premiums, make-whole payments or similar fees, costs, expenses and penalties or other penalties and expenses which would be payable if such liability were paid in full as of the Closing Date (to the extent due and payable as of the Closing Date), unpaid fees and expenses, in each case, due with respect to any of the obligations of the type described in clauses (i) through (ix).

(ww) "Indemnified Parties" has the meaning set forth in Section 8.3.

(xx) "Indemnifying Party" has the meaning set forth in Section 8.5.

(yy) "Insurance Policies" has the meaning set forth in Section 2.19.

(zz) "Intellectual Property" means any and all of the following and all rights therein: (i) Know-How; (ii) inventions, discoveries, whether patentable or not, and all patents and patent applications therefor, including continuations, divisionals, continuations-in-part, renewals, extensions, reissues, reexaminations, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing, and all rights and priorities afforded under any Law with respect to any of the foregoing (collectively, "Patents") and similar or equivalent exclusive rights in inventions and designs; (iii) trademarks, service marks, trade dress, trade names, logos and other designations of origin, all registrations and applications for any of the foregoing, and all goodwill associated therewith and symbolized thereby, including all renewals of same; (iv) domain names and uniform resource locators, Internet Protocol addresses, social media accounts or other names, identifiers and locators associated with Internet addresses, sites and services; (v) copyrights and any other equivalent rights in published and unpublished original works of authorship (including rights in software to the extent it constitutes an original work of authorship) fixed in any tangible media, and all registrations and applications therefor, and all renewals, extensions, restorations, and reversions thereof, and the right to use, reproduce, display, perform, modify, enhance, distribute, and prepare derivative works of all works of authorship, and all other rights corresponding thereto throughout the world; (vi) rights in software and technical data, (vii) rights in databases, compilations of data and aggregated data; (viii) rights, benefits, and priorities afforded under applicable Law with respect to any of the foregoing, including all statutory and common law rights therein and thereto, (ix) all rights in any of the foregoing anywhere in the world to bring an action for past, present and future infringement, dilution, misappropriation or other impairment or violation of rights and to receive damages, proceeds or any other legal or equitable protections and remedies with respect to any of the foregoing, and (x) similar or equivalent rights to any of the foregoing anywhere in the world.

(aaa) "Inventory" means all inventories of raw materials, product packaging and labeling materials, supplies, work-in-process, goods in transit and finished goods and products owned by Seller and used primarily or held for use primarily in the Business.

(bbb) "IRS" means the United States Internal Revenue Service.

(ccc) "Judgment" has the meaning set forth in Section 7.1(b)(i).

(ddd) "Know-How" means any techniques, technology, Inventions, methods, know-how, data and results (including pharmacological, toxicological and non-clinical, pre-clinical, and clinical data and results), analytical and quality control data and results, regulatory documents, business and information, compositions of matter, cells, cell lines, assays, animal models, reagents and other physical, biological, or

chemical material, whether or not confidential or proprietary, confidential or proprietary business or technical information and Trade Secret and industrial secret rights that derive independent economic value, whether actual or potential, from not being known to other Persons, including in information pertaining or relating to inventions, discoveries, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, technology, techniques, designs, correspondence, computer programs, software documents, apparatus, results, strategies, regulatory documentation and submissions, and information pertaining to, or made in association with, filings with any Governmental Authority or patent authority, manufacturing and data descriptions, engineering, and other drawings and manuals, recipes, manufacturing processes, test processes, algorithms, models, methodologies, designs, lab journals, notebooks, schematics, plans, blue prints, research and development reports, technical assistance, engineering and technical data, design and engineering specifications, and similar materials recording or evidencing expertise or information, including those related to processes under development, customer lists, suppliers lists, pricing and cost information and business and marketing plans, market data, financial data or descriptions, databases, data collections, data sets, curated data content, and data layers, devices, assays, specifications, physical, chemical and biological materials and compounds, compound libraries, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable and whether or not confidential or proprietary, and all rights to limit the use or disclosure of any of the foregoing.

(eee) "knowledge" means with respect to Seller, the actual knowledge of each of the individuals identified on Schedule 10.10(eee), or the knowledge any of such individuals would reasonably be expected to have after reasonable inquiry.

(fff) "Landlord Consent" has the meaning set forth in Section 5.6(c).

(ggg) "Law" means any foreign, federal, state and local statute, law (including civil and common law), act, ordinance, rule, regulation, constitution, treaty, code, rule, regulation and any Order.

(hhh) "Lease Assignment" has the meaning set forth in the recitals to this Agreement.

(iii) "Lien" means any hypothecation, claim, mortgage, pledge, security interest, attachment, encumbrance, lien (statutory or otherwise), interest, deed of trust, easement, preference, priority, lease, conveyance of any right, Tax or charge of any kind (including any agreement to give any of the foregoing) or nature, but excluding any non-exclusive license granted with respect to any Intellectual Property.

(jjj) "License and Patent Management Agreement" has the meaning set forth in the recitals to this Agreement.

(kkk) "LLC Agreement" has the meaning set forth in the recitals to this Agreement.

(lll) "Loss" means, without duplication, any and all claims, damages, losses (including lost profits, consequential damages, special damages and incidental or indirect damages), penalties, judgments, settlements, payments, obligations, fines, interest, costs and expenses (including the reasonable out-of-pocket costs and expenses of attorneys incurred in the defense thereof), but excluding punitive or exemplary damages (other than to the extent that any such damages are actually awarded pursuant to an Order against, and actually paid by, an Indemnified Party pursuant to a Third Party Claim).

(mmm) "Material Adverse Effect" means any event, circumstance, state of facts, development, condition, occurrence, change or effect that, individually or in the aggregate with any other event, circumstance, state of facts, development, condition, occurrence, change or effect, has had, or would

reasonably be expected to have, a material adverse effect on (i) the Business or (ii) the ability of the Company or Seller to perform its obligations under this Agreement or to consummate the transaction contemplated hereby, other than compliance with Section 5.1 of this Agreement and provided that this clause (ii) shall not diminish the effect of, and shall be disregarded for purposes of, the representations and warranties contained in Sections 2.2 and 3.2; provided, however, that, for purposes of clause (i), any adverse change, event or effect arising from or related to any of the following shall not be taken into account in determining whether there has been a Material Adverse Effect: (A) the execution, delivery, public announcement, pendency or occurrence of this Agreement or any of the transactions contemplated hereby or any actions taken in compliance herewith, including the impact thereof on the relationships of customers, suppliers, distributors, consultants, employees or independent contractors or other third parties with which the Business has any relationship; (B) conditions affecting the industries in which the Business operates or participates, the political conditions of the United States or any foreign country in any location where the Business operates, the U.S. economy or financial markets or any foreign markets or any foreign economy or financial markets in any location where the Business operates, including changes in interest rates; (C) any change in GAAP or in accounting standards, or applicable Laws (or the enforcement, implementation or interpretation thereof); (D) any acts of God, calamities, acts of war (whether or not declared), terrorism or military action, epidemics or pandemics (including COVID-19), national or international political, general economic, social conditions or changes in the financial or capital markets (or any escalation or worsening of any of the foregoing); (E) any failure, in and of itself, by the Business to meet any projections, forecasts, or revenue or earnings predictions for any period (it being understood that the facts and circumstances giving rise or contributing to such failure may be taken into account in determining whether there has been a Material Adverse Effect); or (F) actions taken by or at the written direction of Purchaser or any of its Affiliates; provided that with respect to any change, event or effect described in the foregoing clauses (B) through (D), such change, event or effect shall be taken into account to the extent such change, event or effect adversely affects the Business disproportionately relative to other comparable companies operating in the industry in which Seller operates.

(nnn) "Material Contracts" has the meaning set forth in Section 2.12(a).

(ooo) " Non-Assignable Asset" means any Transferred Asset that is a Contract pursuant to which an attempted assignment of such Contract, without the consent of, or other action by, any third party, would constitute (with or without notice, lapse of time or both) a violation of applicable Law, a breach under such Contract or adversely affect in any material respect the rights of Seller or the Company, as applicable, thereunder, or the Business.

(ppp) " Order" means any decree, injunction, stay, judgment, determination, order, ruling, decision, stipulation, assessment or writ (whether judicial, executive, legislative, administrative or arbitral) entered by or with any Governmental Authority.

(qqq) "Outside Deadline" has the meaning set forth in Section 7.1(b)(ii).

(rrr) "Parent Guaranty" has the meaning set forth in Section 9.1.

(sss) "Parent Guarantor" has the meaning set forth in the preamble to this Agreement.

(ttt) "Party" has the meaning set forth in the preamble to this Agreement.

(uuu) "Patent Assignment Agreement" has the meaning set forth in the recitals to this Agreement.

(vvv) "Patents" has the meaning set forth in the definition of "Intellectual Property."

(www) "Permits" means all permits, licenses, orders, franchises and other rights and privileges of all Governmental Authorities necessary for the operation of the Business as presently conducted.

(xxx) "Permitted Liens" means, with respect to the Company and the Business, (i) statutory liens of landlords, liens of carriers, warehousepersons, mechanics, workmen, repairmen and material persons or other like liens incurred in the ordinary course of business, (ii) liens incurred or deposits made in connection with workers' compensation, unemployment insurance and other similar types of social security programs, in each case, in the ordinary course of business, (iii) imperfections of title, easements, covenants, rights-of-way, restrictions and other similar charges or encumbrances, in each case, which do not materially interfere with the ordinary conduct of the Business and do not, individually or in the aggregate, materially impair the continued use, occupancy and operation of the Facility as currently used, occupied and operated by the Business as of the date of this Agreement, (iv) liens for Taxes not yet due and payable, (v) liens for assessments and other governmental charges not yet due and payable, (vi) zoning, building codes and other land use Laws regulating the use or occupancy of real property or the activities conducted thereon which are imposed by any Governmental Authority having jurisdiction over such real property which are not violated by the current use or occupancy of such real property or the operation of the Business or any violation of which would not have a material adverse effect on the Business, (vii) Liens on the real property encumbered by the Facility Lease and Liens created by or consented to by the landlord under the Facility Lease and (viii) Liens described on Schedule 10.10(xxx)(viii).

(yyy) " Person" means any individual, corporation, partnership, joint venture, association, trust, unincorporated organization, or other legal entity, or any Governmental Authority or department, agency or political subdivision thereof.

(zzz) "Pre-Closing Tax Period" means any Tax period ending on or before the Closing Date and that portion of any Straddle Period ending on the Closing Date.

(aaaa) "Pre-Closing Taxes" means (i) any Taxes to the extent arising out of the Business or the Transferred Assets for any Pre-Closing Tax Period, determined in accordance with Section 5.8(d), (ii) any Taxes of the Company for any Pre-Closing Tax Period, determined in accordance with Section 5.8(d), (iii) to the extent not described under clauses (i) or (ii), any and all Taxes of Seller or any Affiliate of Seller for any Pre-Closing Tax Period, including Taxes (other than Transfer Taxes described in clause (v)) incurred by Seller or any Affiliate of Seller in connection with the consummation of transactions contemplated by this Agreement, (iv) any and all Taxes arising from an obligation under any Tax sharing, Tax allocation, Tax indemnity or similar agreements with respect to the Business or the Transferred Assets entered into on or prior to the Closing Date, and (v) any Transfer Taxes allocated to Seller pursuant to Section 1.4.

(bbbb) "Purchase Price" has the meaning set forth in the recitals to this Agreement.

(cccc) "Purchased Units" has the meaning set forth in the recitals to this Agreement.

(dddd) "Purchaser" has the meaning set forth in the preamble to this Agreement.

(eeee) "Purchaser Fundamental Representations" means the representations and warranties set forth in each of Section 4.1 (*Organization and Authorization*), Section 4.2 (*Non-Contravention*) and Section 4.10 (*Fees and Expenses*).

(ffff) "Purchaser Indemnified Parties" has the meaning set forth in Section 8.2.

(gggg) "Purchaser Representations" has the meaning set forth in Section 3.7.

(hhhh) "Purchaser Transaction Documents" has the meaning set forth in Section 4.1.

(iiii) "Quality Agreement" has the meaning set forth in the recitals to this Agreement.

(jjjj) "Receiving Party" has the meaning set forth in Section 5.6(a).

(kkkk) " Regulatory Requirements" means Laws applicable to the manufacturing, processing, packing, labeling, holding, and distribution of drugs or biological products, as applicable to the Business, including without limitation: (i) the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and the rules and regulations promulgated thereunder; (ii) the Public Health Service Act (42 U.S.C. § 201 et seq.) and the rules and regulations promulgated thereunder; and (iii) any analogous requirements of any Governmental Authority that regulates the manufacturing, processing, packing, labeling, holding or distribution of drugs or biological products manufactured by the Company.

(llll) " Representative" means, with respect to any specified Person, any director, manager, officer, employee, agent, attorney, advisor including any financial advisor or other representative of such specified Person.

(mmmm) "SEC" means the Securities and Exchange Commission.

(nnnn) "Seller" has the meaning set forth in the preamble to this Agreement.

(oooo) "Seller and Company Representations" has the meaning set forth in Section 2.26.

(pppp) "Seller Fundamental Representations" means the representations and warranties set forth in each of Section 3.1 (*Organization and Authority*), Section 3.2 (*Non-Contravention*), Section 3.3 (*Title to Transferred Units*) and Section 3.6 (*Fees and Expenses*).

(qqqq) "Seller Indemnified Parties" has the meaning set forth in Section 8.3.

(rrrr) "Seller Representations" has the meaning set forth in Section 4.11.

(ssss) "Seller Transaction Documents" has the meaning set forth in Section 3.1.

(tttt) "Straddle Period" means any Tax period beginning before or on and ending after the Closing Date.

(uuuu) "Sublease Agreement" has the meaning set forth in the recitals to this Agreement.

(vvvv) "Subscribed Units" has the meaning set forth in the recitals to this Agreement.

(wwww) "Subscription Price" has the meaning set forth in the recitals to this Agreement.

(xxxx) "Subsidiary" means, with respect to any specified Person, any other Person (other than an individual) (i) the accounts of which would be consolidated with those of such specified Person in such specified Person's consolidated financial statements if such financial statements were prepared in accordance with GAAP or (ii) more than 50% of the outstanding Capital Interests having (in the absence of contingencies) ordinary voting power to elect a majority of the board of directors or other

managing body of such Person of which are owned or controlled, directly or indirectly through one or more intermediaries, by such specified Person.

(yyyy) "Supply Agreement" has the meaning set forth in the recitals to this Agreement.

(zzzz) "Tax Contest" has the meaning set forth in Section 5.8(e).

(aaaaa) "Tax Returns" means federal, state, local, foreign or other tax returns, declarations, reports, claims for refunds, information returns or statements relating to Taxes filed or required to be filed with any Taxing Authority, together with any schedule, attachment, or amendment thereof.

(bbbbb) " Taxes" means federal, state, local, foreign or other taxes, fees, levies, duties, tariffs, imposts, and like assessments or charges of whatever kind in the nature of a tax, including taxes or other similar charges on, measured by or with respect to income, gross receipts, branch profits, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall, profits, environmental, custom duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, escheat, unclaimed property, sales, use, transfer, registration, ad valorem, value added, goods and services, alternative or add-on minimum or estimated tax, including any interest, penalty, or addition thereto, and any penalties, interest or similar payments and fees imposed in respect of a failure to file any Tax Returns in a timely, correct or complete way.

(ccccc) "Taxing Authority" means any Governmental Authority responsible for the administration, assessment, collection or regulation of any Taxes or Tax Returns.

(ddddd) "Third Party Claim" has the meaning set forth in Section 8.5(a).

(eeeee) "Third Party Consent" has the meaning set forth in Section 5.6(a).

(fffff) "Trade Secret" means information, such as a formula, pattern, compilation, program, device, method, technique, or process, that derives actual or potential independent economic value from not being generally well known to, and not being readily ascertainable by proper means, by another Person who can obtain economic value from its disclosure or use, and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

(ggggg) "Transaction Documents" means this Agreement, the LLC Agreement, the License and Patent Management Agreement, the Transitional Services Agreement, the Contribution Agreement, the Supply Agreement, the Lease Assignment, the Sublease Agreement, the Employee Matters Agreement, the Patent Assignment Agreement, the Quality Agreement and any other agreements, documents and instruments contemplated by this Agreement.

(hhhhh) "Transfer Price" has the meaning set forth in the recitals to this Agreement.

(iiiii) "Transfer Taxes" has the meaning set forth in Section 1.4.

(jjjjj) "Transferred Assets" has the meaning set forth in the Contribution Agreement.

(kkkkk) "Transferred Employee" has the meaning set forth in the Employee Matters Agreement.

(lllll) "Transferred Liabilities" has the meaning set forth in the Contribution Agreement.

(mmmmm) "Transferred Patents" has the meaning set forth in Section 2.11(b).

(nnnnn) "Transferred Units" has the meaning set forth in the recitals to this Agreement.

(ooooo) "Transferring Party" has the meaning set forth in Section 5.6(b).

(ppppp) "Transitional Services Agreement" has the meaning set forth in the recitals to this Agreement.

10.11 **Confidentiality; Publicity.** Prior to the Closing Date, no press release or any public disclosure, either written or oral, of this Agreement, the transactions contemplated by this Agreement or negotiations related thereto shall be made by Seller, Purchaser, the Company or any of their respective Representatives without the express prior written consent of Purchaser, the Company and Seller, except to the extent any such Party determines, after consultation with outside legal counsel, such release or public disclosure is required by any applicable Law or any listing agreement with, or rule or regulation of, any securities exchange or association on which the securities of Seller or Purchaser, as applicable, are listed, in which case the Party proposing to issue such press release or make such public disclosure shall consult with the other Party about, and, to the extent permitted by applicable Law, allow the other Party reasonable time (taking into account the circumstances) to comment on, such release or public disclosure in advance of such issuance, and the Party required to make the release or public disclosure will consider such comments in good faith. Unless consented to by Seller and Purchaser, as applicable, in advance or as required by Law (in which case the Party required to make such disclosure will consult with the other Party a reasonable time prior to making such disclosure and will consider in good faith any comments made by the other Party to such disclosure), the Parties shall keep this Agreement strictly confidential and may not make any disclosure of this Agreement to any person or individual other than to their Affiliates. If a Party or its Affiliates, based on the advice of their counsel, determines that this Agreement or any of the other Transaction Documents must be publicly filed with a Governmental Authority, then such Party or its applicable Affiliate, prior to making such filing, shall provide the other Parties and their respective counsel with a redacted version of this Agreement or the applicable Transaction Document that it intends to file, and will consider in good faith any comments provided by such Party or its counsel and use commercially reasonable efforts to ensure the confidential treatment by such Governmental Authority of those provisions specified by such Party or its counsel for redaction and confidentiality.

10.12 **Remedies.** Notwithstanding Section 8.6, the Parties agree that (a) irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached, and (b) accordingly, each of the Parties shall be entitled, without the necessity of posting bond or other undertaking, to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in accordance with this Agreement, this being in addition to any other remedy to which such Party is entitled at law or in equity.

10.13 **Interpretation**. For purposes of this Agreement, the following rules of interpretation apply:

(a) *Descriptive Headings*. The headings of the sections and paragraphs of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

(b) *Calculation of Time Period.* Except as otherwise provided herein, when calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period is excluded. If any period

is to be measured in Business Days and the last day of such period is not a Business Day, the period in question ends on the next succeeding Business Day.

(c) *Currency; Financial Terms*. Any reference in this Agreement to "$" means U.S. dollars. Financial terms used herein shall have the meanings given to such terms under GAAP unless otherwise specified herein.

(d) *Section and Similar References*. Unless the context otherwise requires, all references in this Agreement to any "Annex," "Section," "Schedule" or "Exhibit" are to the corresponding Annex, Section, Schedule or Exhibit of this Agreement.

(e) *References to Contracts and Laws*. References herein to any Contract or other document shall be deemed to be references to such Contract or other document as amended, restated, supplemented or otherwise modified from time to time (subject to any restrictions on amendment, restatement, supplementation or modification thereof set forth therein). References herein to any statute, rule or regulation shall be deemed to be references to such statute, rule or regulation as amended or supplemented from time to time, including through the promulgation of rules or regulations thereunder.

(f) *Mutual Drafting*. The Parties have participated jointly in the negotiation and drafting of this Agreement and have been represented by their own legal counsel in connection with the transactions contemplated hereby, with the opportunity to seek advice as to their legal rights from such legal counsel. In the event that any ambiguity or question of intent or interpretation arises, this Agreement is to be construed as jointly drafted by the Parties and no presumption of burden of proof is to arise favoring or disfavoring any Party by virtue of the authorship of any provision hereof or by reason of the extent to which any such provision is inconsistent with any prior draft hereof.

(g) *Counterparts*. This Agreement may be executed in two or more counterparts and by the different parties hereto on separate counterparts, each of which when so executed and delivered shall be an original, but all of which together shall constitute one and the same instrument.

(h) *Electronic Mail*. The exchange of signature pages to this Agreement (in counterparts or otherwise) by electronic mail transmission, .pdf scan or other electronic transmission (including via www.docusign.com) shall be sufficient to bind the parties to the terms and conditions of this Agreement.

(i) *Other Definitional and Interpretive Matters*. Unless otherwise expressly provided herein, for purposes of this Agreement, the following rules of interpretation shall apply:

(i) Exhibits/Schedules/Annexes. The Exhibits, Schedules and Annexes to this Agreement are hereby incorporated and made a part hereof and are an integral part of this Agreement. All Exhibits, Schedules and Annexes attached hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. The Company may, at its option, include in the Disclosure Schedules items that are not material in order to avoid any misunderstanding, and such inclusion, or any references to dollar amounts, shall not be deemed to be an acknowledgement or representation that such items are material, to establish any standard of materiality or to define further the meaning of such terms for purposes of this Agreement or otherwise. Any capitalized terms used in any Exhibit, Schedule or Annex but not otherwise defined therein shall be defined as set forth in this Agreement. The inclusion of information in the Disclosure Schedules will not be construed as an admission to any third party of any liability or obligation of the Company or Seller.

(ii) Gender and Number. Any reference in this Agreement to gender shall include all genders, and words imparting the singular number shall include the plural and vice versa.

(iii) "License." The word "license" (regardless of the tense when used as a verb or single or plural form when used as a noun) shall include the term "sublicense" (and its corresponding forms) and vice versa.

(iv) "Herein." The words such as "herein," "hereinafter," "hereof," and "hereunder" and any other words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole (including all of the Exhibits, Schedules and Annexes to this Agreement) and not merely to a particular term or provision of this Agreement or subdivision in which such words appear unless the context otherwise requires.

(v) "Including"; "to the Extent." The word "including" or any variation thereof means "including, without limitation," and shall not be construed to limit any general statement that it follows to the specific or similar items or matters immediately following it. The word "extent" in the phrase "to the extent" shall mean the degree to which a subject or other thing extends, and such phrase shall not mean simply "if."

(vi) "Ordinary Course of Business." The words "ordinary course," "ordinary course of business" or words of similar import shall be deemed to mean solely, with respect to the operation of the Business, "ordinary course of business consistent with past practice, including (as applicable) as to scope, duration, amount or other metric" as the same has been or may be modified for any COVID-19 Measures.

(vii) "Made Available." The words "made available," "furnished," "delivered," or words of similar import with respect to any item made available by Seller or the Company shall mean delivered or posted at least one (1) day prior to the date of this Agreement in the Data Room.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first written above.

SELLER:

HOMOLOGY MEDICINES, INC.

By: /s/ Arthur O. Tzianabos
Name: Arthur O. Tzianabos
Title: President and Chief Executive Officer

THE COMPANY:

ROADRUNNER SOLUTIONS LLC

By: /s/ Tim Kelly
Name: Tim Kelly
Title: Chief Executive Officer

PURCHASER:

OXFORD BIOMEDICA (US), INC.

By: /s/ Stuart Paynter
Name: Stuart Paynter
Title: Chief Financial Officer

PARENT GUARANTOR:

OXFORD BIOMEDICA PLC

By: /s/ Stuart Paynter
Name: Stuart Paynter
Title: Chief Financial Officer

EXHIBIT A

Form of Contribution Agreement

See attached.

EXHIBIT B

Form of Patent Management and License Agreement

See attached.

EXHIBIT C

Form of Supply Agreement

See attached.

EXHIBIT D

Form of Transitional Services Agreement

See attached.

EXHIBIT E

Form of Lease Assignment

See attached.

EXHIBIT F

Form of Sublease Agreement

See attached.

EXHIBIT G

Form of Employee Matters Agreement

See attached.

EXHIBIT H

Form of Patent Assignment Agreement

See attached.

EXHIBIT I

Form of Quality Agreement

See attached.

EXHIBIT J

Form of LLC Agreement

See attached.

Oxford Biomedica (US), Inc.
Windrush Court
Transport Way
Watlington Road
Oxford OX4 6LT

March 10, 2022

Homology Medicines, Inc.
One Patriots Park
Bedford, Massachusetts 01730
Attention: Dr. Paul Alloway, Senior Vice President and General Counsel

with a copy to:

Latham & Watkins LLP
200 Clarendon Street, 27th Floor
Boston, Massachusetts 02116
Attention: Peter N. Handrinos and Matthew W. Goulding
Email: Peter.Handrinos@lw.com, Matthew.Goulding@lw.com

VIA EMAIL

RE: Amendment No. 1 to Equity Securities Purchase Agreement

Dear Seller:

Reference is hereby made to the Equity Securities Purchase Agreement, dated as of January 28, 2022 (the "Purchase Agreement"), by and among Homology Medicines, Inc., a Delaware corporation ("Seller"), Roadrunner Solutions LLC, a Delaware limited liability company (the "Company"), Oxford Biomedica (US), Inc., a Delaware corporation ("Purchaser"), and, solely for the purposes of Article IX thereof, Oxford Biomedica plc, a public company organized under the laws of England and Wales ("Parent Guarantor"). Capitalized terms used but not otherwise defined in this amendment shall have the meanings ascribed to them in the Purchase Agreement.

1. Pursuant to Section 10.2 of the Purchase Agreement, the Parties agree to amend and restate Section 8.2 of the Purchase Agreement in its entirety as follows:

8.2 Indemnification for the Benefit of Purchaser. Subject to the other provisions of this Article VIII, from and after the Closing, Seller shall indemnify and hold harmless Purchaser and its Affiliates (other than the Company and any subsidiary of the Company) and their respective directors, managers, officers, employees and agents (collectively, the "Purchaser Indemnified Parties") from and against any Losses that such Purchaser Indemnified Party suffers or incurs to the extent resulting from or arising out of any of the following:

(a) any breach or inaccuracy of any of the Seller and Company Representations or any of the Seller Representations or any representation or warranty made by Seller or the Company in any certificate or writing delivered by the Company or Seller in connection herewith (in each

case, disregarding all qualifications as to materiality, the words "material," "materiality" and Material Adverse Effect);

(b) any failure by the Company or Seller to perform or comply in all material respects with their respective covenants, obligations or agreements contained in this Agreement (other than with respect to any covenants to be performed at or prior to the Closing, which, for the avoidance of doubt, shall expire and have no further force or effect as of the date that is twelve (12) months after the Closing Date);

(c) any Excluded Liability (as defined in the Contribution Agreement);

(d) any Pre-Closing Taxes; or

(e) Seller's proportionate percentage of any payments made by Parent Guarantor in respect of the Lease Guaranty, dated as of March 10, 2022, in favor of Patriots Park Owner, LLC, which such proportionate percentage shall be equal to Seller's ownership interest percentage in the Company at the time a claim against Parent Guarantor under the Lease Guaranty is made.

2. Except as modified by this letter, the Purchase Agreement shall remain unmodified and in full force and effect.

[*Signature page follows*]

Very truly yours,

OXFORD BIOMEDICA (US), INC.

By: /s/ Stuart Paynter
Name: Stuart Paynter
Title: Chief Financial Officer

[*Signature Page to Amendment No. 1 to Equity Securities Purchase Agreement*]

ACCEPTED AND AGREED AS OF
THE DATE FIRST WRITTEN ABOVE:

HOMOLOGY MEDICINES, INC.

By: /s/ Arthur O. Tzianabos
Name: Arthur O. Tzianabos
Title: President and Chief Executive Officer

ROADRUNNER SOLUTIONS LLC

By: /s/ Tim Kelly
Name: Tim Kelly
Title: Chief Executive Officer

OXFORD BIOMEDICA PLC

By: /s/ Stuart Paynter
Name: Stuart Paynter
Title: Chief Financial Officer

Exhibit 10.25

CONTRIBUTION AGREEMENT

THIS CONTRIBUTION AGREEMENT (this "Agreement") is made and entered into as of March 10, 2022, by and between Homology Medicines, Inc., a Delaware corporation (the "Assignor"), and Roadrunner Solutions LLC, a Delaware limited liability company (the "Assignee"). The Assignor and the Assignee are each referred to herein as a "Party" and collectively referred to herein as the "Parties." Capitalized terms used but not defined herein shall have the respective meanings given to them in that certain Equity Securities Purchase Agreement, dated as of January 28, 2022 (the "Purchase Agreement"), by and among the Assignor, the Assignee, Oxford Biomedica (US), Inc., a Delaware corporation ("Purchaser"), and Oxford Biomedica plc, a public company organized under the laws of England and Wales.

RECITALS

WHEREAS, as of the date hereof, the Assignor is engaged, in part, in the business of manufacturing of adeno-associated virus vectors for use in gene therapy or gene editing products (the "Business");

WHEREAS, the Assignor conducts the Business primarily at a certain facility located at One Patriots Park, Bedford, Massachusetts 01730 (the "Facility"), which the Assignor leases pursuant to the Facility Lease;

WHEREAS, prior to the Closing, (a) the Assignor will assign and transfer to the Assignee the Transferred Assets (as defined below), and the Assignee will assume from the Assignor, and agrees to pay, perform and discharge when due, the Transferred Liabilities (as defined below) and (b) in exchange therefor, the Assignee will issue to the Assignor 175,000 of the Assignee's units of limited liability company interest (the "Units," and the transactions described in this Recital, the "Contribution");

WHEREAS, in connection with the Contribution, and at the Closing, the Assignor and the Assignee will enter into (a) a license and patent management agreement (the "License and Patent Management Agreement"), pursuant to which the Assignee will grant licenses under certain intellectual property to the Assignor and the Assignor and the Assignee will cooperate in the management of the Transferred Patents, (b) a manufacturing and supply agreement (the "Supply Agreement"), pursuant to which the Assignee will manufacture and supply Products (as defined in the Supply Agreement) to the Assignor, (c) a transitional services agreement (the "Transitional Services Agreement"), pursuant to which (i) the Assignor will perform certain Services (as defined in the Transitional Services Agreement) and (ii) the Assignee will perform certain services for the benefit of the Assignor, (d) a lease assignment, pursuant to which the Assignor will assign all of its right, title and interest in, to and under the Facility Lease to the Assignee, (e) a sublease agreement, pursuant to which the Assignee will sublease certain premises of the Facility to the Assignor as further described therein, (f) an employee matters agreement, pursuant to which the Parties will agree to allocate certain liabilities and obligations relating to employees associated with the Business, (g) a patent assignment agreement, evidencing the recorded transfer of certain Patent rights from the Assignor to the Assignee as set forth therein, and (h) a quality agreement, pursuant to which the Assignee will comply with certain quality requirements in connection with the manufacturing activities to be performed under the Supply Agreement; and

WHEREAS, at the Closing, the Assignee, Purchaser and the Assignor will enter into an amended and restated limited liability company agreement of the Assignee, which shall, among other things, set forth ongoing rights and obligations of the parties thereto with respect to the governance of the Assignee.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements set forth below, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I
CONTRIBUTION AND ASSIGNMENT

I.1 **Assignment and Assumption of Transferred Assets**.

(a) Subject to the provisions of this Agreement, the Assignee shall accept from the Assignor, and the Assignor shall assign, transfer and convey to the Assignee, all of the Assignor's rights, title and interests of any kind in and to the Transferred Assets as of the Effective Time. "Transferred Assets" means, collectively, all assets of the Assignor primarily used or held for use in the Business (other than the Excluded Assets (as defined below)), and shall include, but not be limited to:

(i) all Inventory of the Assignor or its Affiliates on the Closing Date that is used or held for use solely in the Business, including Inventory of GMP and product and process development raw materials and other laboratory materials (excluding, for the avoidance of doubt, product and process development raw materials and other laboratory materials primarily used or held for use by the Assignor for the research, development or manufacturing of any AAVHSC vectors controlled by the Assignor immediately prior to the Closing but that are not necessary or useful for manufacturing other AAV vectors), including that which is listed on Schedule 1 hereto under the section titled "Inventory";

(ii) the Facility Lease and any subleaseholds and other interests of the Assignor and its Affiliates in real property relating to the Business, as set forth on Schedule 1 hereto under the section titled "Lease," in each case, together with the right, title and interest in and to all buildings, improvements and fixtures thereon and all other appurtenances thereto;

(iii) all fixtures, machinery, equipment, furniture, office equipment, communications equipment, computers, electronic data process equipment, tangible tools, spare and replacement parts and other tangible person property primarily relating to the Business, including any equipment or machinery used in the event of an unexpected disruption of operations, including those as set forth on Schedule 1 hereto under the section titled "Fixed Assets" (collectively, "Personal Property");

(iv) all rights to Intellectual Property, including Know-How and Trade Secrets, but excluding Patents, that are necessary or useful for manufacturing or testing AAV vectors or performing manufacturing process development therefor, including those as set forth on Schedule 1 hereto under the section titled "Intellectual Property";

(v) an undivided one-half interest in Assignor's entire right, title and interest in and to all pending Patent applications as set forth on Schedule 1 hereto under the section titled "Intellectual Property" ("Transferred Patents"), the management of which shall be set forth under the License and Patent Management Agreement;

(vi) all software primarily used or held for use in the Business by the Assignor or any of its Affiliates that is owned by the Assignor or any of its Affiliates and integrated with (A) the equipment listed in Section I.A(a)(iii) or (B) the Facility;

(vii) all Contracts, leases or subleases of Personal Property, leases or subleases of real property in which the Assignor or any of its Affiliates is the lessor or sublessor, licenses, agreements, purchase orders, statements of work and other legally binding arrangements, whether written or oral, to

which the Assignor or any of its Affiliates is a party or by which any other Transferred Asset is bound that, in each case, relate primarily to the Business, including those as set forth on Schedule 1 hereto under the section titled "Agreements";

(viii) all rights, claims and credits, including all guarantees, warranties, indemnities and similar rights, in favor of the Assignor or any of its Affiliates, to the extent relating primarily to the Business, any Transferred Asset or any Transferred Liability;

(ix) all rights to causes of action, lawsuits, judgments, claims and demands primarily relating to the Business or the Transferred Assets;

(x) all books, records, files, documentation, correspondence (including e-mail), lists, research and other materials primarily relating to the Business or the Transferred Assets, including, but not limited to, standard operating procedures, quality system records and forms, analytical test methods, validation protocols and reports, master batch records, risk management reports, audit reports, training materials, engineering documents (including specifications and drawings), hygiene and safety consulting documents, process development documents, manuals, third party customer and supplier correspondence, records necessary to exhibit compliance with good manufacturing practice requirements, materials submitted to the relevant Governmental Authority for the granting and maintenance of Permits, Environmental Permits and all other documents, books, papers and records (in all cases, in any form or medium) of the Assignor or any of its Affiliates, including those as set forth on Schedule 1 hereto under the section titled "Books and Records";

(xi) all certificates, licenses, Permits, authorizations, concessions, registrations, franchises, consents and approvals from Governmental Authorities, including the Environmental Permits, of the Assignor or any of its Affiliates that are primarily used or held for use in the Business or are necessary for the maintenance and operation of the Facility, including those as set forth on Schedule 1 hereto under the section titled "Governmental Approvals"; and

(i) all prepaid expenses and deposits to the extent arising primarily out of, or primarily relating to, the operation of the Business.

For the avoidance of doubt, to the extent any of the foregoing assets in clause (x) above embodies the Assignor's Intellectual Property that (1) does not constitute Transferred Assets or (2) constitutes Excluded Assets, the transfer of assets in accordance with this Section 1.1 shall not operate to transfer or assign, and as between the Parties, the Assignor shall retain sole ownership of, such Intellectual Property.

(c) "Excluded Assets" means, collectively, those assets set out on Schedule 2 hereto.

I.2 **Assumption of Transferred Liabilities; Excluded Liabilities**. Effective as of the Effective Time, the Assignee shall assume and hereby agrees to pay, perform, discharge when due and be liable for all of the Assignor's duties, obligations, liabilities, interests and commitments of any kind under, arising out of or relating to the Transferred Assets, but only to the extent that such duties, obligations, liabilities, interests and commitments relate to any duties, obligations, liabilities, interests and commitments whose benefits accrue to the Assignee from and after the Effective Time and are not attributable to any breach, default or violation on or prior to the Effective Time (collectively, the "Transferred Liabilities"). For the avoidance of doubt, Transferred Liabilities (i) will not include any accounts payable existing at the Effective Time, but, subject to the following sentence, (ii) will include amounts for which the Assignee may be obligated pursuant to the Contracts or accounts payable listed on Schedule 1 hereto under the section titled "Agreements" or Contracts entered into by the Company pursuant to Section 5.6(a) of the Purchase Agreement, provided that the goods or services associated with such Contracts or accounts payable are

delivered to, or performed for, the Assignee following the Effective Time. Other than the Transferred Liabilities, the Assignee shall not, by virtue of this Agreement, assume any liabilities or obligations of the Assignor or its Affiliates of any kind, whether known or unknown, contingent, matured or otherwise, whether currently existing or hereinafter created (individually an "Excluded Liability" and collectively the "Excluded Liabilities"). For purposes of Section 8.2 of the Purchase Agreement, "Excluded Liability" shall have the meaning set forth herein.

I.3 **Consideration**. As consideration for the Contribution, the Assignee agrees to issue to the Assignor the Units.

I.4 **Closing Date**. The closing of the Contribution shall take place remotely (by e-mail, teleconference or videoconference and wire transfer, as applicable), immediately prior to the consummation of the Closing. The time at which the closing of the Contribution occurs is referred to herein as the "Effective Time."

I.5 **Effective Time Deliveries**.

(a) At the Effective Time, the Assignor shall deliver, or cause to be delivered, to the Assignee:

(i) a bill of sale, in form and substance reasonably satisfactory to Purchaser, transferring the Transferred Assets to the Assignee, duly executed by an authorized officer of the Assignor;

(ii) an assignment and assumption agreement, in form and substance reasonably satisfactory to Purchaser, effecting the assignment to the Assignee of the Transferred Assets and the assumption by the Assignee of the Transferred Liabilities, duly executed by an authorized officer of the Assignor;

(iii) an intellectual property assignment agreement, in form and substance reasonably satisfactory to Purchaser, transferring an undivided one-half interest in the Assignor's entire right, title, and interest in and to the Transferred Patents, duly executed by an authorized officer of the Assignor; and

(iv) all other documents, commitments and rights evidencing the Contribution, with such assignments thereof and consents to assignments as are necessary to assure the Assignee of the full benefit of the same (subject to the terms of the Purchase Agreement).

(b) At the Effective Time, the Assignee shall deliver, or cause to be delivered, to the Assignor:

(v) a certificate or certificates in the name of the Assignor representing the Units (or such other documents evidencing the Units as the Assignee and the Assignor may mutually agree); and

(vi) a counterpart of each of the agreements, instruments or documents referenced in Sections 1.5(a)(i), 1.5(a)(ii) and 1.5(a)(iii), duly executed by an authorized officer of the Assignee.

I.6 **Accounts Receivable**. The Parties agree that to the extent payments are received after the Effective Time by the Assignor with respect to any Transferred Assets, the Assignor shall promptly pay or cause to be paid over such amounts to the Assignee. The Parties further agree that to the extent payments are received after the Effective Time by the Assignee with respect to any Excluded Assets, the Assignee shall promptly pay or cause to be paid over such amounts to the Assignor. Any payment pursuant to this

Section 1.6 shall be made in the same currency as the funds received by either the Assignor or the Assignee, as the case may be, unless otherwise agreed by the Parties.

I.7 **Accounts Payable**. The Assignee shall be liable for the payment of any Transferred Liability, and the Assignor shall be liable for the payment of any Excluded Liability.

I.8 **Adjustments and Prorations**. The Parties agree to prorate rent, utilities, real estate taxes and other income and operating expenses of the Transferred Assets, if any, in accordance with this Section 1.8. The Assignor shall be deemed to own or have leasehold title to the Transferred Assets for the entire day upon which the Closing occurs. Each proration will be calculated by *multiplying* the amount of the expense by a fraction, the numerator of which is the number of calendar days from the beginning of the payment period for such expense through the Closing Date and the denominator of which is the number of calendar days in the entire payment period for such expense.

I.9 **Insurance**. The Assignor agrees that with respect to acts, omissions, events or circumstances related to the Business, the Transferred Assets or the Transferred Liabilities that occurred or existed prior to the Closing and that are covered by third party occurrence-based insurance policies under which the Assignor is insured on or prior to the Closing (the "Applicable Policies"), the Assignee may, to the extent permitted under such Applicable Policies, request that the Assignor make claims under such Applicable Policies subject to the terms and conditions of such Applicable Policies and this Agreement; provided that the Assignee shall bear, and the Assignor shall not have any obligation to repay or reimburse the Assignee for, the amount of any deductibles, self-insured retentions or other expenses incurred in connection therewith associated with claims under such Applicable Policies. The Parties shall cooperate with each other with respect to claims made by the Assignor in connection with such claims requested by the Assignee under such Applicable Policies.

I.10 **Cooperation; Further Actions**.

(a) Following the Effective Time, the Parties shall use commercially reasonable efforts (except to the extent a higher standard is provided for herein, in which case, the applicable Party shall use efforts that meet such higher standard) to take, or cause to be taken, all such actions, to execute and deliver, or cause to be executed and delivered, all such additional agreements, instruments and other documents, to make, or cause to be made, all filings and to do, or cause to be done, all such other things as are necessary, proper or advisable, or otherwise reasonably requested by any other Party, in order to enable each Party to perform its obligations under this Agreement, to consummate the transactions contemplated by this Agreement and otherwise to carry out the intent and purposes of this Agreement. In furtherance of the foregoing, the Parties agree that if, after the Effective Time, a Party receives or otherwise holds assets, properties or rights which by the terms hereof were provided to be assigned and transferred to, or retained by, the other Party, then such Party, at its expense, shall promptly use commercially reasonable efforts to assign and transfer, or cause to be assigned and transferred, such assets, properties and rights to the other Party. The Parties agree that, until such assignment or transfer is consummated, the assigning or transferring Party will hold such assets, properties and rights as trustee of the assignee or transferee Party and all benefits (including income) and detriments (including risk of loss) of such assets, properties and rights shall be for the account of the intended owner.

(c) Notwithstanding anything herein to the contrary, nothing in this Agreement shall constitute, or obligate the Assignor to effect, any assignment, lease, license, transfer or conveyance of any Transferred Asset to the extent that, in the absence of any consent, approval, waiver or authorization of any Person other than the Parties, which consent, approval, waiver or authorization has not been obtained prior to the Effective Time, such assignment, lease, license, transfer or conveyance would constitute a breach or other contravention of the rights of such Person or would contravene or be prohibited by any applicable

Law. Following the Effective Time, any Transferred Asset which by the terms hereof (without regard to the immediately preceding sentence) was provided to be assigned or transferred at the Effective Time but was not so assigned or transferred as a result of the immediately preceding sentence shall be deemed automatically assigned or transferred, as applicable, hereunder if and when such assignment or transfer would not constitute a breach or other contravention of the rights of any Person other than the Parties (as a result of the receipt of the requisite consent, approval, waiver or authorization or otherwise) or contravene or be prohibited by any applicable Law, as applicable.

ARTICLE II
REPRESENTATIONS AND WARRANTIES OF THE ASSIGNEE

As an inducement to the Assignor to enter into and perform this Agreement, the Assignee hereby makes the following representations, warranties and covenants to the Assignor as of the date hereof and as of the Effective Time:

II.1 **Organization and Authorization**.

(a) The Assignee is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. The Assignee has full power and authority to enter into this Agreement and to carry out the transactions contemplated hereby and perform its other obligations hereunder. The execution, delivery and performance of this Agreement have been duly authorized by all necessary limited liability company or other action of the Assignee. This Agreement has been duly and validly executed and delivered by the Assignee, and the documents that are contemplated by the terms hereof to be executed and delivered after the date hereof will be duly and validly executed and delivered by the Assignee on or before the respective dates on which such documents are so contemplated to be executed and delivered. This Agreement constitutes a valid and legally binding obligation of the Assignee, enforceable in accordance with its terms, subject to the Enforceability Exceptions. The Assignee has made available to Purchaser or its advisors true and complete copies of the Assignee's organizational documents.

(b) The Assignee has all requisite limited liability company power and authority to own the Transferred Assets and to carry on the Business immediately following the Closing as such Business is currently conducted.

(c) The Assignee is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the character of its property, or the nature of the activities conducted by it, makes such license or qualification necessary, except where the failure to be so licensed or qualified has not had and would not reasonably be expected to be material to the Assignee.

II.2 **Non-Contravention**. The execution, delivery and performance of this Agreement by the Assignee, and the consummation by the Assignee of the transactions contemplated hereby, and compliance with the terms and provisions hereof, do not and will not: (a) violate, conflict with, result in a breach of any provision of, or constitute a default (with or without notice, lapse of time or both) under, any provision of the Assignee's governing documents; (b) violate, conflict with, result in the breach of, constitute a default (with or without notice, lapse of time or both) under, give rise to any right to change in terms or acceleration, modification, cancelation or termination (as distinct from any right to terminate, modify or cancel at will without cause pursuant to the terms thereof) of any material right or obligation of the Assignee under, or require any notice, consent, approval, authorization, waiver or action or filing pursuant to, any agreement, obligation or other instrument to which the Assignee is a party or by which the Assignee or any of its properties or assets, including the Transferred Assets, are bound, or cause the creation of any Lien (other than Permitted Liens and Liens arising from acts of Purchaser or any of its Affiliates other than the Closing of the transactions contemplated under the Purchase Agreement) upon any of the assets of the Assignee;

(c) violate, conflict with or result in a breach or default (whether after the giving of notice, lapse of time or both) under, any provision of any Laws applicable to the Assignee or any of its properties or assets, including the Transferred Assets; (d) require the Assignee give any notice to, or make any declaration or filing with, or obtain any consent, waiver or approval of, any Governmental Authority or other Person other than pursuant to applicable securities Laws or the rules or regulations of any applicable securities exchange or listing authority; or (e) accelerate any obligation under, or give rise to a right of termination of, any permit, license or authorization issued by any Governmental Authority that is applicable to the Assignee or any of its assets, except, in the case of the foregoing clauses (b) through (e), as would not, individually or in the aggregate, reasonably be expected to be material to the Business or the Assignee.

II.3 **Fees and Expenses**. Neither the Assignee nor any of its Affiliates has made any arrangements or taken any other action that has resulted in, or that would result in, the Assignee being or becoming liable for any fees or expenses payable to a third party in connection with the transactions contemplated by this Agreement.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF THE ASSIGNOR

As an inducement to the Assignee to enter into and perform this Agreement, the Assignor hereby makes the following representations and warranties to the Assignee as of the date hereof and as of the Effective Time:

III.1 **Organization and Authorization**. The Assignor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Assignor has full power and authority to enter into this Agreement and to carry out the transactions contemplated hereby and perform its other obligations hereunder. The execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate or other action of the Assignor. This Agreement has been duly and validly executed and delivered by the Assignor. This Agreement constitutes a valid and legally binding obligation of the Assignor, enforceable in accordance with its terms, subject to the Enforceability Exceptions.

III.2 **Title**. The Assignor has good and valid title, free and clear of all Liens (other than Permitted Liens), to, or a valid leasehold interest in, or a valid license or other right to use, all of the real or tangible property included in the Transferred Assets. Upon the consummation of the Contribution, good and valid title, free and clear of all Liens (other than Permitted Liens), to, or a valid leasehold interest in, or a valid license or other right to use, all of the real or tangible property included in the Transferred Assets shall pass to the Assignee.

III.3 **Non-Contravention**. The execution, delivery and performance of this Agreement by the Assignor, and the consummation by the Assignor of the transactions contemplated hereby, and compliance with the terms and provisions hereof, do not and will not: (a) violate, conflict with, result in a breach of any provision of, or constitute a default (with or without notice, lapse of time or both) under, any provision of the Assignor's governing documents; (b) violate, conflict with, result in the breach of, constitute a default (with or without notice, lapse of time or both) under, give rise to any right to change in terms or acceleration, modification, cancelation or termination (as distinct from any right to terminate, modify or cancel at will without cause pursuant to the terms thereof) of any material right or obligation of the Assignor under, or require any notice, consent, approval, authorization, waiver or action or filing pursuant to, any agreement, obligation or other instrument to which the Assignor is a party or by which the Assignor or any of its properties or assets, including the Transferred Assets, are bound, or cause the creation of any Lien (other than Permitted Liens and Liens arising from acts of Purchaser or any of its Affiliates other than the Closing of the transactions contemplated under the Purchase Agreement) upon any of the material assets of the

Assignor; (c) violate, conflict with or result in a breach or default (whether after the giving of notice, lapse of time or both) under, any provision of any Laws applicable to the Assignor or any of its properties or assets, including the Transferred Assets; (d) require the Assignor to give any notice to, or make any declaration or filing with, or obtain any consent, waiver or approval of, any Governmental Authority or other Person other than pursuant to applicable securities Laws or the rules or regulations of any applicable securities exchange or listing authority; or (e) accelerate any obligation under, or give rise to a right of termination of, any permit, license or authorization issued by any Governmental Authority that is applicable to the Assignor or any of its assets, except, in the case of the foregoing (b) through (e), as would not, individually or in the aggregate, reasonably be expected to be material to the Assignee or the Business.

III.4 **Fees and Expenses**. Neither the Assignor nor any of its Affiliates has made any arrangements or taken any other action that has resulted in, or that would result in, Purchaser or the Assignee being or becoming liable for any finder's, broker's, agent's or advisor's fee or commission or like payment payable to a third party in connection with the transactions contemplated by this Agreement or any other Transaction Document.

ARTICLE IV
MISCELLANEOUS

IV.1 **Tax Treatment**. The Assignor and the Assignee intend to treat the Assignee from the date of its formation until the end of the day when the Effective Time occurs as an entity that is disregarded as separate from the Assignor for United States federal income tax purposes, and any applicable state and local income and similar tax purposes, and will file all tax returns accordingly, unless otherwise required as a result of a determination within the meaning of Section 1313 of the Internal Revenue Code of 1986, as amended.

IV.2 **Severability**. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable Law, but if any provision of this Agreement shall be deemed prohibited or invalid under such applicable Law, such provision shall be ineffective to the extent of such prohibition or invalidity, and such prohibition or invalidity shall not invalidate the remainder of such provision or the other provisions of this Agreement.

IV.3 **Governing Law; Venue**.

(a) This Agreement, and all claims or causes of action based upon, arising out of, or related to this Agreement or the transactions contemplated hereby (whether based on contract, tort, equity or otherwise), shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to principles or rules of conflict of Laws (whether of the State of Delaware or of any other jurisdiction) to the extent such principles or rules would require or permit the application of Laws of a jurisdiction other than the State of Delaware.

(b) Any proceeding or Action based upon, arising out of or related to this Agreement or the transactions contemplated hereby must be brought in the Court of Chancery of the State of Delaware (or, to the extent such court does not have subject matter jurisdiction, the Superior Court of the State of Delaware), or, if it has or can acquire jurisdiction, in the United States District Court for the District of Delaware, and each of the Parties irrevocably (i) submits to the exclusive jurisdiction of each such court in any such proceeding or Action, (ii) waives any objection it may now or hereafter have to personal jurisdiction, venue or to convenience of forum, (iii) agrees that all claims in respect of the proceeding or Action shall be heard and determined only in any such court and (iv) agrees not to bring any proceeding or Action arising out of or relating to this Agreement or the transactions contemplated hereby in any other court. Nothing herein contained shall be deemed to affect the right of any Party to serve process in any

manner permitted by Law or to commence Actions or otherwise proceed against any other party in any other jurisdiction, in each case, to enforce judgments obtained in any Action, suit or proceeding brought pursuant to this Section 4.3.

IV.4 **WAIVER OF JURY TRIAL**. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY (A) CERTIFIES THAT NO OTHER PARTY OR REPRESENTATIVE THEREOF OR OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY OR PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE OTHER TRANSACTION DOCUMENTS BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 4.4.

IV.5 **Interpretation**. For purposes of this Agreement, the following rules of interpretation apply:

(a) *Descriptive Headings*. The headings of the sections and paragraphs of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

(b) *Calculation of Time Period*. Except as otherwise provided herein, when calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period is excluded. If any period is to be measured in Business Days and the last day of such period is not a Business Day, the period in question ends on the next succeeding Business Day.

(c) *Currency; Financial Terms*. Any reference in this Agreement to "$" means U.S. dollars. Financial terms used herein shall have the meanings given to such terms under GAAP unless otherwise specified herein.

(d) *Section and Similar References*. Unless the context otherwise requires, all references in this Agreement to any "Annex," "Section," "Schedule" or "Exhibit" are to the corresponding Annex, Section, Schedule or Exhibit of this Agreement.

(e) *References to Contracts and Laws.* References herein to any Contract or other document shall be deemed to be references to such Contract or other document as amended, restated, supplemented or otherwise modified from time to time (subject to any restrictions on amendment, restatement, supplementation or modification thereof set forth therein). References herein to any statute, rule or regulation shall be deemed to be references to such statute, rule or regulation as amended or supplemented from time to time, including through the promulgation of rules or regulations thereunder.

(f) *Mutual Drafting*. The Parties have participated jointly in the negotiation and drafting of this Agreement and have been represented by their own legal counsel in connection with the transactions contemplated hereby, with the opportunity to seek advice as to their legal rights from such legal counsel. In the event that any ambiguity or question of intent or interpretation arises, this Agreement is to be construed as jointly drafted by the Parties and no presumption of burden of proof is to arise favoring or

disfavoring any Party by virtue of the authorship of any provision hereof or by reason of the extent to which any such provision is inconsistent with any prior draft hereof.

(g) *Counterparts*. This Agreement may be executed in two or more counterparts and by the different parties hereto on separate counterparts, each of which when so executed and delivered shall be an original, but all of which together shall constitute one and the same instrument.

(h) *Electronic Mail*. The exchange of signature pages to this Agreement (in counterparts or otherwise) by electronic mail transmission, .pdf scan or other electronic transmission (including via www.docusign.com) shall be sufficient to bind the parties to the terms and conditions of this Agreement.

(i) *Other Definitional and Interpretive Matters*. Unless otherwise expressly provided herein, for purposes of this Agreement, the following rules of interpretation shall apply:

(vii) Exhibits/Schedules/Annexes. The Exhibits, Schedules and Annexes to this Agreement are hereby incorporated and made a part hereof and are an integral part of this Agreement. All Exhibits, Schedules and Annexes attached hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. The Assignor may, at its option, include in the Schedules items that are not material in order to avoid any misunderstanding, and such inclusion, or any references to dollar amounts, shall not be deemed to be an acknowledgement or representation that such items are material, to establish any standard of materiality or to define further the meaning of such terms for purposes of this Agreement or otherwise. Any capitalized terms used in any Exhibit, Schedule or Annex but not otherwise defined therein shall be defined as set forth in the Purchase Agreement. The inclusion of information in any Schedule will not be construed as an admission to any third party of any liability or obligation of the Assignor or the Assignee.

(viii) Gender and Number. Any reference in this Agreement to gender shall include all genders, and words imparting the singular number shall include the plural and vice versa.

(ix) "License." The word "license" (regardless of the tense when used as a verb or single or plural form when used as a noun) shall include the term "sublicense" (and its corresponding forms) and vice versa.

(x) "Herein." The words such as "herein," "hereinafter," "hereof," and "hereunder" and any other words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole (including all of the Exhibits, Schedules and Annexes to this Agreement) and not merely to a particular term or provision of this Agreement or subdivision in which such words appear unless the context otherwise requires.

(xi) "Including"; "to the Extent." The word "including" or any variation thereof means "including, without limitation," and shall not be construed to limit any general statement that it follows to the specific or similar items or matters immediately following it. The word "extent" in the phrase "to the extent" shall mean the degree to which a subject or other thing extends, and such phrase shall not mean simply "if."

(xii) "Made Available." The words "made available," "furnished," "delivered," or words of similar import with respect to any item made available by the Assignor or the Assignee shall mean delivered or posted at least two (2) days prior to the date of this Agreement in the Data Room.

IV.6 **Successors and Assigns**. Except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the respective successors, assigns, heirs,

executors and administrators of the Parties. No Party shall assign, delegate or otherwise transfer any of its rights or obligations under this Agreement (whether by operation of law or otherwise) without the prior written consent of the Assignor (in the case of any proposed assignment, delegation or transfer by the Assignee) or the Assignee (in the case of any proposed assignment, delegation or transfer by the Assignor). Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person other than a Party any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

IV.7 **Waivers**. Any Party may (a) extend the time for the performance of the obligations or acts of any other Party to be performed hereunder, (b) waive any inaccuracy in any of the representations or warranties of any other Party that are contained in this Agreement or (c) waive compliance by any other Party with any of the agreements or conditions contained in this Agreement, but, in the case of each of the foregoing clauses (a) through (c), such extension or waiver shall be valid only if set forth in an instrument in writing duly authorized, executed and delivered by the Party granting such extension or waiver. No waiver by any Party shall operate or be construed as a waiver in respect of any failure, breach, or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any rights, remedy, power, or privilege arising hereunder shall operate or be construed as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

IV.8 **Amendments**. This Agreement may be amended, in whole or in part, only by an agreement in writing which makes reference to this Agreement and has been duly authorized, executed and delivered by each of the Parties. Any purported amendment of this Agreement effected in a manner that does not comply with the preceding sentence shall be void and of no effect.

IV.9 **Fees and Expenses**. Except as otherwise provided herein, all costs and expenses incurred in connection with this Agreement, and the transactions contemplated hereby, and the Contribution (including the fees and expenses of its advisors, accountants and legal counsel) shall be paid by the Assignor.

IV.10 **Entire Agreement**. This Agreement (including the schedules and exhibits hereto and thereto) constitutes the full and entire understanding and agreement among the Parties with respect to the subject matters hereof, and any and all other written or oral agreements existing prior to or contemporaneously herewith are expressly superseded and canceled.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the first date above written.

HOMOLOGY MEDICINES, INC.

By: /s/ Arthur O. Tzianabos
Name: Arthur O. Tzianabos
Title: Chief Executive Officer

ROADRUNNER SOLUTIONS LLC

By: /s/ Tim Kelly
Name: Tim Kelly
Title: Chief Executive Officer

SCHEDULE 1

TRANSFERRED ASSETS

SCHEDULE 2

EXCLUDED ASSETS

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Exhibit 10.26

ROADRUNNER SOLUTIONS LLC

FORM OF AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

Dated as of March 10, 2022

THE UNITS ISSUED PURSUANT TO THIS AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR UNDER ANY OTHER APPLICABLE SECURITIES LAWS. SUCH UNITS MAY NOT BE SOLD, TRANSFERRED, ASSIGNED, PLEDGED OR OTHERWISE DISPOSED OF AT ANY TIME WITHOUT EFFECTIVE REGISTRATION UNDER SUCH ACT AND LAWS OR AN EXEMPTION THEREFROM, AND COMPLIANCE WITH THE OTHER RESTRICTIONS ON TRANSFERABILITY SET FORTH HEREIN.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

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AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

THIS AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT of the Company is entered into as of March 10, 2022 (the "Effective Date") by and among Roadrunner Solutions LLC, a Delaware limited liability company (the "Company"), Homology Medicines, Inc., a Delaware corporation ("HMI"), and Oxford Biomedica (US), Inc., a Delaware corporation ("OXB"). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in ARTICLE I.

WHEREAS, (i) the Company was formed on January 25, 2022 as a limited liability company in accordance with the Delaware Act and (ii) immediately prior to the execution of this Agreement, the Company was governed by that certain Limited Liability Company Agreement of the Company dated as of January 25, 2022 (the "Prior Agreement");

WHEREAS, prior to the execution of this Agreement, HMI and the Company entered into a contribution agreement (the "Contribution Agreement") pursuant to which, among other things, on the terms and subject to the conditions set forth therein, and effective immediately prior to the Closing, (a) HMI assigned and transferred to the Company the Transferred Assets (as defined in the Contribution Agreement), and the Company assumed from HMI, and agreed to pay, perform and discharge when due, the Transferred Liabilities (as defined in the Contribution Agreement) and (b) in exchange therefor, the Company issued to HMI 175,000 of the Company's Units;

WHEREAS, on the terms and subject to the conditions set forth in that certain Equity Securities Purchase Agreement, dated as of January 28, 2022, by and among HMI, the Company and OXB (the "Purchase Agreement"), HMI will sell to OXB, and OXB will purchase from HMI, 130,000 Units in exchange for a cash payment by OXB to HMI at the Closing in the amount of $130,000,000;

WHEREAS, on the terms and subject to the conditions set forth in the Purchase Agreement, and effective as of the Closing, the Company will issue to OXB, and OXB will purchase from the Company 50,000 Units in exchange for a cash contribution by OXB to the Company of $50,000,000;

WHEREAS, immediately following the consummation of the Contribution and contemporaneously with the execution of this Agreement, the Equity Transfer (as defined in the Purchase Agreement) and the Equity Issuance (as defined in the Purchase Agreement) will be consummated in accordance with the Purchase Agreement, pursuant to which (a) OXB will own, in the aggregate, 180,000 Units, collectively representing 80% of the outstanding Units, and (b) HMI will own, in the aggregate, 45,000 Units, collectively representing 20% of the outstanding Units, in each case, as reflected on the Unit Ownership Ledger; and

WHEREAS, in connection with the admission of certain Unitholders at the closing of the transactions contemplated by the Purchase Agreement, the Unitholders desire to amend and restate the Prior Agreement in its entirety.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Unitholders, intending to be legally bound, hereby agree as follows:

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

ARTICLE I
DEFINITIONS

SECTION 1.01. Definitions. Capitalized terms used but not otherwise defined herein shall have the following meanings:

"Additional Unitholder" means a Person admitted to the Company as a Unitholder pursuant to Section 10.02.

"Admission Date" has the meaning set forth in Section 9.06(a).

"Affiliate" of any Person means any other Person controlled by, controlling or under common control with such Person. As used in this definition, "control" (including, with its correlative meanings, "controlling," "controlled by" and "under common control with") shall mean possession, directly or indirectly, of power to direct or cause the direction of management or policies (whether through ownership of securities, by contract or otherwise). For purposes of this Agreement, the Company and its Subsidiaries shall not be deemed to be Affiliates of any Unitholder.

"Agreement" means this Amended and Restated Limited Liability Company Agreement, as it may be amended, modified and/or waived from time to time in accordance with the terms hereof.

"Allocation Period" means the Fiscal Year or such other taxable period for which any allocation of items of income, gain, loss, deduction or credit is required to be calculated.

"Alternative Indemnitors" has the meaning set forth in Section 6.04(c).

"Approved Sale" has the meaning set forth in Section 9.03(a).

"Assignee" means a Person to whom Units have been Transferred in accordance with the terms of this Agreement and the other agreements contemplated hereby, as applicable, but who has not become a Unitholder pursuant to ARTICLE X.

"Assumed Tax Rate" means the highest effective marginal combined federal, state and local tax rate (including the net investment income tax imposed under Section 1411 of the Code) generally applicable to a corporation subject to tax in the jurisdictions in which the Company conducts business. When applying the Assumed Tax Rate hereunder, the Board shall take into account the character of the income and, to the extent the Board reasonably determines such benefits are available, the deductibility of state and local income taxes, and loss carry forwards.

"Available Cash" shall mean, as of any date, the excess of (i) the unrestricted cash and cash equivalent items held by the Company over (ii) the sum of the amount of such items reasonably determined in good faith by the Board to be reasonably necessary for the payment of the Company's expenses, liabilities and other obligations (whether fixed or contingent), and for the establishment of appropriate reserves for such expenses, liabilities and obligations as may reasonably be expected to arise, including the maintenance of adequate working capital for the continued conduct of the Company's business.

"Bankruptcy" means, with respect to any Person, the time (i) a court or Governmental Authority having jurisdiction shall enter a decree or order for relief in respect of such Person in an involuntary case under any applicable bankruptcy, insolvency or other similar law, or appointing a receiver, liquidator, assignee, custodian, trustee, sequestrator (or similar official) of such Person or for any substantial part of its property or ordering the winding up or liquidation of any of its affairs; or (ii) such Person shall

commence a voluntary case under any applicable bankruptcy, insolvency or other similar law, or consent to the entry of an order for relief in an involuntary case under any such law, or consent to the appointment or taking possession by a receiver, liquidator, assignee, custodian, trustee, sequestrator (or similar official) of such Person or for any substantial part of any its property or make any general assignment for the benefit of its creditors.

"Board" means the Board of Directors of the Company established pursuant to Section 5.02, which shall have the power and authority described in this Agreement.

"Book Liability Value" means with respect to any liability of the Company described in Treasury Regulation Section 1.752-7(b)(3)(i), the amount of cash that a willing assignor would pay to a willing assignee to assume such liability in an arm's length transaction. The Book Liability Value of each liability of the Company described in Treasury Regulation Section 1.752-7(b)(3)(i) shall be adjusted at such times as provided in this Agreement for an adjustment to Book Value; provided, however, that such adjustments shall be made only if the Board reasonably determines that such adjustments are necessary or appropriate to reflect the relative economic interests of the Unitholders in the Company.

"Book Value" means, with respect to any property of the Company, such property's adjusted basis for federal income tax purposes, except as follows:

(a) The initial Book Value of any property contributed by a Unitholder to the Company shall be the Fair Market Value of such property as of the date of contribution as reasonably determined by the Board in good faith (and in accordance with ARTICLE XIII);

(b) The Book Values of all properties shall be adjusted to equal their respective Fair Market Values as reasonably determined by the Board in good faith (and in accordance with ARTICLE XIII) in connection with (i) the acquisition of an interest (or additional interest) in the Company by any new or existing Unitholder in exchange for more than a de minimis capital contribution to the Company, (ii) the Distribution by the Company to a Unitholder of more than a de minimis amount of property as consideration for an interest in the Company, (iii) the liquidation of the Company within the meaning of Treasury Regulation Section 1.704-1(b)(2)(ii)(g)(1), (iv) the acquisition of an interest in the Company by any new or existing Unitholder upon the exercise of a non-compensatory option or warrant, (v) the acquisition of an interest in the Company by any new or existing Unitholder as consideration for the provision of services to or for the benefit of the Company or (vi) any other event to the extent reasonably determined by the Board in good faith to be permitted and necessary to properly reflect Book Values in accordance with the standards set forth in Treasury Regulation Section 1.704-1(b)(2)(iv)(q); provided, however, that adjustments pursuant to clauses (i), (ii), (v) and (vi) above shall be made only if the Board in good faith reasonably determines that such adjustments are necessary or appropriate to reflect the relative economic interests of the Unitholders in the Company. If any non-compensatory options or warrants are outstanding upon the occurrence of an event described in this paragraph (b)(i) through (b)(vi), the Company shall adjust the Book Values of its properties in accordance with Treasury Regulation Sections 1.704-1(b)(2)(iv)(f)(1) and 1.704-1(b)(2)(iv)(h)(2);

(c) The Book Value of property distributed to a Unitholder shall be adjusted to equal the Fair Market Value of such property as of the date of Distribution (as determined pursuant to ARTICLE XIII);

(d) The Book Value of all property shall be increased (or decreased) to reflect any adjustments to the adjusted basis of such property pursuant to Section 734(b) or Section 743(b) of the Code, but only to the extent that such adjustments are taken into account in determining Capital Accounts pursuant to Treasury Regulation Section 1.704-1(b)(2)(iv)(m) and clause (g) of the definition of Profits and Losses

or Section 3.05(b)(vi); provided, however, that Book Value shall not be adjusted pursuant to this clause (d) to the extent the Board in good faith reasonably determines that an adjustment pursuant to clause (b) of this definition is necessary or appropriate in connection with the transaction that would otherwise result in an adjustment pursuant to this clause (d);

(e) If the Book Value of property has been determined or adjusted pursuant to clause (b) or (d) of this definition, such Book Value shall thereafter be adjusted by the Depreciation taken into account with respect to such property for purposes of computing Profits and Losses and other items allocated pursuant to ARTICLE III.

"Business" means the business of the manufacturing of adeno-associated virus vectors for use in gene therapy or gene editing products.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or the United Kingdom or any day on which banking institutions in New York City or London, United Kingdom are authorized or required by law or other governmental action to close.

"Business Opportunities" has the meaning set forth in Section 6.06.

"Capital Account" means the capital account maintained for a Unitholder pursuant to Section 3.04 and the other applicable provisions of this Agreement.

"Capital Contributions" means any cash, cash equivalents or the Fair Market Value of other property that a Unitholder contributes or is deemed by the Board to have contributed to the Company with respect to any Unit pursuant to Section 3.01 or Section 3.02, net of any liabilities assumed by the Company for such Unitholder in connection with such contribution and net of any liabilities to which the assets contributed by such Unitholder are subject.

"CEO" has the meaning set forth in Section 5.02(a)(iii).

"Certificate" means the Company's Certificate of Formation as filed with the Secretary of State of Delaware, as the same may be amended from time to time.

"Chosen Courts" has the meaning set forth in Section 14.08.

"Closing Date" means March 10, 2022.

"Code" means the United States Internal Revenue Code of 1986, as amended.

"Common Unit" means a Unit having the rights and obligations specified with respect to a Common Unit in this Agreement.

"Company" means Roadrunner Solutions LLC, a Delaware limited liability company.

"Company Group" means the Company and its Subsidiaries.

"Company Minimum Gain" shall have the meaning ascribed to the term "Partnership Minimum Gain" in the Treasury Regulations Section 1.704-2(d).

"Court of Chancery" has the meaning set forth in Section 14.08.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

"Covered Person" means (a) any Unitholder, any Affiliate of a Unitholder, any officers, managers, directors, trustees, shareholders, members, beneficiaries, partners, employees, representatives or agents of any Unitholder or its Affiliates, (b) any non-employee officer, manager or director of the Company or its Subsidiaries and (c) any Partnership Representative or Designated Individual to the extent acting in the capacity as Partnership Representative or Designated Individual, as applicable.

"Delaware Act" means the Delaware Limited Liability Company Act, 6 Del. L. § 18 101, et seq., as it may be amended from time to time, and any successor thereto.

"Delaware Federal Court" has the meaning set forth in Section 14.08.

"Depreciation" means, for each Allocation Period, an amount equal to the depreciation, amortization or other cost recovery deduction (excluding depletion) allowable for federal income tax purposes with respect to property for the Allocation Period, except that (i) with respect to any property the Book Value of which differs from its adjusted tax basis for federal income tax purposes and which difference is being eliminated by use of the remedial allocation method pursuant to Treasury Regulation Section 1.704-3(d), Depreciation for the Allocation Period shall be the amount of book basis recovered for the Allocation Period under the rules prescribed by Treasury Regulation Section 1.704-3(d)(2), and (ii) with respect to any other property the Book Value of which differs from its adjusted tax basis at the beginning of the Allocation Period, Depreciation shall be an amount which bears the same ratio to such beginning Book Value as the federal income tax depreciation, amortization or other cost recovery deduction for the Allocation Period bears to such beginning adjusted tax basis; provided, however, that if the adjusted tax basis of any property at the beginning of the Allocation Period is zero, Depreciation with respect to such property shall be determined with reference to such beginning value using any reasonable method selected by the Board.

"Director" means a Director serving on the Board at any given time, who, for purposes of the Delaware Act, will be deemed a "manager" (as defined in the Delaware Act), but will be subject to the rights, obligations and limitations set forth in this Agreement.

"Disputed Amount" means with respect to a particular Indemnification Claim, the amount of such Indemnification Claim with respect to which there remains a dispute between the parties.

"Dissolution" of a Unitholder which is not a natural person means that such Unitholder has terminated its existence, whether partnership, limited liability company or corporation, wound up its affairs and dissolved; provided that a change in the membership of any Unitholder that is a partnership shall not constitute a "Dissolution" hereunder, whether or not the Unitholder is deemed technically dissolved for partnership law purposes, so long as the business of the Unitholder is continued.

"Distribution" means each distribution made by the Company to a Unitholder with respect to such Person's Units, whether in cash, property or securities and whether by interim or liquidating Distribution, redemption, repurchase or otherwise; provided that, without limiting the rights of any Unitholders pursuant to Section 5.03(b) or Section 5.03(c), none of the following shall be deemed to be a Distribution hereunder: (i) any pro rata redemption of Units by the Company or (ii) any recapitalization, exchange or conversion of securities of the Company, and any subdivision (by unit split or otherwise) or any combination (by reverse unit split or otherwise) of any outstanding Units.

"Electing Unitholders" has the meaning set forth in Section 9.02.

"Equity Securities" means (i) any Units, capital stock, partnership interests, membership or limited liability company interests or other equity interests (including other classes, groups or series

thereof having such relative rights, powers and/or obligations as may from time to time be established by the Board, including rights, powers and/or duties different from, senior to or more favorable than existing classes, groups and series of Units, capital stock, partnership interests, membership or limited liability company interests or other equity interests, and including any profits interests), (ii) obligations, evidences of indebtedness or other securities or interests convertible or exchangeable into Units, capital stock, partnership interests, membership or limited liability company interests or other equity interests, and (iii) warrants, options or other rights to purchase or otherwise acquire Units, capital stock, partnership interests, membership or limited liability company interests or other equity interests. Unless the context otherwise indicates, the term "Equity Securities" refers to Equity Securities of the Company.

"Event of Withdrawal" means the death, retirement, resignation, expulsion, Bankruptcy or Dissolution of a Unitholder or the occurrence of any other event that terminates the continued membership of a Unitholder in the Company.

"Excluded Issuances" means issuances of (i) Common Units on the date hereof, (ii) Equity Securities upon exercise, conversion or exchange of other Equity Securities which were issued in compliance with Section 3.03, (iii) Equity Securities issued by a Subsidiary of the Company to another Subsidiary of the Company or the Company, (iv) Equity Securities issued in connection with any acquisitions involving the Company or any of its Subsidiaries and other Persons that are determined by the Board (including the HMI Director) in good faith to be "strategic" transactions (including Equity Securities issued in connection with joint ventures and similar arrangements), (v) Equity Securities issued to officers, directors, managers, consultants, employees or other service providers to the Company or any of its Subsidiaries, in each case, that are not affiliated with any Unitholder, pursuant to any agreement or any incentive or other compensation plans or agreements approved by the Board, or (vi) Equity Securities issued in connection with any Unit split, Unit Distribution or recapitalization of the Company in which holders of the same class of Units participate on a Pro Rata Basis.

"Fair Market Value" means, with respect to any asset or Equity Securities, its fair market value determined according to ARTICLE XIII.

"FCA" means the Financial Conduct Authority of the United Kingdom, or any successor authority or authorities.

"Fiscal Quarter" means each calendar quarter ending March 31, June 30, September 30 and December 31, or such other quarterly accounting period as may be established by the Board or as required by the Code.

"Fiscal Year" means the 12-month period ending on December 31, or such other annual accounting period as may be established by the Board or as may be required by the Code.

"GAAP" means United States generally accepted accounting principles, consistently applied.

"Governmental Authority" means any foreign, federal, state, local, county, municipal, provincial, multinational government or other governmental or quasi-governmental authority or regulatory board, court, tribunal, arbitrating body, governmental department, commission, board, body, self-regulating authority, bureau or agency, as well as any other instrumentality or entity designated to act for or on behalf of any of the foregoing and any business entity owned or chartered by any of the foregoing.

"HSR Act" has the meaning set forth in Section 12.06.

"Indemnified Person" has the meaning set forth in Section 6.04(a).

"Liquidation Assets" has the meaning set forth in Section 12.02(b).

"Liquidation FMV" has the meaning set forth in Section 12.02(b).

"Liquidation Statement" has the meaning set forth in Section 12.02(b).

"London Stock Exchange" means London Stock Exchange plc.

"Losses" means items of the Company loss and deduction determined by the Board.

"Maximum Put/Call Amount" [***].

"Nonrecourse Liability" shall have the meaning set forth in Treasury Regulations Section 1.752-l(a)(2).

"Offeree Investors" has the meaning set forth in Section 3.03(a).

"Officers" means each person designated as an officer of the Company to whom authority and duties have been delegated pursuant to Section 5.06, subject to any resolution of the Board appointing or removing such person as an officer or relating to such appointment.

"Ordinary Shares" means ordinary shares of 50 pence each in the capital of Oxford Biomedica plc.

"OXB" has the meaning set forth in the preamble.

"OXB Change of Control" means (i) the sale (in one or a series of related transactions and whether by merger, consolidation, reorganization, combination, sale or transfer of OXB's or OXB Biomedica plc's Equity Securities) of all or substantially all of the assets of OXB or OXB Biomedica plc to a third party; or (ii) a sale (in one or a series of related transactions and whether by merger, consolidation, reorganization, combination, sale or transfer of OXB's or OXB Biomedica plc's Equity Securities) resulting in more than 50% of the Equity Securities of OXB or OXB Biomedica plc being held by a third party.

[***].

"Permitted Transferee" means, with respect to any Unitholder, any of its controlled Affiliates, or in the case of OXB, Oxford Biomedica plc or any of its controlled Affiliates.

"Person" means an individual, a partnership, a corporation, a limited liability company, an association, a joint stock company, a trust, a joint venture, an unincorporated organization, association or other entity or a Governmental Authority.

"Preemptive Rights Notice" has the meaning set forth in Section 3.03(b).

"Prior Agreement" has the meaning set forth in the recitals of this Agreement.

"Pro Rata Basis" means, with respect to each Unitholder, and as determined with respect to any particular expense, liability or obligation incurred (or amount of proceeds withheld) in connection with any Transfer of Equity Securities pursuant to Section 9.02 or any Approved Sale, the amount such Unitholder's proceeds would be reduced as a percentage of the aggregate reduction in proceeds to

applicable Unitholders assuming the Company's Total Equity Value implied by such Transfer or Approved Sale were being distributed to the Unitholders in accordance with Section 4.01(a) in connection with such Transfer or Approved Sale and as if such expense, liability or obligation were incurred and satisfied (or such amount of proceeds were withheld) prior to such Distribution, as determined in good faith by the Board.

"Pro Rata Share" means (i) with respect to each Unit, the proportionate amount such Unit would receive if an amount equal to the Total Equity Value were distributed to all Units in accordance with Section 4.01(a), and (ii) with respect to each Unitholder, such Unitholder's pro rata share of Total Equity Value represented by all Units owned by such Unitholder, in each case, as determined in good faith by the Board.

"Profits" or "Losses" means, for each Allocation Period, each item of income, gain, loss and deduction entering into the Company's taxable income or loss for the Allocation Period, determined in accordance with Section 703(a) of the Code (including, for this purpose, all items of income, gain, loss, or deduction required to be stated separately pursuant to Section 703(a)(1) of the Code), with the following adjustments (without duplication):

(a) Any income of the Company that is exempt from federal income tax and not otherwise taken into account in computing Profits and Losses pursuant to this definition shall be added to such taxable income or loss;

(b) Any expenditures of the Company described in Section 705(a)(2)(B) of the Code or treated as Section 705(a)(2)(B) expenditures pursuant to Treasury Regulations Section 1.704-1(b)(2)(iv)(i) and not otherwise taken into account in computing Profits or Losses pursuant to this definition shall be subtracted from such taxable income or loss;

(c) In the event the Book Value of any asset is adjusted pursuant to clause (b) or clause (c) of the definition of Book Value, the amount of such adjustment shall be treated as an item of gain (if the adjustment increases the Book Value of the asset) or an item of loss (if the adjustment decreases the Book Value of the asset) from the disposition of such asset and shall be taken into account for purposes of computing Profits or Losses;

(d) Gain or loss resulting from any disposition of property with respect to which gain or loss is recognized for federal income tax purposes shall be computed by reference to the Book Value of the property disposed of, notwithstanding that the adjusted tax basis of such property differs from its Book Value;

(e) In lieu of the depreciation, amortization, and other cost recovery deductions taken into account in computing such taxable income or loss, there shall be taken into account Depreciation for such Allocation Period;

(f) To the extent an adjustment to the adjusted tax basis of any asset pursuant to Section 734(b) of the Code is required, pursuant to Treasury Regulations Section 1.704-1(b)(2)(iv)(m)(4), to be taken into account in determining Capital Account balances as a result of a Distribution other than in liquidation of a Unitholder's interest in the Company, the amount of such adjustment shall be treated as an item of gain (if the adjustment increases the basis of the asset) or an item of loss (if the adjustment decreases such basis) from the disposition of such asset and shall be taken into account for purposes of computing Profits or Losses;

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(g) In the event the Book Liability Value of any liability of the Company described in Treasury Regulations Section 1.752-7(b)(3)(i) is adjusted as required by this Agreement, the amount of such adjustment shall be treated as an item of loss (if the adjustment increases the Book Liability Value of such liability of the Company) or an item of gain (if the adjustment decreases the Book Liability Value of such liability of the Company) and such items, and any other items relating to Book Liability Values determined by the Board to be appropriate in determining Capital Accounts, shall be taken into account for purposes of computing Profits or Losses; and

(h) Any items that are allocated pursuant to Section 3.06 shall be determined by applying rules analogous to those set forth in clauses (a) through (g) of this definition but shall not be taken into account in computing Profits and Losses.

"Purchase Agreement" has the meaning set forth in the Recitals.

"Required Consent" has the meaning set forth in Section 9.01(a).

"Sale of the Company" means any transaction or series of related transactions pursuant to which any Person or group of related Persons (other than OXB and/or its Affiliates) in the aggregate acquire(s) (i) Equity Securities of the Company possessing the voting or designation power (other than voting rights accruing only in the event of a default or breach) to elect Board members which, in the aggregate, control a majority of the votes on the Board (whether by merger, consolidation, reorganization, combination, sale or transfer of the Company's Equity Securities, securityholder or voting agreement, proxy, power of attorney or otherwise) or (ii) all or substantially all of the Company's assets determined on a consolidated basis.

"SEC" means the Securities and Exchange Commission of the United States, or any successor authority or authorities.

"Selling Unitholders" has the meaning set forth in Section 9.02(a).

"Specified Persons" has the meaning set forth in Section 6.06.

"Subsidiary" means, with respect to any Person, any corporation, limited liability company, partnership, association or business entity of which (i) if a corporation, a majority of the total voting power of shares of stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person or a combination thereof, or (ii) if a limited liability company, partnership, association or other business entity (other than a corporation), a majority of partnership or other similar ownership interests thereof is at the time owned or controlled, directly or indirectly, by any Person or one or more Subsidiaries of that Person or a combination thereof. For purposes hereof and without limitation, a Person or Persons shall be deemed to have a majority ownership interest in a limited liability company, partnership, association or other business entity (other than a corporation) if such Person or Persons shall be allocated a majority of limited liability company, partnership, association or other business entity gains or losses or shall be or control the manager, managing member, managing director (or a board comprised of any of the foregoing) or general partner of such limited liability company, partnership, association or other business entity. For purposes hereof, references to a "Subsidiary" of any Person shall be given effect only at such times that such Person has one or more Subsidiaries, and, unless otherwise indicated, the term "Subsidiary" refers to a Subsidiary of the Company.

"Substituted Unitholder" means a Person that is admitted as a Unitholder to the Company pursuant to Section 10.01.

"Supplemental Indemnification Rights" has the meaning set forth in Section 6.04(b).

"Tag Along Sale" has the meaning set forth in Section 9.02(a).

"Tag Along Sale Notice" has the meaning set forth in Section 9.02(a).

"Tax" or "Taxes" means any federal, state, local or foreign income, gross receipts, franchise, estimated, alternative minimum, add on minimum, sales, use, transfer, registration, value added, excise, natural resources, severance, stamp, occupation, premium, windfall profit, environmental, customs, duties, real property, personal property, capital stock, social security, unemployment, disability, payroll, license, employee or other withholding, or other tax, of any kind whatsoever, including any Transferee liability and any interest, penalties or additions to tax or additional amounts in respect of the foregoing.

[***].

"Total Equity Value" means, in the case of a Transfer contemplated by Section 9.02 or Section 9.03, the aggregate proceeds to be received by the Unitholders in connection with such Transfer and, otherwise, the aggregate proceeds that would be received by the Unitholders in the case of any Transfer if: (i) the assets of the Company were sold at their Fair Market Value on arm's length terms, with neither the seller nor the buyer being under compulsion to buy or sell such assets; (ii) the Company satisfied and paid in full all of its then-outstanding obligations and liabilities; and (iii) such net sale proceeds were then distributed in accordance with Section 4.01(a), all as determined by the Board in good faith.

"Transfer" means any direct or indirect sale, transfer, assignment, pledge, mortgage, exchange, hypothecation, grant of a security interest or other disposition or encumbrance of an interest (whether with or without consideration, whether voluntarily or involuntarily or by operation of law), but excluding conversions of Equity Securities by the Company made in accordance with this Agreement or any merger or consolidation of the Company. The terms "Transferee," "Transferor," "Transferred," and other forms of the word "Transfer" shall have the correlative meanings.

"Unit" means a limited liability company interest in the Company of a Unitholder or an Assignee in the Company representing a fractional part of the interests in Profits, Losses and Distributions of the Company held by all Unitholders and Assignees and shall include, without limitation, Common Units; provided that any class, group or series of Units issued shall have the relative rights, powers and obligations set forth in this Agreement.

"Unitholder" means any owner of one or more Units, including any person admitted to the Company as an Additional Unitholder or Substituted Unitholder, but in each case, only to the extent such Person is shown on the Company's books and records as the owner of such Units as of the applicable date. As provided in Section 18-101(7) of the Delaware Act, each Unitholder shall be bound by this Agreement, whether or not such Unitholder shall have executed this Agreement.

"Unit Ownership Ledger" has the meaning set forth in Section 3.01(b).

"Unitholder Nonrecourse Debt" shall have the meaning ascribed to the term "Partner Nonrecourse Debts" in Treasury Regulations Section 1.704-2(b)(4).

"Unitholder Nonrecourse Debt Minimum Gain" has the meaning assigned to the term "partner nonrecourse debt minimum gain" in Treasury Regulation Section 1.704-2(i)(2).

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"Unitholder Nonrecourse Deductions" shall mean items of Company loss, deduction, or Section 705(a)(2)(B) expenditures which are attributable to Unitholder Nonrecourse Debt.

ARTICLE II
ORGANIZATIONAL MATTERS

SECTION 2.01. Formation of LLC. The Company was formed on January 25, 2022 pursuant to the provisions of the Delaware Act.

SECTION 2.02. Limited Liability Company Agreement. The Unitholders hereby execute this Agreement for the purpose of amending and restating the Prior Agreement and establishing the affairs of the Company and the conduct of its business in accordance with the provisions of the Delaware Act. The Unitholders hereby agree that during the term of the Company set forth in Section 2.06 the rights, powers and obligations of the Unitholders with respect to the Company will be determined solely in accordance with the terms and conditions of this Agreement and, except where the Delaware Act provides that such rights, powers and obligations specified in the Delaware Act shall apply "unless otherwise provided in a limited liability company agreement" or words of similar effect and such rights, powers and obligations are set forth in this Agreement, the Delaware Act; provided that, notwithstanding the foregoing and anything else to the contrary, Section 18-210 of the Delaware Act (entitled "Contractual Appraisal Rights") and Section 18-305(a) of the Delaware Act (entitled "Access to and Confidentiality of Information; Records") shall not apply to or be incorporated into this Agreement and each Unitholder hereby expressly waives any and all rights under such Sections of the Delaware Act.

SECTION 2.03. Name. The name of the Company shall be "Roadrunner Solutions LLC". The Board may change the name of the Company at any time and from time to time. Notification of any such name change shall be given to all Unitholders. The Company's business may be conducted under its name and/or any other name or names deemed advisable by the Board.

SECTION 2.04. Purpose. The purpose and business of the Company shall be to manage and direct the business operations and affairs of the Company and its Subsidiaries and to engage in any other lawful acts or activities for which limited liability companies may be organized under the Delaware Act.

SECTION 2.05. Principal Office; Registered Office. The principal office of the Company shall be located at such place inside or outside the state of Delaware as the Board may from time to time designate, and all business and activities of the Company shall be deemed to have occurred at its principal office. The Company may maintain offices at such other place or places as the Board deems advisable. The address of the registered office of the Company in the State of Delaware shall be the office of the initial registered agent named in the Certificate or such other office (which need not be a place of business of the Company) as the Board may designate from time to time in the manner provided by applicable law, and the registered agent for service of process on the Company in the State of Delaware at such registered office shall be the registered agent named in the Certificate or such Person or Persons as the Board may designate from time to time in the manner provided by applicable law.

SECTION 2.06. Term. The term of the Company commenced upon the filing of the Certificate in accordance with the Delaware Act and shall continue in existence until the Company shall be terminated and dissolved in accordance with the provisions of ARTICLE XII.

SECTION 2.07. Tax Treatment. The Unitholders intend that the Company be treated as a partnership for U.S. federal and, if applicable, state or local income tax purposes, that the Company shall not take any action (including any entity classification election on IRS Form 8832) to be classified as anything other than a partnership for U.S. federal income tax purposes, and that each Unitholder and the

Company shall file all Tax returns and shall otherwise take all Tax and financial reporting positions in a manner consistent with such treatment.

SECTION 2.08. No State-Law Partnership. The Unitholders intend that the Company not be a partnership (including, without limitation, a limited partnership) or joint venture, and that no Unitholder be a partner or joint venturer of any other Unitholder by virtue of this Agreement, for any purposes other than as set forth in Section 2.07, and neither this Agreement nor any other document entered into by the Company or any Unitholder relating to the subject matter hereof shall be construed to suggest otherwise.

ARTICLE III
UNITS, CAPITAL CONTRIBUTIONS AND CAPITAL ACCOUNTS

SECTION 3.01. Units.

(a) Authorized Units. Subject to Section 3.02, the total Units which the Company has authority to issue shall be determined by the Board from time to time and shall, as of the Effective Date, be as set forth in the Prior Agreement. The Company may not issue fractional Units. The ownership by a Unitholder of Units shall entitle such Unitholder to allocations of Profits and Losses and other items and Distributions of cash and other property as set forth in ARTICLE IV hereof. All Units issued hereunder shall be certificated.

(b) Unit Ownership Ledger; Capital Contributions. The Company shall maintain a ledger (the "Unit Ownership Ledger"), which shall be appended to this Agreement as Appendix A, that sets forth the name and address of each Unitholder, the number of each class of Units held of record by each such Unitholder, the amount of the Capital Contribution made with respect to each class of Units and the date of such Capital Contribution, the percentage interest held in the Company by each Unitholder, the issuance date of each Unitholder's units and the certificate number(s) of each Unitholder's Units. Upon any change in the number or ownership of outstanding Units (whether upon an issuance of Units, a Transfer of Units, a cancellation of Units or otherwise), the Company shall amend and update the Unit Ownership Ledger and cancel, issue or reissue any certificates, as applicable, to reflect such corresponding changes in the Unit Ownership Ledger. Unless otherwise determined by the Board, in an individual case or a general case, the Unit Ownership Ledger will only be provided to Unitholders in summary form. Absent manifest error, the ownership interests recorded on the Unit Ownership Ledger shall be the conclusive record of the Units that have been issued and are outstanding. Each Unitholder named in the Unit Ownership Ledger has made (or shall be deemed to have made) Capital Contributions to the Company as set forth in the Unit Ownership Ledger in exchange for the Units specified in the Unit Ownership Ledger. Any reference in this Agreement to the Unit Ownership Ledger shall be deemed a reference to the Unit Ownership Ledger as amended and in effect from time to time. No subsequent capital contributions shall be required from any Unitholder.

SECTION 3.02. Issuance of Additional Units and Interests. Subject to Section 3.03, Section 5.03(b) and Section 5.03(c), the Board shall have the right at any time and from time to time to cause the Company to create and/or issue Equity Securities (including other classes, groups or series thereof having such relative rights, powers, and/or obligations as may from time to time be established by the Board, including rights, powers, and/or obligations different from, senior to or more favorable than existing classes, groups and series of Equity Securities), in which event, (a) all Unitholders holding the same class of Units shall be diluted in an equal manner with respect to such issuance with respect to such same class of Units (it being understood that different classes of Units may be treated differently) and (b) the Board, shall have the power to amend this Agreement and/or the Unit Ownership Ledger to reflect such additional issuances and dilution and to make any such other amendments as it deems necessary or desirable (in its sole discretion) to reflect such additional issuances (including, without limitation, authorizing an increase in the

authorized number of Equity Securities of any class, group or series, amending this Agreement to create and authorize a new class, group or series of Equity Securities and to add the terms of such new class, group or series of Equity Securities, including economic and governance rights which may be different from, senior to or more favorable than the other existing Equity Securities), in each case, without the approval or consent of any other Person. In connection with any issuance of Units (whether on or after the date hereof), the Person who acquires such Units shall execute a joinder or counterpart to this Agreement accepting and agreeing to be bound by all terms and conditions hereof, and shall enter into such other documents, instruments and agreements to effect such purchase as are required by the Board. Each Person who acquires Units shall, in exchange for such Units, make a Capital Contribution to the Company in an amount to be determined by the Board in its sole discretion.

SECTION 3.03. Preemptive Rights.

(a) Except for Excluded Issuances, following the date hereof, if the Company offers to sell or grant the right to purchase any Equity Securities or debt securities (referred to collectively for the purposes of this Section 3.03 as the "Offeree Investors"), the Company shall offer to sell to each other Unitholder holding Common Units a portion of such securities equal to (x) the number of Equity Securities of the Company or its Subsidiaries being sold multiplied by (y) a fraction, the numerator of which is the total number of Common Units held by such Unitholder and the denominator of which is the total number of Common Units outstanding. Each Unitholder having rights pursuant to this Section 3.03 shall be entitled to purchase the offered securities at the most favorable price as such securities are to be offered to any Offeree Investor; provided that if any Offeree Investor is required to also purchase other securities or debt of the Company or any of its Subsidiaries, the Unitholder(s) exercising their rights pursuant to this Section 3.03 shall also be required to purchase their Pro Rata Share of the same strip of securities (on the same terms and conditions) that such Offeree Investor is required to purchase. The purchase price for all securities purchased under this Section 3.03 shall be payable in cash.

(b) In order to exercise its purchase rights hereunder, a Unitholder having preemptive rights pursuant to this Section 3.03 must, within 10 calendar days after delivery to such Unitholder of written notice in accordance with Section 14.09 (a "Preemptive Rights Notice") from the Company describing in reasonable detail (i) the securities being offered, (ii) the purchase price thereof, (iii) the payment terms and (iv) the amount such Person is eligible to purchase hereunder, deliver a written notice to the Company irrevocably exercising such Unitholder's purchase rights pursuant to this Section 3.03.

(c) Upon the expiration of the offering periods described above, the Company shall be entitled to sell such securities which such Unitholders having rights pursuant to this Section 3.03 have not elected to purchase during the 90 calendar days following such expiration at a price not less than the price set forth in the Preemptive Rights Notice. Any securities offered or sold by the Company after such 90 day period must be reoffered pursuant to the terms of this Section 3.03 to the extent this Section 3.03 applies to such offering.

(d) Each Unitholder exercising its purchase rights hereunder shall take all reasonably necessary and desirable actions as directed by the Company in connection with such Person's participation in the applicable issuance, including executing a purchase (or similar) agreement and making representations and warranties therein and agreeing to provide indemnification as directed by the Company.

SECTION 3.04. Capital Accounts.

(a) There shall be established on the books and records of the Company a Capital Account for each Unitholder.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

(b) The Board shall cause the Unitholders' Capital Accounts to be adjusted and maintained in accordance with the principles of Section 704(b) of the Code and the Treasury Regulations thereunder. Without limiting the foregoing, the balance in each Unitholder's Capital Account shall be adjusted by (i) increasing such balance by (A) such Unitholder's allocable share of each item of the Company's Profits (allocated in accordance with Section 3.05 and Section 3.06) and (B) the Capital Contributions, if any, made by such Unitholder; and (ii) decreasing such balance by (A) the amount of cash or the value of other property distributed to such Unitholder pursuant to this Agreement (net of liabilities secured by the distributed property that such Unitholder is considered to assume or take subject to under Section 752 of the Code) and (B) such Unitholder's allocable share of each item of the Company's Losses allocated in accordance with Section 3.05 and Section 3.06).

(c) Except as provided in this Agreement or required by law, no Unitholder shall be required to make up a negative balance in such Unitholder's Capital Account.

SECTION 3.05. Allocations of Profits and Losses.

(a) Subject to the special allocations provided in Section 3.05(b), Profits and Losses (and, to the extent necessary, items of income, gain, loss and deduction) for each Allocation Period shall be allocated among the Unitholders with respect to each such Allocation Period to equal, as nearly as possible, (i) the amount such Unitholders would receive if all assets of the Company on hand at the end of such Allocation Period were sold for cash equal to their Book Values, all liabilities of the Company were satisfied in cash in accordance with their terms (limited in the case of non-recourse liabilities to the Book Value of the property securing such liabilities), and all remaining or resulting cash (including any withheld amounts) were distributed to the Unitholders under Section 12.02(c)) minus (ii) such Unitholder's share of Company Minimum Gain and Unitholder Nonrecourse Debt Minimum Gain, computed immediately prior to the hypothetical sale of assets, and the amount any such Unitholder is treated as obligated to contribute to the Company, computed immediately after the hypothetical sale of assets.

(b) Special Allocations. Notwithstanding any other provision in this Section 3.05, the following special allocations shall be made in the following order:

(i) Minimum Gain Chargeback. If there is a net decrease in Company Minimum Gain during any Allocation Period, each Unitholder shall be specially allocated items of Company income and gain for such Allocation Period (and, if necessary, in subsequent Allocation Periods) in an amount equal to the portion of such Unitholder's share of the net decrease in Company Minimum Gain that is allocable to the disposition of Company property subject to a Nonrecourse Liability, which share of such net decrease shall be determined in accordance with Treasury Regulations Section 1.704-2(g)(2). The items to be so allocated shall be determined in accordance with Treasury Regulations Section 1.704-2(f). This Section 3.05(b)(i) is intended to comply with the minimum gain chargeback requirement contained in Treasury Regulations Section 1.704-2(f) and shall be interpreted consistent therewith.

(ii) Chargeback of Minimum Gain Attributable to Unitholder Nonrecourse Debt. If there is a net decrease in unitholder Nonrecourse Debt Minimum Gain attributable to any Unitholder Nonrecourse Debt during any Allocation Period, each Unitholder who has a share of the Unitholder Nonrecourse Debt Minimum Gain (which share shall be determined in accordance with Treasury Regulations Section 1.704-2(i)(5)) shall be specially allocated items of Company income and gain for such Allocation Period (and, if necessary, in subsequent Allocation Periods) in an amount equal to that portion of such Unitholder's share of the net decrease in Unitholder Nonrecourse Debt Minimum Gain that is allocable to the disposition of Company property subject to such Unitholder Nonrecourse Debt (which share of such net decrease shall be determined in accordance with Treasury Regulations Section 1.704-2(i)(5)). The items to be so allocated shall be determined in accordance with Treasury Regulations Section

1.704-2(i)(4). This Section 3.05(b)(ii) is intended to comply with the minimum gain chargeback requirement contained in Treasury Regulations Section 1.704-2(i)(4) and shall be interpreted consistent therewith.

(iii) Nonrecourse Deductions. Any nonrecourse deductions (as defined in Treasury Regulations Section 1.704-2(b)(1)) for any Allocation Period shall be specially allocated to the Unitholders in proportion to their percentage interests.

(iv) Unitholder Nonrecourse Deductions. Those items of Company loss, deduction, or expenditures pursuant to Section 705(a)(2)(B) of the Code that are attributable to Unitholder Nonrecourse Debt for any Allocation Period shall be specially allocated to the Unitholder that bears the economic risk of loss with respect to the Unitholder Nonrecourse Debt to which such items are attributable in accordance with Treasury Regulations Section 1.704-2(i).

(v) Qualified Income Offset. If a Unitholder unexpectedly receives any adjustments, allocations, or Distributions described in Treasury Regulations Section 1.704-l(b)(2)(ii)(d)(4), (5) or (6), or any other event creates a deficit balance in such Unitholder's Capital Account in excess of such Unitholder's share of Company Minimum Gain, items of Company income and gain shall be specially allocated to such Unitholder in an amount and manner sufficient to eliminate such excess deficit balance as quickly as possible. This Section 3.05(b)(v) is intended to qualify and be construed as a "qualified income offset" within the meaning of Treasury Regulation Section 1.704-1(b)(2)(ii)(d) and shall be interpreted consistently therewith.

(vi) If there is a change in the percentage interest of the Unitholders as a result of Capital Contributions pursuant to Section 3.01(b), any gain or loss resulting from the adjustment of the Book Value of any Company asset in connection with such capital contribution shall be allocated among the Unitholders so as to cause (to the nearest extent possible) the Capital Account of the Unitholders (as calculated after taking into account any adjustments to the Percentage Interests and such capital contributions) to be in proportion to (A) the amount each Unitholder would receive if all assets of the Company on hand at the end of such Allocation Period were sold for cash equal to their Book Values, all liabilities of the Company were satisfied in cash in accordance with their terms (limited in the case of non-recourse liabilities to the Book Value of the property securing such liabilities), and all remaining or resulting cash (including any withheld amounts) were distributed to the Unitholders under Section 12.02(c) minus (B) such Unitholder's share of Company Minimum Gain and Unitholder Nonrecourse Debt Minimum Gain, computed immediately prior to the hypothetical sale of assets, and the amount any such Unitholder is treated as obligated to contribute to the Company, computed immediately after the hypothetical sale of assets.

(vii) Any special allocations of items of income and gain pursuant to this Section 3.05 shall be taken into account in computing subsequent allocations of income and gain pursuant to this ARTICLE III so that the net amount of any item so allocated and the income, gain, and losses allocated to each Unitholder pursuant to this ARTICLE III to the extent possible, shall be equal to the net amount that would have been allocated to each such Unitholder as if the special allocations pursuant to this Section 3.05 had not occurred.

SECTION 3.06. Income Tax Allocations.

(a) Except as provided in this Section 3.06, each item of income, gain, loss and deduction of the Company for federal income tax purposes shall be allocated, to the maximum extent possible, among the Unitholders in the same manner as the corresponding items (if any) are allocated for purposes of maintaining Capital Accounts under Section 3.05.

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(b) The Unitholders recognize that there may be a difference between the Book Value of a Company asset and the asset's adjusted tax basis at the time of the property's contribution or revaluation pursuant to this Agreement. In such a case, all items of tax depreciation, cost recovery, amortization, and gain or loss with respect to such asset shall be allocated among the Unitholders to take into account the disparities between the Book Values and the adjusted tax basis with respect to such properties in accordance with the "remedial" method under Sections 704(b) and 704(c) of the Code.

(c) All items of income, gain, loss, deduction and credit allocated to the Unitholders in accordance with the provisions hereof shall be determined without regard to any election under Section 754 of the Code which may be made by the Company; provided, however, that such allocations, once made, shall be adjusted as necessary or appropriate to take into account the adjustments permitted by Sections 734 and 743 of the Code.

(d) If any deductions for depreciation, amortization or cost recovery are recaptured as ordinary income upon the sale or other disposition of Company properties, the ordinary income character of the gain from such sale or disposition shall be allocated among the Unitholders in the same ratio as the deductions giving rise to such ordinary income character were allocated in accordance with Treasury Regulations Section 1.1245-1.

(e) The Unitholders' proportionate shares of the "excess nonrecourse liabilities" of the Company, within the meaning of Treasury Regulation Section 1.752-3(a)(3), shall be allocated to the holders of Units in accordance with their respective percentage interests.

(f) Tax credits of the Company shall be allocated among the Unitholders as provided in Treasury Regulation Sections 1.704-1(b)(4)(ii) and 1.704-1(b)(4)(viii).

(g) Allocations pursuant to this Section 3.06 are solely for purposes of federal, state, and local taxes and except as specifically provided shall not affect, or in any way be taken into account in computing, any Unitholder's Capital Account or share of Profits, Losses, other items or Distributions pursuant to any provision of this Agreement.

ARTICLE IV
DISTRIBUTIONS

SECTION 4.01. Distributions.

(a) Distribution Priorities. Except as otherwise set forth in this ARTICLE IV, and subject to the provisions of Section 18-607 of the Delaware Act, the Board may in its discretion make Distributions at any time or from time to time. All Distributions shall be made to the Unitholders of Common Units (ratably among such holders based upon the number of Common Units held immediately prior to such Distribution);

(b) The Board may apply Section 4.01(a) by breaking a single Distribution into two or more Distributions treated as separate Distributions occurring in order.

(c) Reserves Against Distributions. The Board shall have the right to (i) withhold from Distributions payable to any Unitholder under this Agreement an amount sufficient to pay and discharge such Unitholder's indirect Pro Rata Share of any contingent liabilities of the Company or any of its Subsidiaries and/or (ii) condition any Distributions payable to any Unitholder under this Agreement on such Unitholder agreeing to return to the Company, on demand, an amount sufficient to pay and discharge such Unitholder's indirect Pro Rata Share of any contingent liabilities of the Company or any of its Subsidiaries.

Any amounts remaining after payment and discharge of any such contingent liabilities of the Company or any of its Subsidiaries will be paid to the Unitholders from whom the Distributions were withheld.

SECTION 4.02. Tax Distributions. Notwithstanding Section 4.01, the Company shall make a Distribution to each Unitholder to the extent of Available Cash no later than five (5) days prior to the U.S. federal estimated income tax payment dates applicable to corporations (and, if necessary, no later than 30 days after the end of the Fiscal Year) in an amount equal to the excess (if any) of (a) the product of the Assumed Tax Rate and all taxable income and gain allocable to such Unitholder pursuant to this Agreement (including, for the avoidance of doubt, any income allocable as a result of Section 704(c) of the Code) for the applicable quarterly estimated tax period or Fiscal Year and (b) the aggregate amounts previously distributed to such Unitholder pursuant to Section 4.01 and this Section 4.02 with respect to such Fiscal Year. Any amount distributed to a Unitholder pursuant to this Section 4.02 shall be deemed to be an advance Distribution of amounts otherwise distributable to such Unitholder pursuant to Section 4.01 and shall reduce the amounts that would subsequently otherwise be distributable to such Unitholder pursuant to Section 4.01 in the order in which such amounts would otherwise have been distributable.

SECTION 4.03. Withholding. Notwithstanding any contrary provision of this Agreement, the Company shall be permitted to withhold and deduct any amounts required by applicable law to be withheld or deducted with respect to any Unitholder. The Company shall timely remit any amounts so withheld or deducted to the appropriate taxing authority. If and to the extent that the Company is required to withhold or pay any such withholding or other taxes on behalf of, or with respect to, a Unitholder, such Unitholder shall be deemed for all purposes of this Agreement to have received a payment from the Company as of the time that such withholding or other tax is required to be paid, which payment shall be deemed to be a Distribution with respect to such Unitholder's interest in the Company to the extent that such Unitholder (or any successor to such Unitholder's interest in the Company) would have received a cash Distribution but for such withholding. To the extent that such payment exceeds the cash Distribution that such Unitholder would have received but for such withholding, the Board shall notify such Unitholder as to the amount of such excess, and such Unitholder shall make a prompt payment to the Company of such amount, which payment will not constitute a Capital Contribution. Each Unitholder and the Company shall use commercially reasonable efforts to reduce or eliminate the amount required to be withheld or deducted with respect to such Unitholder. The obligations of a Unitholder pursuant to this Section 4.03 shall survive the termination, dissolution, liquidation and winding up of the Company and the withdrawal of such Unitholder from the Company or transfer of its interests.

ARTICLE V
GOVERNANCE

SECTION 5.01. Authority.

(a) Authority of Board. Pursuant to Section 18-402 of the Delaware Act and subject in all respects to the limitations set forth in Section 5.03, as provided in this Section 5.01, (i) the Board shall conduct, direct and exercise full control over all activities of the Company (including all decisions relating to the issuance of additional Equity Securities, and the voting and sale of, and the exercise of other rights with respect to, the equity securities of its Subsidiaries), (ii) all management powers over the business and affairs of the Company shall be exclusively vested in the Board and (iii) the Board shall have the sole power to bind or take any action on behalf of the Company, or to exercise any rights and powers (including the rights and powers to take certain actions, give or withhold certain consents or approvals, or make certain determinations, opinions, judgments, or other decisions) granted to the Company under this Agreement or any other agreement, instrument, or other document to which the Company is a party.

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(b) Certain Actions. Without limiting the generality of the foregoing, but subject in all respects to the limitations set forth in Section 5.03, (i) the Board shall exercise all rights and powers of the Company and/or its Subsidiaries (including all rights and powers to take actions, give or withhold consents or approvals, waive or require the satisfaction of conditions, or make determinations, opinions, judgments, or other decisions, and whether such rights and powers are granted to the Company under the terms of an agreement to which the Company is a party, or arise as a result of the Company's direct or indirect ownership of securities or otherwise) which are granted to the Company and/or its Subsidiaries under the Purchase Agreement and the agreements, instruments or documents contemplated respectively thereby; and (ii) subject only to the terms and conditions of Section 3.02, the Board may determine the timing and amount and other terms of any equity investment in the Company and may effect amendments to this Agreement necessary in order to effectuate such equity investments, in each case without any vote or other approval by the Unitholders.

SECTION 5.02. Composition of the Board.

(a) Number and Appointment. The number of Directors on the Board and the appointment rights in respect thereof shall be determined pursuant to this Section 5.02(a) (and subject to Section 5.03, as applicable), and the Board shall be comprised of the following Persons:

(i) three Directors as designated by OXB from time to time (the "OXB Directors");

(ii) one Director designated by HMI from time to time (the "HMI Director"); and

(iii) the chief executive officer of the Company (the "CEO"), so long as (and only so long as) such person remains the chief executive officer of the Company.

(b) Term. Each Director shall serve until a successor is appointed in accordance with the terms hereof or his or her earlier resignation, death or removal. A person shall become a Director effective upon receipt by the Company of written notice (or at such later time or upon the happening of some other event specified in such notice) of such person's designation by the Person or Persons entitled to designate such Director pursuant to Section 5.02(a) above; provided that the persons identified in Section 5.02(a) above, if any, by name shall become Directors effective upon the date hereof. A Director may resign at any time by delivering written notice to the Company. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

(c) Removal. If a CEO ceases to be the chief executive officer of the Company for any reason, such CEO shall be removed automatically from the Board and each committee thereof upon such cessation (without any action on the part of such CEO, the Board or such committees). The removal from the Board or any of its committees (with or without cause) of any OXB Director shall be upon (and only upon) the written request of OXB. The removal from the Board or any of its committees (with or without cause) of any HMI Director shall be upon (and only upon) the written request of HMI.

(d) Vacancies. A vacancy on the Board because of resignation, death or removal of a Director will be filled by the Person or Persons entitled to appoint such Director pursuant to the terms of Section 5.02(a) above. If any Person or Persons fail to appoint a Director pursuant to the terms of Section 5.02(a) above or the immediately preceding sentence, such position on the Board shall remain vacant until such Person or Persons exercise their right to appoint a Director as provided hereunder.

(e) Reimbursement. The Company shall pay, or shall cause one of its Subsidiaries to pay, the out-of-pocket costs and expenses incurred by each Director in the course of his or her service to the Company and/or its Subsidiaries, including in connection with attending regular and special meetings

of the Board, any board of managers or board of directors of each of the Company's Subsidiaries and/or any of their respective committees.

(f) Compensation of Directors. Except for reimbursement of reasonable out-of-pocket costs and expenses, OXB Directors, the HMI Director and the CEO shall not be compensated for their services as Directors.

(g) Sub Boards; Committees. The composition of the board of directors or board of managers of any Subsidiary of the Company shall be identical to the composition of the Board, unless otherwise approved by the Board (including the HMI Director). The voting rights on the board of directors or board of managers of each of the Company's Subsidiaries of the Directors serving on any such boards shall be commensurate with the voting rights of the Directors with respect to the Board. The composition of any committee of the Board shall be determined by the Board, but shall include the HMI Director.

SECTION 5.03. Board Actions; Meetings.

(a) Quorum; Voting. All OXB Directors and the HMI Director must be present at any meeting of the Board or any committee thereof (including for purposes of actions taken pursuant to Section 5.03(e)) in order to constitute a quorum for the transaction of business of the Board or such committee; provided, that if the HMI Director is not present at a duly called meeting of the Board, such meeting may be adjourned and reconvened with not less than 48 hours' notice and the HMI Director's presence shall not be necessary for a quorum at such reconvened meeting. Except as otherwise provided in this Agreement, the act of the Directors that have a majority of the total votes present at a meeting of the Board or such committee at which a quorum is present shall be the act of the Board or such committee. Notwithstanding the foregoing, once a quorum is present to commence a meeting of the Board or any committee thereof, such quorum shall be broken as soon as any OXB Director is no longer present at such meeting and no further business may be transacted at such meeting until such time as a quorum shall again be present. If a quorum shall not be present during a meeting of the Board or any committee thereof, the Directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present. Each Director shall have one vote on all matters voted on by the Board or any committee thereof of which such Director is a member.

(b) Matters Requiring Consent of the OXB Directors. So long as OXB holds a majority of the Units, the Company will not, and will cause its Subsidiaries not to, without approval of the Board, which must include the approval of the OXB Directors:

(i) amend the certificate of formation or this Agreement;

(ii) waive, or consent to the waiver by the Company of, any rights under this Agreement;

(iii) make any material change to the nature of the Business or change the principal place of business of the Company;

(iv) file any applications for, or materially modify, any material permit;

(v) issue, purchase or redeem any Equity Securities, admit any additional Unitholders, accept any additional Capital Contribution or grant any equity or equity-linked securities;

(vi) divide the Units into series or classes;

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(vii) approve the Budget for any Fiscal Year or any amendment thereto;

(viii) authorize Distributions (other than Tax Distributions);

(ix) establish any reserves on the Company's balance sheet (other than ordinary course reserves established in accordance with GAAP);

(x) incur any indebtedness for borrowed money, pledge or grant liens on any assets, or guarantee, assume, endorse or otherwise become responsible for the obligations of any other person, in each case in excess of $100,000;

(xi) make any loan, advance, capital contribution or other investment in or to any person in excess of $100,000;

(xii) enter into any transaction or series of related transactions involving the purchase, lease, license, exchange or other acquisition (including by merger, consolidation, acquisition of stock or acquisition of assets) of any assets and/or equity interests of any person, other than in the ordinary course of business;

(xiii) enter into or effect any transaction involving the sale, lease, license, exchange or other disposition (including by merger, consolidation, sale of stock or sale of assets) of any assets in excess of $100,000;

(xiv) approve any merger, consolidation or combination with or into any other person including any Sale of the Company;

(xv) establish a Subsidiary or enter into any joint venture or similar business arrangement;

(xvi) settle any lawsuit, action, dispute or other proceeding or assume any liability in excess of a certain amount;

(xvii) initiate or consummate an initial public offering or make a public offering and sale of any Units or any other securities of the Company or any successor entity;

(xviii) appoint or remove the Company's auditors or make any changes in the accounting methods or policies of the Company (other than as required by GAAP);

(xix) enter into, amend, waive, supplement or terminate any agreement between the Company or any of its Subsidiaries, on the one hand, and HMI or its controlled Affiliates, on the other hand;

(xx) initiate a bankruptcy proceeding (or consent to any involuntary bankruptcy proceeding);

(xxi) (1) hire or terminate the CEO or any other officer with the title of "Head of Department" or more senior, (2) change any compensation policies applicable to any such officer, or (3) enter into any material agreement with respect to such officer's employment, severance, consultancy or other service to the Company;

(xxii) hire any employees other than in accordance with the Budget, or as approved by the Board from time to time;

(xxiii) adopt any equity incentive plan;

(xxiv) establish, dissolve, modify in any material respect the role or authority of, or change the composition of, a board committee;

(xxv) approve any investment policy of the Company;

(xxvi) establish the corporate strategy of the Company, including with respect to the technological direction of the Business;

(xxvii) sell or exclusively out-license any material technology or intellectual property assets, other than licenses in the ordinary course of business;

(xxviii) voluntarily liquidate, wind up or dissolve the Company or initiate a bankruptcy proceeding (or consent to any involuntary bankruptcy proceeding);

(xxix) sell, transfer, license, pledge or encumber technology or intellectual property, other than licenses granted in the ordinary course of business and ordinary course disposal or replacement of obsolete technology or unused intellectual property; or

(xxx) make any commitment or enter into any binding agreement with respect to any of the foregoing matters.

(c) Matters Requiring Consent of the HMI Director. So long as HMI holds Units, the Company will not, and will cause its Subsidiaries not to, without approval of the Board, which must include the approval of the HMI Director:

(i) make any material change to the nature of the Business or change the principal place of business of the Company;

(ii) authorize Distributions on (other than Tax Distributions), or redeem or repurchase, any Equity Securities of the Company, in each case, on a non-Pro Rata Basis for the same class of Units;

(iii) approve or effect any Sale of the Company; provided that, for the avoidance of doubt, a change of control of OXB will not require the approval of the Board or the HMI Director;

(iv) enter into any transaction or series of related transactions involving the purchase, lease, license, exchange or other acquisition (including by merger, consolidation, acquisition of stock or acquisition of assets) of any assets and/or equity interests of any person, in each case having a value in excess of $5,000,000, other than in the ordinary course of business;

(v) voluntarily liquidate, wind up or dissolve the Company or initiate a bankruptcy proceeding (or consent to any involuntary bankruptcy proceeding);

(vi) take any action that would result in a change in the tax status of the Company;

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(vii) amend, alter or repeal HMI's rights set forth in this Agreement in a manner that adversely affects HMI's rights hereunder;

(viii) enter into a non-arms-length transaction with OXB or any of its Affiliates; provided that, without limiting and in all respects subject to the provisions set forth in Section 6.06, Board approval shall not be required in connection with the Company licensing intellectual property, know-how, trade secrets or materials, or providing other information and technology to OXB, or as otherwise set forth in any of the transaction documents;

(ix) other than Excluded Issuances and issuances in connection with any working capital-related financings, issue any Equity Securities; or

(x) enter into arrangements that restrict HMI from exercising the foregoing consent rights or contain restrictive covenants binding, limiting or restricting HMI or its affiliates (other than the Company).

Notwithstanding the foregoing, following the three-year anniversary of the Closing Date, clauses (i), (iii), (iv), (v), (ix) and, solely as it relates to the foregoing clauses following the three-year anniversary of the Closing Date, clause (x), of this Section 5.03(c) shall no longer apply.

(d) Meetings. Meetings of the Board and any committee thereof shall be held at the principal office of the Company or at such other place as may be determined by the Board or such committee. Regular meetings of the Board shall be held on such dates and at such times and places as shall be determined by the Board. Special meetings of the Board may be called by the chairman or any OXB Director or the HMI Director, and special meetings of any committee may be called by the chairman or any OXB Director on such committee. Notice of each special meeting of the Board or committee stating the date, place and time of such meeting shall be given to each Director (in the case of a Board meeting) or each Director on such committee (in the case of a committee meeting) by hand, telephone, electronic mail, overnight courier or the U.S. mail at least two (2) Business Days prior to such meeting. Notice may be waived before or after a meeting or by attendance without protest at such meeting.

(e) Action by Written Consent or Telephone Conference. Any action permitted or required by the Delaware Act, the Certificate or this Agreement to be taken at a meeting of the Board or any committee designated by the Board may be taken without a meeting, without notice and without a vote if a consent in writing, setting forth the action to be taken, is signed by all of the Directors (or all of the Directors comprising such committee). Such consent shall have the same force and effect as a vote at a meeting and may be stated as such in any document or instrument filed with the Secretary of State of Delaware, and the execution of such consent shall constitute attendance or presence in person at a meeting of the Board or any such committee, as the case may be. Subject to the requirements of the Delaware Act, the Certificate or this Agreement for notice of meetings, unless otherwise restricted by the Certificate, the Directors or members of any committee designated by the Board may participate in and hold a meeting of the Board or any committee, as the case may be, by means of a conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and participation in such meeting shall constitute attendance and presence in person at such meeting, except where a person participates in the meeting for the express purpose of objecting to the transaction of any business on the ground that the meeting is not lawfully called or convened.

SECTION 5.04. Delegation of Authority. Without limiting and subject in all respects to Section 5.03(b) and Section 5.03(c), the Board may, from time to time, delegate to one or more Persons (including any Unitholder or Officer and including through the creation and establishment of one or more other committees) such authority and duties as the Board may deem advisable. Any delegation pursuant to this

Section 5.04 may be revoked at any time by the Board. The members (and observers) of any committee of the Board shall be determined by the Board in its discretion in accordance with the requirements in Section 5.02(g).

SECTION 5.05. Purchase of Units. Subject to the Company's compliance with the other applicable provisions of this Agreement, the Board may cause the Company to purchase, repurchase or otherwise acquire Units on a Pro Rata Basis (as applicable); provided that this provision shall not in and of itself obligate any Unitholder to sell any Units to the Company. So long as any such Units are owned by the Company, such Units will not be considered outstanding for any purpose and shall be deemed cancelled upon the acquisition thereof by the Company.

SECTION 5.06. Officers.

(a) Designation and Appointment. The Board may (but need not), from time to time, designate and appoint one or more persons as an Officer of the Company. No Officer need be a resident of the State of Delaware, a Unitholder or a Director. Any Officers so designated shall have such authority and perform such duties as the Board may, from time to time, delegate to them. The Board may assign titles to particular Officers (including, without limitation, Executive Chairman, Chairman, Chief Executive Officer, President, Chief Financial Officer, Chief Operating Officer, Vice President, Executive Vice President, Secretary, Assistant Secretary, Treasurer, or Assistant Treasurer). Unless the Board otherwise decides, if the title is one commonly used for officers of a business corporation formed, the assignment of such title shall constitute the delegation to such Officer of the authority and duties that are normally associated with that office, subject to (i) any specific delegation of authority and duties made to such Officer by the Board pursuant to the third sentence of this Section 5.06(a) and (ii) any delegation of authority and duties made to one or more Officers pursuant to the terms of Section 5.04. Each Officer shall hold office until such Officer's successor shall be duly designated or until such Officer's death or until such Officer shall resign or shall have been removed in the manner hereinafter provided. Any number of offices may be held by the same individual. The salaries or other compensation, if any, of the Officers and agents of the Company shall be fixed from time to time by the Board.

(b) Resignation; Removal; Vacancies. Any Officer (subject to any contract rights available to the Company, if applicable) may resign as such at any time. Such resignation shall be made in writing and shall take effect at the time specified therein, or if no time be specified, at the time of its receipt by the Board. The acceptance of a resignation shall not be necessary to make it effective, unless expressly so provided in the resignation. Any Officer may be removed as such, either with or without cause, by the Board in its discretion at any time; provided, however, that such removal shall be without prejudice to the contract rights, if any, of the individual so removed. Designation of an Officer shall not of itself create contract rights. Any vacancy occurring in any office of the Company may be filled by the Board and shall remain vacant until filled by the Board.

(c) Duties of Officers; Generally. The Officers, in the performance of their duties as such, shall owe to the Company and the Unitholders duties of loyalty and due care of the type owed by the officers of a corporation to such corporation and its stockholders under the laws of the State of Delaware.

SECTION 5.07. Limitations.

(a) Waiver of Fiduciary Duties. The Unitholders expressly acknowledge and agree hereby that their relationship to the Company, the Board and each other is strictly contractual in nature and is not that of partners, joint venturers or any similarly situated persons and is not fiduciary in nature. This Agreement is not intended to, and does not, create or impose any fiduciary duty or liability on any Covered Person. To the extent that, at law or in equity, a Covered Person has duties (including fiduciary duties) and

liabilities relating to such Covered Person to the Company or to any other Person, a Covered Person acting under this Agreement shall not be liable to the Company or to any other Person for its good faith reliance on the provisions of this Agreement. The Unitholders hereby acknowledge and agree that the provisions of this Agreement, to the extent that they restrict the duties and liabilities of a Covered Person otherwise existing at law or in equity, will replace such other duties and liabilities of such Covered Person. No Unitholder shall take, or cause or permit its Affiliates, directors, managers, members, partners, officers, employees or agents to take, any action that would bind or obligate the Company in any manner not expressly authorized by this Agreement.

(b) Board Discretion. Whenever in this Agreement or any other agreement contemplated herein or to which the Company is a party the Board (or any committee thereof) is permitted or required to take any action or to make a decision or determination, the Board (or such committee) shall take such action or make such decision or determination in its sole discretion, unless another standard is expressly set forth herein or therein. Whenever in this Agreement or any other agreement contemplated herein the Board (or any committee thereof) is permitted or required to take any action or to make a decision or determination in its "sole discretion" or "discretion," with "complete discretion" or under a grant of similar authority or latitude, each Director shall be entitled to consider such interests and factors as such Director desires.

(c) Good Faith and Other Standards. Whenever in this Agreement or any other agreement contemplated herein or to which the Company is a party the Board (or any committee thereof) is permitted or required to take any action or to make a decision or determination in its "good faith" or under another express standard, each Director shall act under such express standard and, to the extent permitted by applicable law, shall not be subject to any other or different standards imposed by this Agreement or any other agreement contemplated herein or to which the Company is a party.

ARTICLE VI
RIGHTS AND OBLIGATIONS OF UNITHOLDERS

SECTION 6.01. Limitation of Liability. Except as otherwise provided by non-waivable provisions of the Delaware Act, the debts, obligations and liabilities of the Company, whether arising in contract, tort or otherwise, shall be solely the debts, obligations and liabilities of the Company, and no Covered Person shall be obligated personally for any such debt, obligation or liability of the Company solely by reason of being a Unitholder or acting as a Director of the Company. Except as otherwise provided in this Agreement, a Unitholder's liability (in its capacity as such) for debts, liabilities and losses of the Company shall be such Unitholder's share of the Company's assets; provided that a Unitholder shall be required to return to the Company any Distribution made to it (a) in clear and manifest accounting or similar error or (b) in clear, manifest and material breach of this Agreement, in each case, with respect to which written notice thereof has been delivered to the applicable Unitholder(s) within 60 days after the applicable Distribution. The immediately preceding sentence shall constitute a compromise to which all Unitholders have consented within the meaning of the Delaware Act. Notwithstanding anything contained herein to the contrary, the failure of the Company to observe any formalities or requirements relating to the exercise of its powers or management of its business and affairs under this Agreement or the Delaware Act shall not be grounds for imposing personal liability on the Covered Person for liabilities of the Company. Any amendment, modification or repeal of this Section 6.01 shall be prospective only and shall not in any way affect the limitations on the liability of the Unitholders under this Section 6.01 as in effect immediately prior to such amendment, modification or repeal with respect to claims arising from or relating to matters occurring, in whole or in part, prior to such amendment, modification or repeal, regardless of when such claims may arise or be asserted, and provided such Person became a Unitholder hereunder prior to such amendment, modification or repeal.

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SECTION 6.02. Lack of Authority. Except as expressly set forth herein, no Unitholder in its capacity as such has the authority or power to act for or on behalf of the Company in any manner or way, to bind the Company, or do any act that would be (or could be construed as) binding on the Company, in any manner or way, or to make any expenditures on behalf of the Company, unless such specific authority and power has been expressly granted to and not revoked from such Unitholder by the Board or pursuant to this Agreement (including pursuant to Section 5.03(b) or Section 5.03(c)), and the Unitholders hereby consent to the good faith exercise by the Board of the powers conferred on it by law and this Agreement.

SECTION 6.03. No Right of Partition. No Unitholder shall have the right to seek or obtain partition by court decree or operation of law of any Company property, or the right to own or use particular or individual assets of the Company.

SECTION 6.04. Indemnification.

(a) Generally. The Company hereby agrees to indemnify and hold harmless any Covered Person (each an "Indemnified Person") to the fullest extent permitted under the Delaware Act, as the same now exists or may hereafter be amended, substituted or replaced (but, in the case of any such amendment, substitution or replacement only to the extent that such amendment, substitution or replacement permits the Company to provide broader indemnification rights than the Company is providing immediately prior to such amendment, substitution or replacement), against all expenses, liabilities and losses whatsoever (including attorney fees and expenses, judgments, fines, excise Taxes or penalties) incurred or suffered by such Person (or one or more of such Person's Affiliates) by reason of the fact that such Person is or was a controlling Affiliate of the Company, or is or was serving as a Director, officer or director of the Company or is or was serving at the request of the Company as a managing member, manager, officer or director of another corporation, partnership, joint venture, limited liability company, trust or other enterprise or is or was a controlling Unitholder of the Company; provided that, unless the Board otherwise consents in writing, no Indemnified Person shall be indemnified for any expenses, liabilities and losses suffered that are attributable to actions or omissions by an Indemnified Person or its Affiliates to the extent the act or omission was attributable to such Indemnified Person's or its Affiliates' breach of this Agreement as determined by a final judgment, order or decree of an arbitrator or a court of competent jurisdiction (which is not appealable or with respect to which the time for appeal therefrom has expired and no appeal has been perfected) or for any present or future breaches of any representations, warranties or covenants by such Indemnified Person or its Affiliates' (excluding, for purposes hereof, the Company's and its Subsidiaries'), employees, agents or representatives contained herein or in any other agreement with the Company or any of its Subsidiaries; provided, further, that, unless the Board otherwise determines, no Person shall be entitled to indemnification hereunder with respect to a proceeding initiated by such Person or with respect to a proceeding between such Person on the one hand and either of the Company or its Subsidiaries on the other (other than a proceeding to enforce such Indemnified Person's rights under this Section 6.04). Expenses, including attorneys' fees and expenses, incurred by any such Indemnified Person in defending a proceeding (but not a proceeding initiated by such Indemnified Person, other than a proceeding to enforce such Indemnified Person's rights under this Section 6.04) may be paid by the Company in advance of the final disposition of such proceeding, including any appeal therefrom, upon approval of the Board and receipt of an undertaking by or on behalf of such Indemnified Person (in form and substance acceptable to the Board) to repay such amount if it shall ultimately be determined that such Indemnified Person is not entitled to be indemnified by the Company.

(b) Nonexclusivity of Rights. The right to indemnification and the advancement of expenses conferred in this Section 6.04 shall not be exclusive of any other right which any Person may have or hereafter acquire under any statute, agreement, law, vote of the Board or otherwise (such other rights, "Supplemental Indemnification Rights"). The Board may grant any rights comparable to those set forth in this Section 6.04 to any employee, agent or representative of the Company or such other Persons as it may

determine. In the event any provider of Supplemental Indemnification Rights pays any amount with respect to an Indemnified Person, such provider of Supplemental Indemnification Rights shall be subrogated to such Indemnified Person's rights to indemnification hereunder to the extent of payment made by such holder of Supplemental Indemnification Rights on behalf of such Indemnified Person. The Company and each Unitholder acknowledge and agree that the indemnification obligations of the Company hereunder and under any insurance policy contemplated pursuant to Section 6.04(d) shall be deemed primary coverage and in no event shall the Company (or any provider of insurance pursuant to Section 6.04(d)) be entitled to any contribution from any provider of Supplemental Indemnification Rights.

(c) Primacy of Obligations. In furtherance of Section 6.04(b), the Company acknowledges that certain Indemnified Persons may have rights to indemnification, advancement of expenses and/or insurance provided by OXB, HMI and/or certain of its Affiliates (collectively, the "Alternative Indemnitors"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to such Indemnified Persons are primary and any obligation of any Alternative Indemnitor, as applicable, to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Indemnified Persons are secondary), (ii) that it shall be required to advance the full amount of expenses incurred by such Indemnified Persons and shall be liable for the full amount of all expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement (or any other agreement between the Company and such Indemnified Persons), without regard to any rights such Indemnified Persons may have against the respective Alternative Indemnitors, and (iii) that it irrevocably waives, relinquishes and releases the Alternative Indemnitors from any and all claims against the Alternative Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the applicable Alternative Indemnitors on behalf of any such Indemnified Person with respect to any claim for which such Indemnified Person has sought indemnification from the Company shall affect the foregoing, and such Alternative Indemnitors shall have a right of contribution and/or be subrogated to the extent of any such advancement or payment to all of the rights of recovery of such Indemnified Person against the Company. The Company agrees that the Alternative Indemnitors are express third-party beneficiaries of the terms of this Section 6.04(c).

(d) Insurance. The Company may maintain insurance, at its expense, to protect any Indemnified Person against any expense, liability or loss of the nature described in Section 6.04(a) above whether or not the Company would have the power to indemnify such Indemnified Person against such expense, liability or loss under the provisions of this Section 6.04. If the Company does obtain such insurance, each Director shall be entitled to the same benefits under such insurance as each other Director. The Company shall ensure that any such insurance policies comply with Section 6.04(b), including that there be no right of contribution against any provider of Supplemental Indemnification Rights and that providers of Supplemental Indemnification Rights are subrogated to an Indemnified Person's rights under such insurance policies.

(e) Limitation. Notwithstanding anything contained herein to the contrary (including in this Section 6.04), any indemnity by the Company relating to the matters covered in this Section 6.04 shall be provided out of and to the extent of the Company's assets only, and no Unitholder (unless such Unitholder otherwise agrees in writing or is found in a final decision by a court of competent jurisdiction to have personal liability on account thereof) shall have personal liability on account thereof or shall be required to make additional Capital Contributions to help satisfy such indemnity of the Company (except as expressly provided herein).

(f) Savings Clause. If this Section 6.04 or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Company shall nevertheless indemnify and hold harmless each Indemnified Person pursuant to this Section 6.04 to the fullest extent permitted by any

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applicable portion of this Section 6.04 that shall not have been invalidated and to the fullest extent permitted by applicable law. The indemnification provisions set forth in this Section 6.04 shall be deemed to be a contract between the Company and each of the persons constituting Indemnified Persons at any time while the provisions of Section 6.04 remain in effect, whether or not such Person continues to serve in such capacity and whether or not such Person is a party hereto. In addition, this Section 6.04 cannot be retroactively amended to adversely affect the rights of any Indemnified Persons arising in connection with any acts, omissions, facts or circumstances occurring prior to such amendment.

SECTION 6.05. Unitholders' Right to Act. Except as expressly and specifically provided in this Agreement (for example, with respect to matters requiring the consent of any Person required under Section 14.01), no Unitholder shall have any right to vote on, approve or consent to any Company matter, including, without limitation, any matter described in Section 6.01. Without limiting the other provisions of this Agreement, no Unitholder shall owe any obligations or duties (including fiduciary duties) to the Company or any other Unitholder with respect actions taken by such Unitholder.

SECTION 6.06. Investment Opportunities and Conflicts of Interest. The Unitholders (on behalf of themselves and their Affiliates and representatives and including, for the avoidance of doubt, OXB , HMI, or any of the OXB Directors or the HMI Director, and collectively for purposes of this Section 6.06, the "Specified Persons") expressly acknowledge and agree that any business opportunities that are, from time to time, presented to any Specified Person or of which any Specified Person otherwise becomes aware relating to the manufacturing of adeno-associated vectors using transient transfection (each, an "AAV Opportunity") and/or plasmid DNA manufacture by bacterial fermentation (each a "Plasmid Opportunity" and, together with an AAV Opportunity, an "Opportunity") shall be presented in writing by or on behalf of such Specified Person to the CEO, [***]. For the avoidance of doubt, the involvement of OXB or any of its Affiliates, in their respective capacities as Specified Persons, in any such Opportunity in accordance with this Section 6.06 will not constitute a conflict of interest or breach of this Agreement.

SECTION 6.07. Confidentiality.

(a) Each Unitholder agrees that it will not disclose any Confidential Information without the prior written consent of the Company, except in all instances, subject to Section 6.06 in all respects, (x) OXB may disclose Confidential Information to its Affiliates and its and its Affiliates' respective managers, directors, officers, shareholders, partners, members, employees, representatives, and agents, (y) with respect to other Unitholders, to its employees, auditors, advisors, partners, prospective partners, investors, prospective investors or counsel or to any other Unitholder if it or its holding or parent company reasonably determines that any such party should have access to such information, in each case, to the extent such disclosure reasonably relates to the administration of this Agreement; provided, in the case of clause (x) and (y) above, such Persons (i) expressly agree in writing to be subject to the provisions of this Section 6.07 to the same extent as such disclosing Unitholder or (ii) are otherwise bound by customary and equivalent duties and obligations of confidentiality as set forth in this Section 6.07, and (z) as is required to be disclosed by order of a court of competent jurisdiction, administrative body or governmental body, or by subpoena, summons or legal process, or by law, rule or regulation; provided that the Unitholder required to make such disclosure pursuant to clause (z) above shall provide to the Company, to the extent not prohibited by law, rule or regulation, prompt written notice of such disclosure to enable the Company to seek an appropriate protective order or confidential treatment with respect to the Confidential Information required to be disclosed and such Unitholder shall use commercially reasonable efforts to obtain, at the request and expense of the Company, an order or other assurance that confidential treatment shall be accorded to such portion of the Confidential Information required to be disclosed as the Company shall designate. For the avoidance of doubt and notwithstanding anything contained herein to the contrary, but subject in all respects to Section 6.06, it is acknowledged and agreed that the OXB Directors may disclose Confidential Information to OXB and its Affiliates and its and its Affiliates' respective managers, directors,

officers, shareholders, partners, members, employees, representatives, and agents, provided that such recipients of Confidential Information comply with the provisions of Section 6.06 and this Section 6.07. "Confidential Information" means any and all confidential or proprietary information of and concerning the Business, the Company or the Company Group; provided that Confidential Information shall not include (and any Unitholder may disclose) any information (1) that has become generally available to the public other than as a result of (x) disclosure by a Unitholder or any of its or its Affiliates' respective managers, directors, officers, shareholders, partners, members, employees, representatives, and agents or (y) a direct or indirect breach of this Section 6.07, (2) that is obtained from a source other than (x) a Unitholder or any of its or its Affiliates' respective managers, directors, officers, shareholders, partners, members, employees, representatives, and agents or (y) the Company or any of its Subsidiaries, or any of their respective representatives, employees, agents or other service providers, and in each case, who is not known by such Person to be bound by a confidentiality obligation to any Unitholder or any of its Affiliates or the Company or any of its Subsidiaries or (3) is independently developed by such Person or such Person's Affiliates without reference to the Confidential Information.

(b) Notwithstanding the foregoing, each Unitholder and each other Person to whom such Unitholder has provided such information as permitted by this Section 6.07 may disclose Confidential Information as may be required in any report, statement or testimony submitted to (A) any municipal, state or federal regulatory body, rating agency or self-regulatory organization (including the National Association of Insurance Commissioners and any state insurance regulators) having or claiming to have jurisdiction over such Unitholder or its beneficial owner or, as may be required in respect of any summons or subpoena or in connection with any litigation, and in order to comply with any law, order, regulation or ruling applicable to such Unitholder or Person; provided that such Unitholder or Person shall only disclose Confidential Information to the minimum extent necessary to comply with any such requirement; provided, further, that with respect to clause (i), to the extent practicable, such Unitholder or Person shall in each such case promptly inform the Company of such requirement and shall cooperate with the Company in attempting to obtain a protective order or to otherwise restrict such disclosure or shall otherwise use commercially reasonable efforts to seek confidential treatment of such information; provided, further, that with respect to clauses (ii) or (iii), such Unitholder or Person shall in each such case promptly inform the Company of such requirement and shall reasonably cooperate with the Company in attempting to obtain a protective order or to otherwise restrict such disclosure. Each Unitholder understands that the restrictions set forth in this Section 6.07 will survive and continue to apply after this Agreement terminates for a period of two years after such termination. Each Unitholder acknowledges and agrees that the covenants under this Section 6.07 have a unique, substantial and immeasurable value to the Company Group, and that, as a result of the foregoing, in the event of any breach hereof monetary damages would be an insufficient remedy for the Company Group and equitable enforcement of such covenant would be proper. Therefore, each Unitholder agrees that the Company and each member of the Company Group, in addition to any other remedies available to it, shall be entitled to seek preliminary and permanent injunctive relief against any breach of the covenants set forth in this Section 6.07, without the necessity of posting of a bond or other security. Notwithstanding anything to the contrary herein, none of the foregoing provisions in any way limits HMI's confidentiality obligations set forth in the Purchase Agreement or Contribution Agreement or otherwise arising from the contemplated transactions.

SECTION 6.08. Non-Solicitation. For a period commencing on the date of this Agreement and ending on the shorter of (a) 12 months following the date hereof and (b) the maximum period permitted by applicable law in each applicable jurisdiction, (i) neither OXB nor HMI shall, directly or indirectly, hire or solicit for hire any employee of the Company or any of its Subsidiaries and (ii) the Company shall not hire or solicit for hire any employee of any of OXB or HMI; provided that OXB and HMI may mutually agree in writing to waive this provision as to any employee; and provided, further, that nothing in this Section 6.08 shall prohibit general advertisements not specifically targeted at any such employee to the extent that neither clause (i) nor clause (ii) of this Section 6.08 is breached in connection therewith.

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ARTICLE VII
RECORDS, ACCOUNTING; INSPECTION

SECTION 7.01. Records and Accounting. The Company shall keep, or cause to be kept, appropriate books and records with respect to the Company's business. The Company will deliver the following to each Unitholder: (a) annual audited financial statements of the Company within 50 days after the end of each Fiscal Year prepared in accordance with or adjusted to comply with GAAP; (b) quarterly unaudited financial statements of the Company within 25 days after the end of each Fiscal Quarter prepared in accordance with or adjusted to comply with GAAP; (c) a final copy of the Board-approved annual operating budget forecasting the Company's revenues, expenses, and cash position for each Fiscal Year promptly following the Company's adoption at the start of each Fiscal Year; and (d) such other financial information regarding the Company and its financial performance that is required for each Unitholder to complete its FCA or SEC (or any other applicable regulatory) filings and file its tax returns. All matters concerning (x) the determination of the relative amount of allocations and Distributions among the Unitholders pursuant to ARTICLE III and ARTICLE IV not specifically and expressly provided by the terms of this Agreement, and (y) accounting procedures and determinations, and other determinations not specifically and expressly provided by the terms of this Agreement, shall be determined by the Board in good faith, which determination shall be final and conclusive as to all of the Unitholders absent manifest clerical error.

SECTION 7.02. Transmission of Communications. Each Person that owns or controls Units on behalf of, or for the benefit of, another Person or Persons shall be responsible for conveying any report, notice or other communication received from the Company to such other Person or Persons.

ARTICLE VIII
TAX MATTERS

SECTION 8.01. Preparation of Tax Returns. As soon as reasonably practicable after the end of each Fiscal Year, but in no event later than 75 days after the end of such Fiscal Year, the Company shall send to each Person that was a Unitholder at any time during such Fiscal Year, U.S. Internal Revenue Service Schedule K-l, "Partner's Share of Income, Credits, Deductions, Etc.," or any successor schedule or form, for such Person. Except as otherwise expressly provided in this Agreement, the Company's tax returns, including all applicable elections, and any matters relating to taxes, shall be prepared, made or determined in the Board's reasonable discretion.

SECTION 8.02. Tax Controversies.

(a) The "partnership representative" of the Company within the meaning of Section 6223 of the Code shall be OXB or such other Person designated from time to time by the Board subject to replacement by the Board (any Person who is designated as the partnership representative is referred to herein as the "Company Representative"). The Company Representative shall be permitted to select any eligible individual to act as the "designated individual" of the Company within the meaning of Treasury Regulations Section 3011.6223-1(b)(3)(ii) (the "Designated Individual"). The Company Representative shall inform each Unitholder of all significant matters that may come to its attention in its capacity as Company Representative and shall forward to each Unitholder copies of all significant written communications it may receive in that capacity. Any reasonable, documented cost or expense incurred by the Company Representative in connection with its duties, including the preparation for or pursuance of administrative or judicial proceedings, shall be paid by the Company. The Company Representative shall not enter into any extension of the period of limitations for making assessments on behalf of the Unitholders or bind any Unitholders to a settlement agreement without first obtaining the consent of a majority interest

of the Unitholders or, if the settlement would have an adverse and disproportionate impact, other than an immaterial impact, on HMI, without the consent of HMI.

(b) For any tax year in which the Company is eligible to make the election described in Section 6221(b) of the Code, the Company shall so elect out and each Unitholder agrees not to take any action that would cause the Company to be ineligible to so elect out. For any tax year in which the Company is not able to make the election described in Section 6221(b) of the Code and is eligible to make an election under Section 6226(a) of the Code, the Company may, in the reasonable discretion of the Company Representative, so elect and each Member agrees not to take any action that would cause the Company to be ineligible to so elect.

(c) Subject to Section 5.01(b), each Unitholder agrees to reasonably cooperate with the Company Representative in connection with the taxation matters of the Company and to do or refrain from doing any or all things reasonably requested by the Company Representative with respect to the conduct of any tax proceedings.

(d) The provisions of this Section 8.02 shall survive the Unitholders' ceasing to be a Unitholder of the Company indefinitely.

SECTION 8.03. Section 754 Election. The Company shall make an election pursuant to Section 754 of the Code (and any corresponding election for state and local income Tax purposes) in connection with any Transfer of Units in the Company or Distributions to Unitholders.

ARTICLE IX
TRANSFER OF UNITS

SECTION 9.01. Required Consent.

(a) Other than (i) to a Permitted Transferee and (ii) Transfers expressly contemplated by Section 9.02, Section 9.03, Section 9.04 or Section 9.05, no Unitholder shall Transfer at any time any interest in any Units. If a Unitholder Transfers any interests in any Units to a Permitted Transferee and such Transferee ceases to be a Permitted Transferee of such Unitholder, then such Transferee shall, prior to ceasing to be a Permitted Transferee, Transfer such interest to the Unitholder (or other Permitted Transferee thereof) who made such Transfer.

(b) No Unitholder shall or shall seek to avoid, directly or indirectly, the provisions of this Agreement by (i) making one or more Transfers to one or more Permitted Transferees and then disposing of all or any portion of such Person's interest in any such Permitted Transferee, or (ii) issuing or permitting any Transfer of any equity securities of or interests in such Unitholder. Each Unitholder that is not a natural Person shall cause the holders of legal and beneficial interests in such Unitholder to not avoid the provisions of this Agreement by disposing of all or any portion of such Person's interest in such Unitholder. Any Transfer or attempted Transfer in violation of Section 9.01(a) or this Section 9.01(b) shall be void and otherwise subject to ARTICLE IX. Notwithstanding anything herein to the contrary, in no event shall this Section 9.01(b) apply to any direct or indirect Transfer or issuance of all or any portion of any direct interest in OXB or HMI, or their respective direct or indirect equityholders.

SECTION 9.02. Tag Along Rights.

(a) Participation Right. Except for Transfers (i) pursuant to Section 9.03, (ii) to a Permitted Transferee or (iii) arising out of an OXB Change of Control, in the event OXB desires to Transfer any outstanding Common Units (any such transaction subject to this Section 9.02, a "Tag Along Sale"),

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OXB, desiring to effect such Tag Along Sale (the "Selling Unitholders") shall give written notice, at least 10 days prior to any such Tag Along Sale, to each Unitholder holding one or more of the same classes of Units proposed to be Transferred (the "Tag Along Rights Holders" and such written notice, the "Tag Along Sale Notice") specifying in reasonable detail the identity of the prospective Transferee(s), the number and class of Units to be Transferred and the material terms and conditions of the Transfer. The Tag Along Rights Holders may irrevocably elect to participate in such Tag Along Sale by giving written notice of such irrevocable election to the Selling Unitholders within five days after delivery of the Tag Along Sale Notice (such Unitholders delivering such notice of election in accordance with this Section 9.02, collectively, the "Electing Unitholders"). For each Electing Unitholder, with respect to the Units for each class of Units to be transferred, such participation shall be based upon the Pro Rata Share represented by the Units of such class requested to be included in such Tag Along Sale by such Electing Unitholder relative to the Pro Rata Share of all Units of such class participating in such Tag Along Sale (including the Selling Unitholder and the Electing Unitholders). Each Unitholder participating in such Tag Along Sale shall Transfer its Units of such class on the same terms and conditions and the aggregate consideration to be paid in connection with such Tag Along Sale to each class of Units to be transferred and shall be allocated among each Unit of such class included therein based on such Unit's Pro Rata Share, determined based upon the Total Equity Value implied by the price offered in the Tag Along Sale. If the Tag Along Rights Holders have not elected to participate in the contemplated Transfer (through notice to such effect or expiration of the five day period after delivery of the Tag Along Sale Notice), then the Selling Unitholders may Transfer the Units specified in the Tag Along Sale Notice at a price and on other material terms no more favorable in the aggregate to the Transferee(s) thereof than specified in the Tag Along Sale Notice during the 120 day period beginning with the delivery of the Tag Along Sale Notice. Any Selling Unitholders' Units not Transferred during such 120 day period shall be subject to the provisions of this Section 9.02 upon subsequent Transfer. Each Tag Along Rights Holder shall take all necessary or desirable actions in connection with the consummation of the Tag Along Sale (whether in such Person's capacity as a Unitholder, Director or otherwise) as reasonably requested by the Selling Unitholders (including (A) executing and delivering any and all agreements, instruments, consents, waivers, releases and other documents in substantially the same forms executed, and on substantially the same terms agreed to, by the Selling Unitholders (including any applicable purchase agreement, stockholders agreement and/or indemnification and/or contribution agreement), (B) furnishing information and copies of documents, (C) filing applications, reports, returns, filings and other documents or instruments with Governmental Authorities, (D) participating in management meetings and preparing pitchbooks and confidential information memorandums, (E) providing assistance with legal, accounting, tax, financial, benefits and other forms of due diligence and (F) cooperating with the Company and the Selling Unitholders with such Tag Along Sale).

(b) Participation Procedure; Conditions. With respect to any Tag Along Sale, each Selling Unitholder shall use commercially reasonable efforts to obtain the agreement of the Transferee to the participation of the Electing Unitholders in such contemplated Tag Along Sale, and no Selling Unitholder shall Transfer any of its Units to any prospective Transferee pursuant to such Tag Along Sale if such prospective Transferee(s) declines to allow the participation of the Electing Unitholders on the terms provided herein, unless in connection with such Tag Along Sale, one or more of the Selling Unitholders or their Affiliates purchase the number and class of Units from each Electing Unitholder which such Electing Unitholder would have been entitled to sell pursuant to Section 9.02(a) at the same price and on the same terms and conditions on which such Units were sold to the Transferee(s). Each Electing Unitholder Transferring Units pursuant to a Tag Along Sale shall pay its share (determined on a Pro Rata Basis) of the expenses incurred by the Selling Unitholders in connection with such Transfer and each Electing Unitholder shall be obligated to join in any indemnification or other obligation the Selling Unitholders have agreed to in connection with such Tag Along Sale (including any such obligations that relate specifically to a particular Unitholder, such as indemnification with respect to representations and warranties given by a Unitholder regarding such Unitholder's title to and ownership of Units and tax status; provided that, unless the prospective Transferees permit a Unitholder to give a guarantee, letter of credit or other mechanism

(which shall be dealt with on an individual basis), any escrow of proceeds of any such transaction shall be withheld on a Pro Rata Basis among all participating Unitholders; provided, further, that the Selling Unitholders and Electing Unitholders shall share in indemnification liabilities related to such Tag Along Sale on a Pro Rata Basis (other than liabilities (if any) related solely to a participating Unitholder, which may be several).

SECTION 9.03. Approved Sale; Drag Along Obligations.

(a) Approved Sale. Subject to Section 5.03(c), if OXB approves or desires to pursue a Sale of the Company (an "Approved Sale"), each Unitholder (and each Person that retains voting control of any Units Transferred in accordance with Section 9.01) shall (including in such Person's capacity as a Director or by causing any Director(s) entitled to be appointed by such Person to) vote for, cooperate with, consent to and raise no objections against, and not otherwise impede or delay, such Approved Sale. Unless otherwise determined by OXB after good faith consultation with HMI, the Board shall establish a special committee of the Board to manage and facilitate the Approved Sale on behalf of the Company and the Unitholders, and the special committee shall have the authority to retain an investment banker with a nationally recognized reputation, attorneys, accountants and other professionals to advise and assist the Company and the special committee regarding the Approved Sale. In furtherance of the foregoing, if the Approved Sale is structured as a (x) merger or consolidation, each Unitholder shall waive and hereby waives any dissenters rights, appraisal rights or similar rights in connection with such merger or consolidation or (y) sale of Equity Securities, each Unitholder shall agree and hereby agrees to sell and Transfer, and shall sell and Transfer, all (or such lesser portion reflecting such Person's proportionate interest in the aggregate portion of the Total Equity Value being sold or disposed of in such Approved Sale) of such Unitholder's Units and other Equity Securities (regardless of whether each such Unitholder has rights to exercise a Put Option hereunder) on the terms and conditions approved by OXB. Each Unitholder shall take all reasonably necessary or desirable actions in connection with the consummation of the Approved Sale (whether in such Person's capacity as a Unitholder, Director or otherwise) as reasonably requested by OXB (including (A) executing and delivering any and all agreements, instruments, consents, waivers, releases and other documents in substantially the same forms executed by OXB (including any applicable purchase agreement, stockholders agreement and/or indemnification and/or contribution agreement), (B) furnishing information and copies of documents, (C) filing applications, reports, returns, filings and other documents or instruments with Governmental Authorities, (D) participating in management meetings and preparing pitchbooks and confidential information memorandums, (E) providing assistance with legal, accounting, tax, financial, benefits and other forms of due diligence, and (F) cooperating with the Company and OXB with such Approved Sale).

(b) Conditions. The obligations of the Unitholders with respect to the Approved Sale are subject to the satisfaction of the following conditions: (i) the consideration payable upon consummation of such Approved Sale to all Unitholders shall be allocated among the Unitholders based upon the Pro Rata Share represented by the Units Transferred by such Unitholder pursuant to such Approved Sale; (ii) upon the consummation of the Approved Sale, all of the Unitholders of a particular class of Unit shall receive (or shall have the option to receive) the same form of consideration for such class of Unit; and (iii) if any Unitholder of a particular class of Units are given an option as to the form and amount of consideration to be received or any other right or benefit with respect to the Approved Sale, each other Unitholder of such class of Units shall be given the same option, right or benefit (other than, in the case of clause (ii) and clause (iii) of this Section 9.03(b), any consideration, option, right or benefit to be received by a Unitholder on account of such individual's employment relationship with the Company or any of its Subsidiaries (e.g., stay bonus, noncompetition agreement or right to reinvest)).

(c) Indemnification; Expenses. Notwithstanding anything to the contrary, the Unitholders shall be obligated to join, on a Pro Rata Basis of such Unitholder's share of the aggregate

proceeds of such Approved Sale, in any indemnification obligation OXB has agreed to in connection with such Approved Sale (including any such obligations that relate specifically to a particular Unitholder, such as indemnification with respect to representations and warranties given by a Unitholder regarding such Unitholder's title to and ownership of Units and tax status); provided that (i) unless a prospective Transferee permits a Unitholder to give a guarantee, letter of credit or other mechanism (which shall be dealt with on an individual basis), any escrow of proceeds of any such transaction shall be withheld on a Pro Rata Basis among all Unitholders and (ii) the aggregate liability for any such Unitholder with respect to such indemnification obligations will be limited to the proceeds received by such Unitholder in the Approved Sale (other than in the case of fraud). Each Unitholder shall enter into any indemnification or contribution or other agreement reasonably requested by OXB to ensure compliance with this Section 9.03(c). Each Unitholder shall pay its portion (determined on a Pro Rata Basis) of the expenses incurred by the Unitholders pursuant to an Approved Sale to the extent such expenses are incurred for the benefit of all Unitholders (including the costs and expenses (including reasonable attorney's fees and expenses) incurred in connection with enforcing or implementing the terms and provisions of this Section 9.03). Expenses incurred by any Unitholder on its own behalf (including the fees and disbursements of counsel, advisors and other Persons retained by such holder in connection with the Approved Sale) will not be considered costs incurred for the benefit of all Unitholders and, to the extent not paid by the Company, will be the responsibility of such Unitholder. Notwithstanding the foregoing, the Company shall promptly reimburse OXB and HMI for any reasonable out-of-pocket expenses they respectively incur in connection with an Approved Sale.

(d) No Grant of Dissenters Rights or Appraisal Rights. In no manner shall this Section 9.03 be construed to grant to any Unitholder any dissenters rights or appraisal rights.

(e) Waiver. OXB may, in its sole discretion, decide whether or not to pursue, consummate, postpone or abandon any Approved Sale and the terms and conditions thereof. Neither the Board, OXB nor any of their Affiliates shall have any liability to any other Unitholder arising from, relating to or in connection with the pursuit, consummation, postponement, abandonment or terms and conditions of any such Approved Sale except to the extent OXB shall have failed to comply with the provisions of this Section 9.03. Subject to the provisions herein, to the maximum extent permitted by law, in connection with any Approved Sale, each Unitholder hereby waives all claims (including claims related to the fairness of the Approved Sale, the price paid (including the type of consideration received) for the Units in such Approved Sale, the process or timing of such Approved Sale, or any similar claim) arising from or relating to an Approved Sale, even if such Approved Sale results in no consideration being paid or payable to such Unitholder.

SECTION 9.04. Put Option; Call Option.

(a) Put Option; Call Option. At any time following the three-year anniversary of the Effective Date, OXB shall have the option, but not the obligation (the "Call Option"), to purchase, or cause any of its Affiliates to purchase, all the Units held by HMI or its Permitted Transferees on the terms set forth in this Section 9.04. At any time following the three-year anniversary of the Effective Date, HMI or its individual transferees (or its or their respective Affiliates) shall have the option, but not the obligation (the "Put Option"), to require OXB or the Company to purchase all the Units held by HMI or its Permitted Transferees on the terms set forth in this Section 9.04.

(b) Purchase Price of Units. The purchase price for the Units held by HMI or its Permitted Transferee in connection with the exercise of a Call Option or Put Option, as applicable, shall be equal to the amount to which HMI or its Permitted Transferee would be entitled to receive upon a liquidation of the Company, in accordance with Section 12.02, [***].

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(c) Exercise of the Call Option and Put Option. OXB or its Permitted Transferees may exercise the Call Option, and HMI or its Permitted Transferees may exercise the Put Option, by notifying the other in writing of its desire to exercise the Call Option or Put Option in accordance with this Section 9.04(c), as applicable (the "Option Notice"), at any time on or after the date that is the three-year anniversary of the date hereof.

(d) Unitholder Cooperation. Without limitation of the other provisions of this ARTICLE IX, each Unitholder shall take all necessary or desirable actions in connection with the consummation of the exercise of the rights set forth in this Section 9.04 (whether in such Person's capacity as a Unitholder, Director or otherwise) as reasonably requested by the selling holders (including (A) executing and delivering any and all agreements, instruments, consents, waivers, releases and other documents in substantially the same forms executed by the selling holders (including any applicable purchase agreement, stockholders agreement and/or indemnification and/or contribution agreement), (B) furnishing information and copies of documents, (C) filing applications, reports, returns, filings and other documents or instruments with Governmental Authorities, (D) participating in management meetings and preparing pitchbooks and confidential information memorandums, (E) providing assistance with legal, accounting, tax, financial, benefits and other forms of due diligence and (F) cooperating with the Company and the selling holders with the exercise of such rights.

SECTION 9.05. Rights upon a Change of Control of HMI. Subject to the provisions of this ARTICLE IX, upon a Change of Control of HMI, OXB may purchase all, but not less than all, of the Common Units held by HMI or its Permitted Transferee for a purchase price, payable in cash, equal to the amount to which HMI or its Permitted Transferee would be entitled to receive upon a liquidation of the Company, in accordance with Section 12.02, [***]. For purposes of this Section 9.05, a "Change of Control" means (i) the sale (in one or a series of related transactions and whether by merger, consolidation, reorganization, combination, sale or transfer of HMI's Equity Securities) of all or substantially all of the assets of HMI to a third party; (ii) a sale (in one or a series of related transactions and whether by merger, consolidation, reorganization, combination, sale or transfer of HMI's Equity Securities) resulting in more than 50% of the equity interests of HMI being held by a third party; or (iii) a merger, consolidation, recapitalization resulting in ownership of more than 50% of the issued and outstanding voting Equity Securities in HMI by a third party.

SECTION 9.06. Effect of Assignment.

(a) Termination of Rights. Any Unitholder who shall assign any Units or other interest in the Company shall cease to be a Unitholder with respect to such Units or other interest and shall no longer have any rights or privileges of a Unitholder with respect to such Units or other interest, except as provided in Section 9.01 with respect to any Units over which such Person retains voting control; provided that, notwithstanding the foregoing, unless and until the Assignee is admitted as a Substituted Unitholder in accordance with the provisions of ARTICLE X (the "Admission Date"), the Board may, in its sole discretion, reinstate all or any portion of the rights and privileges of such Unitholder with respect to such Units or other interest for any period of time prior to the Admission Date. Nothing contained herein shall relieve any Unitholder who Transfers any Units or other interest in the Company from any liability of such Unitholder to the Company or the other Unitholders with respect to such Units or other interest that may exist on the Admission Date or that is otherwise specified in the Delaware Act and incorporated into this Agreement or for any liability to the Company or any other Person or for any breaches of any representations, warranties or covenants by such Unitholder (in its capacity as such) contained herein or in the other agreements with the Company or any of its Subsidiaries or Affiliates.

(b) Deemed Agreement. Any Person who acquires in any manner whatsoever any Units or other interest in the Company, irrespective of whether such Person has accepted and adopted in writing

the terms and provisions of this Agreement, shall be deemed by the acceptance of the benefits of the acquisition thereof, to have agreed to be subject to and bound by all of the terms and conditions of this Agreement that any predecessor in such Units or other interest in the Company of such Person was subject to or by which such predecessor was bound.

(c) Assignee's Rights. A Transfer of Units permitted hereunder shall be effective as of the date of assignment and compliance with the conditions to such Transfer and such Transfer shall be shown on the books and records of the Company. Distributions made before the effective date of such Transfer shall be paid to the Transferor, and Distributions made after such date shall be paid to the Assignee. Unless and until an Assignee becomes a Unitholder pursuant to ARTICLE X hereof, the Assignee shall not be entitled to any of the rights or privileges granted to a Unitholder hereunder or under applicable law, other than the rights and privileges specifically granted to Assignees pursuant to this Agreement; such Assignee shall be bound by any limitations and obligations of a Unitholder contained herein by which a Unitholder would be bound on account of the ownership of Units by the Assignee (including the obligation, if any, to make Capital Contributions on account of such Units and the obligations set forth in ARTICLE IX).

(d) Execution of Counterpart. Except in connection with an Approved Sale, each Transferee of Units or other interests in the Company shall, as a condition prior to such Transfer, execute and deliver to the Company a joinder or counterpart to this Agreement in form and substance acceptable to the Board pursuant to which such Transferee shall agree to be bound by the provisions of this Agreement.

(e) Notice. In connection with the Transfer of any Units (other than pursuant to Section 9.02, Section 9.03, Section 9.04 or Section 10.01), the holder of such Units will deliver written notice to the Company describing in reasonable detail the Transfer or proposed Transfer.

SECTION 9.07. Transfer Fees and Expenses. Except for a Transfer pursuant to Section 9.02 or Section 9.03, the Transferor and Transferee of any Units or other interest in the Company shall be jointly and severally obligated to reimburse the Company for all reasonable expenses (including attorneys' fees and expenses) of any Transfer or proposed Transfer, whether or not consummated.

SECTION 9.08. Void Transfers. Except pursuant to Section 10.01, any Transfer by any Unitholder of any Units or other interest in the Company in contravention of this Agreement, or which would cause the Company to not be treated as a partnership for U.S. federal income tax purposes, shall be void and ineffectual and shall not bind or be recognized by the Company or any other party. No purported assignee shall have any right to any Distributions of the Company.

SECTION 9.09. Section 7704 Limits. Notwithstanding anything to the contrary in this Agreement, no Transfer of any Unit or economic interest shall be permitted or recognized by the Company or the Board (within the meaning of Treasury Regulations Section 1.7704-1(d)) if such Transfer (i) would cause the Company to have more than 100 partners, as determined for purposes of Treasury Regulations Section 1.7704-1(h) or (ii) would cause the Company to (or create any risk that the Company would) be treated as a publicly traded partnership within the meaning of Section 7704 of the Code and Treasury Regulations Section 1.7704-1, or (iii) cause the Company to fail to qualify for any "safe harbor" provided for in Section 7704 of the Code and the Treasury Regulations thereunder that otherwise would have been available.

ARTICLE X
ADMISSION OF UNITHOLDERS

SECTION 10.01. Substituted Unitholders. In connection with any Transfer of Units by a Unitholder permitted by and in accordance with the terms of ARTICLE IX hereof, the Transferee shall

become a Substituted Unitholder on the later of (a) the effective date of such Transfer, and (b) the date on which the Board approves such Transferee as a Substituted Unitholder (such approval not to be unreasonably withheld, conditioned or delayed), and such admission shall be shown on the books and records of the Company; provided, however, in connection with the Transfer of Units by a Unitholder to a Permitted Transferee permitted under the terms of this Agreement and the other agreements contemplated hereby and thereby, the Transferee shall become a Substituted Unitholder on the effective date of such Transfer.

SECTION 10.02. Additional Unitholders. A Person may be admitted to the Company as an Additional Unitholder only as contemplated under Section 3.02 and only upon furnishing to the Company (a) a joinder or counterpart to this Agreement in form and substance acceptable to the Board pursuant to which such Person shall agree to be bound by the provisions of this Agreement, and (b) such other documents or instruments as may be deemed necessary or appropriate by the Board to effect such Person's admission as a Unitholder. Such admission shall become effective on the date on which the Board determines that such conditions have been satisfied and when any such admission is shown on the books and records of the Company.

ARTICLE XI
WITHDRAWAL OF UNITHOLDERS

SECTION 11.01. Withdrawal of Unitholders. No Unitholder shall have the power or right to disclaim or abandon such Unitholder's Units or otherwise withdraw from the Company or cease to be subject to the provisions of this Agreement prior to the dissolution and winding up of the Company pursuant to ARTICLE XII, without the prior written consent of the Board (which consent may be withheld by the Board in each's Directors' sole discretion), except as otherwise expressly permitted by this Agreement. Upon a Transfer of all of a Unitholder's Units in a Transfer permitted by this Agreement, such Unitholder shall cease to be a Unitholder. Notwithstanding that payment on account of a withdrawal may be made after the effective time of such withdrawal, any completely withdrawing Unitholder will not be considered a Unitholder for any purpose after the effective time of such complete withdrawal, and, in the case of a partial withdrawal, such Unitholder's Capital Account (and corresponding voting and other rights) shall be reduced for all other purposes hereunder upon the effective time of such partial withdrawal.

ARTICLE XII
DISSOLUTION AND LIQUIDATION

SECTION 12.01. Dissolution. Subject to Section 5.03(b) and Section 5.03(c), the Company shall dissolve, and its affairs shall be wound up upon the first of the following to occur:

(a) the election of the Board (with the prior written consent of OXB); and

(b) a Sale of the Company.

(c) Except as otherwise set forth in this ARTICLE XII, the Company is intended to have perpetual existence. An Event of Withdrawal shall not cause a dissolution of the Company and the Company shall continue in existence subject to the terms and conditions of this Agreement.

SECTION 12.02. Liquidation and Termination. On the dissolution of the Company, the Board shall act as liquidator or may appoint one or more representatives, Unitholders or other Persons as liquidator(s) (with the prior written approval of OXB). The liquidators shall proceed diligently to wind up the affairs of the Company and make final Distributions as provided herein and in the Delaware Act. The costs of liquidation shall be borne as the Company's expense. Until final Distribution, the liquidators shall

continue to operate Company properties with all of the power and authority of the Board. The steps to be accomplished by the liquidators are as follows:

(a) The liquidators shall pay, satisfy or discharge from the Company's funds all of the debts, liabilities and obligations of the Company (including all expenses incurred in liquidation) or otherwise make adequate provision for payment and discharge thereof (including the establishment of a cash fund for contingent liabilities in such amount and for such term as the liquidators may reasonably determine).

(b) As promptly as practicable after dissolution, the liquidators shall (i) determine the Fair Market Value (the "Liquidation FMV") of the Company's remaining assets (the "Liquidation Assets") in accordance with ARTICLE XIII hereof, (ii) determine the amounts to be distributed to each Unitholder in accordance with Section 4.01, and (iii) deliver to each Unitholder a statement (the "Liquidation Statement") setting forth the Liquidation FMV and the amounts and recipients of such Distributions, which Liquidation Statement shall be final and binding on all Unitholders.

(c) As soon as the Liquidation FMV and the proper amounts of Distributions have been determined in accordance with Section 12.02(b), the liquidators shall promptly distribute the Company's Liquidation Assets to the holders of Units in accordance with Section 4.01. In making such Distributions, the liquidators shall allocate each type of Liquidation Assets (e.g., cash or cash equivalents, preferred or common equity securities) among the Unitholders ratably based upon the aggregate amounts to be distributed with respect to the Units held by each such holder; provided that the liquidators may allocate each type of Liquidation Assets so as to give effect to and take into account the relative priorities of the different Units. Any non-cash Liquidation Assets will first be written up or down to their Fair Market Value, thus creating Profit or Loss (if any), which shall be allocated in accordance with Section 4.01. If any Unitholder's Capital Account is not equal to the amount to be distributed to such Unitholder pursuant to Section 12.02(b), Profits and Losses for the Fiscal Year in which the Company is dissolved shall be allocated among the Unitholders in such a manner as to cause, to the extent possible, each Unitholder's Capital Account to be equal to the amount to be distributed to such Unitholder pursuant to Section 112.02(b). The Distribution of cash and/or property to a Unitholder in accordance with the provisions of this Section 12.02(c) constitutes a complete Distribution to the Unitholder of its interest in the Company and all Company property and constitutes a compromise to which all Unitholders have consented within the meaning of the Delaware Act. To the extent that a Unitholder returns funds to the Company, it has no claim against any other Unitholder for those funds.

SECTION 12.03. Securityholders Agreement. To the extent that units or other equity securities of any Subsidiary are distributed to any Unitholders and unless otherwise agreed to by the Board, such Unitholders hereby agree to enter into a securityholder's agreement with such Subsidiary and each other Unitholder which contains rights and restrictions in form and substance similar to the provisions and restrictions set forth herein (including in ARTICLE V and ARTICLE IX).

SECTION 12.04. Cancellation of Certificate. On completion of the Distribution of the Company's assets as provided herein, the Company shall be terminated (and the Company shall not be terminated prior to such time), and the Board (or such other Person or Persons as the Delaware Act may require or permit) shall file a certificate of cancellation with the Secretary of State of Delaware, cancel any other filings made pursuant to this Agreement that are or should be canceled and take such other actions as may be necessary to terminate the Company. The Company shall be deemed to continue in existence for all purposes of this Agreement until it is terminated pursuant to this Section 12.04.

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SECTION 12.05. Reasonable Time for Winding Up. A reasonable time shall be allowed for the orderly winding up of the business and affairs of the Company and the liquidation of its assets pursuant to Section 12.02 in order to minimize any losses otherwise attendant upon such winding up.

SECTION 12.06. Hart Scott Rodino. In the event the Hart Scott Rodino Antitrust Improvements Act of 1976 (the "HSR Act") is applicable to any Unitholder, the dissolution of the Company shall not be consummated until such time as the applicable waiting period (and extensions thereof) under the HSR Act have expired or otherwise been terminated with respect to each such Unitholder.

ARTICLE XIII
VALUATION

SECTION 13.01. Valuation of Units. The "Fair Market Value" of each Unit shall be the fair value of each such Unit as determined in good faith by the Board and based on the portion of the Total Equity Value to which each such Unit would be entitled as of the date of valuation and using all factors, information and data deemed by them to be pertinent.

SECTION 13.02. Valuation of Securities. The "Fair Market Value" of any other securities shall mean the average of the closing prices of the sales of the securities on all securities exchanges on which the securities may at the time be listed, or, if there have been no sales on any such exchange on any day, the average of the highest bid and lowest asked prices on all such exchanges at the end of such day, or, if on any day such securities are not so listed, the average of the representative bid and asked prices quoted in the NASDAQ System as of 4:00 P.M., New York time, or, if on any day such securities are not quoted in the NASDAQ System, the average of the highest bid and lowest asked prices on such day in the domestic over the counter market as reported by the National Quotation Bureau Incorporated, or any similar successor organization, in each such case averaged over a period of 21 days consisting of the day as of which the Fair Market Value is being determined and the 20 consecutive Business Days prior to such day. If at any time the securities are not listed on any securities exchange or quoted in the NASDAQ System or the over the counter market, the Fair Market Value of each such security shall be equal to the fair value thereof as of the date of valuation as determined by the Board in good faith.

SECTION 13.03. Valuation of Other Assets. The "Fair Market Value" of all other non-cash assets shall mean the fair value thereof as of the date of valuation as reasonably determined by the Board in good faith on the basis of an orderly sale to a willing, unaffiliated buyer in an arm's-length transaction occurring on the date of valuation, taking into account all relevant factors determinative of value as the Board reasonably deems relevant (and giving effect to any transfer Taxes payable or discounts in connection with such sale).

SECTION 13.04. Dispute Resolution. If a Unitholder disagrees with the Board's determination of Fair Market Value for any reason or purpose in this Agreement, such Unitholder (a "Disputing Unitholder") shall deliver to the Board written notice (a "Dispute Notice") of such dispute within ten Business Days of its receipt of the Board's determination of Fair Market Value. The Dispute Notice shall set forth the initial determination of such Disputing Unitholder of the Fair Market Value of the Units. The Board and the Disputing Unitholder shall then negotiate in good faith, including through reasonable engagement of such parties and their respective counsels, for ten (10) Business Days (or for such longer period as they mutually agree) in an effort to reach agreement on the Fair Market Value of the Units. If such negotiation is unsuccessful, the Board and the Disputing Unitholder shall promptly designate a mutually agreeable independent valuation firm, acting as a valuation expert and not as an arbitrator to resolve any remaining disputes set forth in the Dispute Notice in accordance with this Section 13.04. No later than the fifth Business Day after appointment of the independent appraiser, each of the Board and the Disputing Unitholder shall deliver to the independent appraiser a written notice of its final determination

of the Fair Market Value of the Units (each, a "Valuation Notice"). The independent appraiser shall be instructed to determine the final Fair Market Value of the Units within 30 calendar days of its receipt of both Valuation Notices. In making such determination, the independent appraiser (x) shall be instructed that the initial determinations by each of the Board and the Disputing Unitholder of the Fair Market Value shall not be used as evidence of the actual Fair Market Value or the correctness of either the Board's or the Disputing Unitholder's determination of the Fair Market Value set forth in the Valuation Notice and (y) may request additional submissions of information from the Board and/or the Disputing Notice (and the Board and/or the Disputing Unitholder shall promptly comply). The opinion of the independent appraiser shall be binding upon the Company, the Board and the Disputing Unitholder. The fees and expenses of the independent appraiser shall be borne equally by the Company and the Disputing Unitholder.

ARTICLE XIV
GENERAL PROVISIONS

SECTION 14.01. Amendments. Subject (x) in all respects to Section 5.03(b) and Section 5.03(c), and to (i) the right of the Board to amend this Agreement as expressly provided herein (including pursuant to Section 3.02), (ii) any amendment pursuant to a merger or consolidation that is approved in accordance with the terms of this Agreement, (iii) Section 6.04(f) regarding certain indemnification rights, (iv) Section 2.07 regarding the tax treatment of the Company, and (v) the last sentence of Section 3.01(b) regarding capital contributions, this Agreement may be amended, modified, or waived by or with the written consent of OXB or its Permitted Transferee, and such amendment, modification or waiver shall be binding upon and effective as to the Company, the Board and each other Unitholder; provided that any such amendment, modification or waiver that would alter or change the economic rights, economic obligations, economic powers or economic preferences of one or more Unitholders holding Common Units in a disproportionate and materially adverse manner compared to the economic rights, economic obligations, economic powers and economic preferences specific to other Unitholders in their capacities as the holders of Common Units shall also require the prior written consent of the Unitholders so disproportionately and materially adversely affected.

SECTION 14.02. Title to Company Assets. The Company's assets shall be deemed to be owned by the Company as an entity, and no Unitholder, individually or collectively, shall have any ownership interest in such assets or any portion thereof. Legal title to any or all of such assets may be held in the name of the Company or one or more nominees, as the Board may determine. The Board hereby declares and warrants that any Company assets for which legal title is held in the name of any nominee shall be held in trust by such nominee for the use and benefit of the Company in accordance with the provisions of this Agreement. All Company assets shall be recorded as the property of the Company on its books and records, irrespective of the name in which legal title to such assets is held.

SECTION 14.03. Remedies. Each Unitholder and the Company shall have all rights and remedies set forth in this Agreement and all rights and remedies which such Person has been granted at any time under any other agreement or contract and all of the rights which such Person has under any law. Any Person having any rights under any provision of this Agreement or any other agreements contemplated hereby shall be entitled to enforce such rights specifically (without posting a bond or other security), to recover damages by reason of any breach of any provision of this Agreement and to exercise all other rights granted by law.

SECTION 14.04. Successors and Assigns. All covenants and agreements contained in this Agreement shall bind and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors, legal representatives and permitted assigns, whether so expressed or not.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

SECTION 14.05. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or the effectiveness or validity of any provision in any other jurisdiction, and this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had never been contained herein or if such term or provision could be drawn more narrowly so as not to be illegal, invalid, prohibited or unenforceable in such jurisdiction, it shall be so narrowly drawn, as to such jurisdiction, without invalidating the remaining terms and provisions of this Agreement or affecting the legality, validity or enforceability of such term or provision in any other jurisdiction.

SECTION 14.06. Counterparts; Binding Agreement. This Agreement may be executed simultaneously in two or more separate counterparts, any one of which need not contain the signatures of more than one party, but each of which will be an original and all of which together shall constitute one and the same agreement binding on all the parties hereto. This Agreement and all of the provisions hereof shall be binding upon and effective as to each Person who (a) is issued or otherwise holds Units (other than as a result of a Transfer by such Unitholder after the date hereof made not in accordance with this Agreement) (whether or not they execute a counterpart to this Agreement), (b) executes this Agreement in the appropriate space provided in the signature pages hereto notwithstanding the fact that other Persons who have not executed this Agreement may be listed on the signature pages hereto and (c) may from time to time become a party to this Agreement by executing a counterpart of or joinder to this Agreement.

SECTION 14.07. Descriptive Headings; Interpretation. The descriptive headings of this Agreement are inserted for convenience only and do not constitute a substantive part of this Agreement. Whenever required by the context, any pronoun used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns, pronouns and verbs shall include the plural and vice versa. The use of the word “including” in this Agreement shall be by way of example rather than by limitation. Reference to any agreement, document or instrument means such agreement, document or instrument as amended or otherwise modified from time to time in accordance with the terms thereof, and if applicable hereof. Whenever required by the context, references to a Fiscal Year shall refer to a portion thereof. The use of the words “or,” “either” and “any” shall not be exclusive. The use of the word “class” shall be deemed to mean “class and/or series.” The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement. Wherever a conflict exists between this Agreement and any other agreement, this Agreement shall control but solely to the extent of such conflict.

SECTION 14.08. Applicable Law; Jurisdiction; Service of Process. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware. Each Unitholder irrevocably submits to the exclusive jurisdiction of the Court of Chancery of the State of Delaware (the “Court of Chancery”) or, to the extent the Court of Chancery does not have subject matter jurisdiction, the United States District Court for the District of Delaware and the appellate courts having jurisdiction of appeals in such courts (the “Delaware Federal Court”) or, to the extent neither the Court of Chancery nor the Delaware Federal Court has subject matter jurisdiction, the Superior Court of the State of Delaware (the “Chosen Courts”), for the purposes of any suit, action or other proceeding arising out of this Agreement or any transaction contemplated hereby and agrees that a final judgment in any such suit, action or other proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each Unitholder further agrees that service

of any process, summons, notice or document by United States certified or registered mail to such Unitholder's respective address set forth in the Company's books and records or such other address or to the attention of such other person as the recipient party has specified by prior written notice to the sending party shall be effective service of process in any action, suit or proceeding in the Chosen Courts with respect to any matters to which it has submitted to jurisdiction as set forth in the immediately preceding sentence. Each Unitholder irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the Chosen Courts and hereby irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in such Chosen Courts has been brought in an inconvenient forum.

SECTION 14.09. Addresses and Notices. All notices, demands or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given or made when (a) delivered personally to the recipient, (b) delivered by means of electronic mail (with hard copy sent to the recipient by reputable overnight courier service (charges prepaid) that same day) if emailed before 5:00 p.m. New York City time on a Business Day, and otherwise on the next Business Day, or (c) one Business Day after being sent to the recipient by reputable overnight courier service (charges prepaid). Such notices, demands and other communications shall be sent to the address for such recipient set forth in the Company's books and records, or to such other address or to the attention of such other person as the recipient party has specified by prior written notice to the sending party. Any notice to the Board shall be deemed given if delivered to each member of the Board at the last known address of such members, or in the case of (x) the OXB Directors, the address set forth on the Unit Ownership Ledger and (y) the HMI Director, the address for the HMI Director set forth on the Unit Ownership Ledger.

SECTION 14.10. Creditors. None of the provisions of this Agreement shall be for the benefit of or enforceable by any creditors of the Company or any of its Affiliates, and no creditor who makes a loan to the Company or any of its Affiliates may have or acquire (except pursuant to the terms of a separate agreement executed by the Company in favor of such creditor) at any time as a result of making the loan any direct or indirect interest in the Company's Profits, Losses, Distributions, capital or property other than as a secured creditor. Notwithstanding the foregoing, each of the Indemnified Persons is an intended third-party beneficiary of Section 6.04 and shall be entitled to enforce such provision (as it may be in effect from time to time).

SECTION 14.11. No Waiver. No failure by any party to insist upon the strict performance of any covenant, duty, agreement or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof shall constitute a waiver of any such breach or any other covenant, duty, agreement or condition.

SECTION 14.12. Further Action. The parties agree to execute and deliver all documents, provide all information and take or refrain from taking such actions as may be necessary or appropriate to achieve the purposes of this Agreement.

SECTION 14.13. Escrow for Disputed Amounts. In the event that OXB has made a claim against HMI for indemnification under and in accordance with Article VIII of the Purchase Agreement (an "Indemnification Claim"), and there is a Disputed Amount outstanding on the date on which a payment is to be paid by OXB or the Company, to HMI pursuant to Section 4.01, Section 9.04 or Section 9.05 of this Agreement (the "Payment Amount"), HMI shall be entitled to receive the Payment Amount less the Disputed Amount, which Disputed Amount shall be deposited into an escrow account with an independent third-party escrow agent mutually agreed in writing by OXB and HMI. Such escrow account shall be

governed by an agreement that shall provide for a release of the Disputed Amounts to the parties based on the resolution of such dispute in accordance with Article VIII of the Purchase Agreement.

SECTION 14.14. Entire Agreement. This Agreement, each Unitholder's respective investment agreement, purchase agreement, grant agreement or other similar agreement, the documents expressly referred to herein, related documents of even date herewith, the other agreements contemplated hereby and thereby and any other agreement identified by the Board, in its sole discretion, embody the complete agreement and understanding among the parties and terminate, supersede and preempt any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way.

SECTION 14.15. Delivery by Electronic Means. This Agreement, the agreements referred to herein, and each other agreement or instrument entered into in connection herewith or therewith or contemplated hereby or thereby, and any amendments hereto or thereto, to the extent signed and delivered by means of a facsimile machine or electronic transmission in portable document format (pdf) or comparable electronic transmission, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such agreement or instrument, each other party hereto or thereto shall re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such agreement or instrument shall raise the use of a facsimile machine or pdf electronic transmission or comparable electronic transmission to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of a facsimile machine as a defense to the formation or enforceability of a contract and each such party forever waives any such defense.

SECTION 14.16. Survival. Section 3.01(b), Section 6.01 and Section 6.04 shall survive and continue in full force in accordance with its terms notwithstanding any termination of this Agreement or the dissolution of the Company.

SECTION 14.17. WAIVER OF JURY TRIAL. AS A SPECIFICALLY BARGAINED FOR INDUCEMENT FOR EACH OF THE PARTIES HERETO TO ENTER INTO THIS AGREEMENT (AFTER HAVING THE OPPORTUNITY TO CONSULT WITH COUNSEL), EACH PARTY HERETO EXPRESSLY WAIVES THE RIGHT TO TRIAL BY JURY IN ANY LAWSUIT OR PROCEEDING RELATING TO OR ARISING IN ANY WAY FROM THIS AGREEMENT OR THE MATTERS CONTEMPLATED HEREBY.

SECTION 14.18. No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto, and no presumption or burden of proof shall arise favoring or disfavoring any party hereto by virtue of the authorship of any of the provisions of this Agreement.

* * * *

IN WITNESS WHEREOF, the undersigned have executed or caused to be executed on their behalf this Amended and Restated Limited Liability Company Agreement as of the date first written above.

THE COMPANY

ROADRUNNER SOLUTIONS LLC

By: /s/ Tim Kelly

Name: Tim Kelly

Title: Chief Executive Officer

UNITHOLDERS

OXFORD BIOMEDICA (US), INC.

By: /s/ Stuart Paynter

Name: Stuart Paynter

Title: Chief Financial Officer

HOMOLOGY MEDICINES, INC.

By: /s/ Arthur Tzianabos

Name: Arthur O. Tzianabos

Title: President and Chief Executive Officer

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

Joinder

The undersigned hereby agrees to become a party to the Amended and Restated Limited Liability Company Agreement of Roadrunner Solutions LLC, a Delaware limited liability company (the "Company"), dated as of March 10, 2022 (as amended from time to time, the "Agreement"), and shall accept and be subject to, and comply with the terms, conditions and provisions of the Agreement as a "Unitholder" thereunder, and shall be entitled to the rights and benefits and subject to the obligations of a Unitholder thereunder.

UNITHOLDER:

[_____]

By: _____
Its:

Address for Notices:

[_____]
[_____]
[_____]
[_____]

APPENDIX A

UNIT OWNERSHIP LEDGER

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Exhibit 10.27

MANUFACTURING AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement (this "**Agreement**"), dated as of March 10, 2022 (this "**Effective Date**"), is entered into by and between Homology Medicines, Inc., a Delaware corporation having an address at One Patriots Park, Bedford, MA 01730 ("**HMI**"), Roadrunner Solutions LLC, a Delaware limited liability company having an address at One Patriots Park, Bedford, MA 01730 ("**Supplier**", and together with HMI, the "**Parties**", and each, a "**Party**"), and, solely for purposes of Section 2.3(b)(iii), Oxford Biomedica UK Limited, a company incorporated in England and Wales with company registration number 03028927, whose registered office is at Windrush Court, Transport Way, Oxford, OX4 6LT, UK ("**OXB**").

RECITALS

WHEREAS, HMI is in the business of developing and commercializing biopharmaceutical products, including gene therapy and gene editing products, and in connection therewith has manufactured such products at a certain manufacturing facility located in Bedford, MA;

WHEREAS, Supplier is in the business of manufacturing biopharmaceutical products;

WHEREAS, HMI and Supplier are parties to a certain Contribution Agreement dated as of the date hereof (the "**Contribution Agreement**"), pursuant to which, among other things, HMI has agreed to assign, transfer, convey to Supplier the Transferred Assets (as defined in the Contribution Agreement), including those that are used, held for use or intended for use by HMI in connection with the manufacturing of pharmaceutical products;

WHEREAS, as of the Contribution Closing (as defined in the Contribution Agreement) HMI has assigned, transferred and conveyed to Supplier, the Transferred Assets; and

WHEREAS, as contemplated by the Contribution Agreement, HMI and Supplier have entered into this Agreement to establish the terms and conditions under which Supplier will perform certain development activities, manufacture certain products and supply the same to HMI, including for clinical purposes.

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise defined herein, defined terms shall have the same meaning as in the Contribution Agreement. For purposes of this Agreement, the following capitalized terms shall have the following definitions:

1.1 "**Affiliate(s)**" means any Person that directly or indirectly, controls, is controlled by, or is under common control with either Party. The term "control", "controlled by" or "under common control with" means (a) the possession of the power to direct or cause the direction of management and policies of such corporation or business entity, whether through direct or indirect ownership of voting securities or otherwise or (b) the ownership, directly or indirectly, of 50% or more of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). For clarity, for purposes of this Agreement, Supplier and HMI shall not be deemed Affiliates of each other; and Supplier and OXB shall not be deemed Affiliates of each other.

1.2 "**Agreement**" shall have the meaning set forth in the preamble.

1.3 "**Alternate Manufacturer**" means (a) HMI, or a Third Party selected by HMI to Manufacture for HMI a Product in (i) [***] or (ii) any other country or region approved by Supplier in writing, such approval not to be unreasonably withheld, delayed or conditioned, or (b) a Third Party described in Section 2.11(a)(iii), or a designee thereof, that requests in writing to Manufacture a Product, provided that such Third Party consults with Supplier with respect to protection of trade secrets to be transferred to enable Manufacturing such Product in any country other than those listed in clause (a)(i) above.

1.4 "**Annual Purchase Minimums**" shall have the meaning set forth in Section 2.3(a)(v).

1.5 "**API**" means an active pharmaceutical ingredient as defined by ICH Harmonised Guideline Q7.

1.6 "**Applicable Law**" means the applicable Laws of the United States, the European Union and any other jurisdictions as agreed to in writing by both Parties.

1.7 "**Batch**" means the amount of Drug Substance or Drug Product [***] by Supplier pursuant to this Agreement.

1.8 "**Binding Forecast**" shall have the meaning defined in Section 3.1(b).

1.9 "**Business Day**" means any day except Saturday, Sunday or any other day on which commercial banks located in New York or Massachusetts are authorized or required by Law to be closed for business.

1.10 "**Certificate of Analysis**" means the document accompanying each Batch of Product delivered by Supplier to HMI demonstrating compliance of the corresponding Batch to the Product Specifications.

1.11 "**cGMP Products**" means any Product that is intended to be Manufactured under cGMP. For clarity, cGMP Products are delivered hereunder as Products, whereas any Products that are delivered hereunder that are not intended to be cGMP compliant are delivered as a result of Services hereunder.

1.12 "**Change of Control**" means with respect to a Party, the occurrence of any of the following events: (a) the sale, transfer, conveyance or other disposition of all or a majority of the assets of such Party to a Third Party; (b) the acquisition of beneficial ownership, directly or indirectly, by a Third Party of common shares or other equity interests representing more than fifty percent (50%) of the aggregate ordinary voting power of such Party; or (c) a merger, reorganization or consolidation involving such Party and a Third Party in which the stockholders of such Party, immediately prior to the merger, reorganization or consolidation, would not, immediately after the merger, reorganization or consolidation, beneficially own, directly or indirectly, shares representing in the aggregate more than fifty percent (50%) of the combined ordinary voting power of the resulting ultimate parent company; *provided* that neither of the following shall constitute a Change of Control: (i) a transaction or series of transactions in which (1) a majority of the members of the Board of Directors of such Party prior to such transaction or series of transactions become members of the Board of Directors of the resulting parent company following such transaction(s) and represent a majority of such Board of Directors and (2) a majority of the members of the senior management of such Party prior to such transaction or series of transactions become members of the senior management of the resulting parent company following such transaction(s); or (ii) a public offering of equity securities of such Party or any Affiliate of such Party pursuant to an effective registration statement under the Securities Act of 1933, as amended.

1.13 "**CMO**" means a contract manufacturing organization.

1.14 "**Commercial Product**" shall have the meaning defined in Section 2.3(b).

1.15 "**Commercial Supply Agreement**" shall have the meaning defined in Section 2.3(b)(ii).

1.16 "**Confidential Information**" shall have the meaning defined in Section 10.1.

1.17 "**Contribution Agreement**" shall have the meaning defined in the preamble.

1.18 "**Control**" or "**Controlled**" means, with respect to Intellectual Property Rights, the possession (whether by ownership, license, covenant not to sue or otherwise) by a Party or its Affiliate of the ability to grant to the other Party a license, sublicense, access or other right as provided herein to or under such Intellectual Property Rights, without violating the terms of any agreement or other arrangement of such Party with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access, or subjecting the granting Party to any additional fee or charge.

1.19 [***].

1.20 "**Defect**" means a material quality attribute in a Batch of cGMP Product that does not meet the requirements set forth in the Product Specifications, the Quality Agreement or Applicable Law, in each case applicable to such Product. "**Defective**" shall have the correlative meaning.

1.21 "**Demand Based Purchase Minimums**" shall have the meaning set forth in Section 2.3(a)(v).

1.22 "**Designee**" shall have the meaning defined in the Quality Agreement.

1.23 "**Disclosing Party**" shall have the meaning defined in Section 10.1.

1.24 "**Dispute**" shall have the meaning defined in Section 11.15.

1.25 "**Dispute Notice**" shall have the meaning defined in Section 11.15.

1.26 "**Drug Product**" means the final dosage form of a product that contains a Drug Substance as the API.

1.27 "**Drug Substance**" means the applicable viral vector in liquid bulk or other bulk form.

1.28 "**Drug Substance Batch Price**" means (a) with respect to a Named HMI Product, the price for each Batch of the applicable Drug Substance Manufactured and/or supplied by Supplier hereunder, which price shall be [***] as of the Effective Date and may be adjusted in accordance with Section 5.3, and (b) with respect to an Other HMI Product, the price for each Batch of the Drug Substance Manufactured and/or supplied by Supplier hereunder, which price shall be determined and may be adjusted in accordance with Section 5.3. For clarity, [***].

1.29 "**Effective Date**" means the date first set forth in the preamble of this Agreement.

1.30 "**Exploit**" means to make, have made, import, export, use, sell, have sold, or offer for sale, including to research, develop, commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of. Cognates of the word "Exploit" shall have correlative meanings.

1.31 "**Explorative Activities**" shall have the meaning defined in Section 2.2(a).

1.32 "**Facility**" means the facility or facilities at which Supplier will Manufacture or store biopharmaceutical products after the Effective Date, which as of the Effective Date will be a portion of the facility located at 1 Patriots Park, Bedford, MA 01730 at which HMI Manufactured biopharmaceutical products prior to the Effective Date, or such other facility or facilities at which Supplier will Manufacture or store, or have Manufactured or stored, such products, as mutually agreed to in writing by both Parties.

1.33 "**Filling Price**" means with respect to a Drug Product, the price for Manufacturing each Batch of the Drug Product from the applicable Drug Substance using Drug Substance that has already been Manufactured, which price shall be [***] as of the Effective Date, and may be adjusted in accordance with Section 5.3. For clarity, [***].

1.34 "**Firm Order**" means a Purchase Order for Products accepted by Supplier in accordance with Section 3.2(a).

1.35 "**Force Majeure Event**" shall have the meaning defined in Section 11.20.

1.36 "**FTE**" shall have the meaning defined in Section 2.11(c).

1.37 "**FTE Rate**" means the dollar amount per full-time equivalent employee (or consultant, as applicable) per year, which amount represents the fully-burdened rate (for calendar year 2023, the FTE Rate shall be the rate set forth in Section 5.4(b)) and shall be determined, and may be adjusted, in accordance with Section 5.4.

1.38 "**GAAP**" means generally accepted accounting principles.

1.39 "**GMP**" or "**cGMP**" means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4 - Good Manufacturing Practice (GMP) guidelines, parts I to IV and relevant associated annexes, (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Laws in any other regulatory jurisdictions as agreed to in writing by both Parties.

1.40 "**Governmental Authority**" means any federal, state, local or foreign government or political subdivision thereof, or any agency or instrumentality of such government or political subdivision, or any court or tribunal of competent jurisdiction.

1.41 "**HMI Indemnified Parties**" shall have the meaning defined in Section 9.8(a).

1.42 "**HMI Intellectual Property Rights**" means all Intellectual Property Rights Controlled by HMI as of the Effective Date or during the Term relating to a Product that is necessary or reasonably useful for Supplier's performance of its obligations hereunder.

1.43 "**HMI-Owned Inventions**" means any and all inventions, discoveries and improvements and Intellectual Property Rights therein that are first conceived or made by or on behalf of one or both Parties under this Agreement that relate specifically to one or more Product(s) and are not generally applicable to Manufacturing of one or more other products that are not Products.

1.44 "**HMI Raw Materials**" means raw materials for the Manufacture of Products and performance of Services as may be provided by HMI to Supplier as specified on Appendix 4 of the Quality Agreement or the applicable SOWs, or as mutually agreed to by the Parties in writing.

1.45 "**HMI Raw Materials Warranty**" shall have the meaning defined in Section 9.3.

1.46 "**HMI Regulatory Approvals**" means all regulatory approvals relating the Products Controlled by HMI as of the Effective Date or during the Term that is necessary or reasonably useful for Supplier's performance of its obligations hereunder.

1.47 "**Improvement Plan**" shall have the meaning defined in Section 2.7(b).

1.48 "**Information**" means either Party's and/or its Affiliates' confidential information of a commercial, industrial, economic, scientific, medical, or technical nature, whether in written, oral, electronic or other form.

1.49 "**Initial SOW Plan**" shall have the meaning defined in Section 2.7(a).

1.50 "**Initial Term**" shall have the meaning defined in Section 6.1.

1.51 "**Intellectual Property Rights**" means all intellectual property rights comprising or relating to: (a) Patents; (b) Trademarks; (c) works of authorship, expressions, designs and design registrations, whether or not copyrightable, including copyrights and copyrightable works, software and firmware, application programming interfaces, architecture, files, records, schematics, data, data files, and databases and other specifications and documentation; (d) Know-How and (e) all industrial and other intellectual property rights, and all rights, interests and protections that are associated with, equivalent or similar to, or required for the exercise of, any of the foregoing, however arising, in each case whether registered or unregistered and including all registrations and applications for, and renewals or extensions of, such rights or forms of protection pursuant to the Laws of any jurisdiction throughout in any part of the world.

1.52 "**Joint Steering Committee**" shall have the meaning defined in Section 2.7.

1.53 "**Key Performance Indicators**" means certain key performance indicators designed to provide the basis for the Joint Steering Committee's objective assessment of Supplier's performance of its Manufacture and supply obligations hereunder.

1.54 "**Key Positions**" shall be listed on Schedule 2.6, as amended from time-to-time by mutual agreement.

1.55 "**Know-How**" means any techniques, technology, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, business and Information, compositions of matter, information and technologies relating to cells, cell lines, assays, animal models, reagents and other physical, biological, or chemical material, that is not in the public domain.

1.56 "**Latent Defect**" means any Defect which HMI cannot reasonably notice or be expected to have noticed on visual inspection of the applicable cGMP Product.

1.57 "**Law**" means any statute, law, ordinance, regulation, rule, code, directives, constitution, treaty, common law, governmental order or other requirement or rule of law of any Governmental Authority, and Licenses and Permits.

1.58 "**License and Patent Management Agreement**" means that certain License and Patent Management Agreement by and between Supplier and HMI, dated on or about the date hereof.

1.59 "**Licenses and Permits**" means any and all licenses, authorizations, and permits issued by Governmental Authorities that are necessary for the Manufacture of Products or performance of Services hereunder, including HMI Regulatory Approvals.

1.60 "**Losses**" means any damage and loss suffered by a Party as defined in Section 9.8.

1.61 "**Manufacture**" and "**Manufacturing**" means any process (or step in any process) used or planned to be used for manufacturing pharmaceutical products or intermediates thereof, including Products, including quality control, stability and other testing, and primary and secondary packaging.

1.62 "**Manufacturer's Release**" shall have the meaning defined in the Quality Agreement.

1.63 "**Manufacturing Change**" shall have the meaning defined in Section 2.4.

1.64 "**Member**" shall have the meaning defined in Section 2.7.

1.65 "**Named HMI Product**" means the HMI products set forth on Schedule 1.65 hereof.

1.66 "**Notice**" shall have the meaning defined in Section 11.4.

1.67 "**Opportunities**" shall have the meaning defined in Section 2.3(c)(i).

1.68 "**Other HMI Products**" means any biopharmaceutical product, other than Named HMI Products, that is developed by or on behalf of HMI or its Affiliates, excluding any product developed by or on behalf of HMI's acquiror or any of such acquiror's Affiliates (that becomes an Affiliate of HMI after the Effective Date directly or indirectly as a result of a Change of Control of HMI) independently of HMI.

1.69 "**Patent Defect(s)**" means any Defect that is capable of being detected upon reasonable visual inspection.

1.70 "**Patents**" means (a) all patents, priority patent filings and patent applications, and (b) any divisional, continuation (in whole or in part), or request for continued examination of any of such patents, and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reviews, reexaminations, extensions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.71 "**Permitted Subcontractor(s)**" means the Third Party subcontractors or vendors specified in the Quality Agreement, or in the case of Services, as specified in the applicable SOW.

1.72 "**Person**" means any individual, corporation, partnership (whether general, limited or limited liability), association, joint venture, limited liability company, joint stock company, unincorporated organization, trust or other legal entity or organization, having legal personality, or the right to sue in its own name.

1.73 [***].

1.74 "**Process**" means the Manufacturing process for the Products as reflected in Manufacturing SOPs, process control strategy and process descriptions in use at the Facility(ies) as of the Effective Date or during the Term.

1.75 "**Product**" means a Named HMI Product or an Other HMI Product. A Product refers to either (a) the Drug Substance or (b) the Drug Product, as applicable.

1.76 "**Product Specifications**" shall have the meaning defined in the Quality Agreement.

1.77 "**Product Warranty**" shall have the meaning defined in Section 9.1.

1.78 "**Project Manager**" means the individual member of the Joint Steering Committee appointed by a Party with the responsibility for overseeing such Party's day-to-day activities under this Agreement.

1.79 "**Project Team**" shall have the meaning defined in Section 2.8(a).

1.80 "**Purchase Agreement**" means that certain Equity Securities Purchase Agreement by and among Supplier, HMI and OXB, dated on or about the date hereof.

1.81 "**Purchase Order**" shall have the meaning defined in Section 3.2(a).

1.82 "**Quality Agreement**" means the technical agreement(s) notably defining the responsibilities of each Party with respect to the quality of the Products, to be entered into by the Parties on or about the Effective Date which shall once executed be incorporated into this Agreement. In the event of a conflict between the provisions of this Agreement and the Quality Agreement, the provisions of the Quality Agreement shall prevail for the terms and conditions that are solely related to quality assurance aspects and the provisions of this Agreement shall prevail for all other aspects.

1.83 "**Receiving Party**" shall have the meaning defined in Section 10.1.

1.84 "**Representatives**" means a Party's Affiliates and each of their respective employees, officers, directors, and agents.

1.85 "**[***]**" shall have the meaning defined in [***].

1.86 "**Services**" means product development services including Explorative Activities, and other Manufacturing-related services that HMI may request from Supplier from time-to-time hereunder.

1.87 "**SOP**" means standard operating procedures.

1.88 "**SOW**" means statements of work describing the Services to be performed by Supplier for HMI or its designees. Each SOW will be numbered for identification and will set forth the material terms of the applicable services, the scope of work, specified services, deliverables, estimated timelines, milestones (if any), service fees, payment schedules and such

other details and special arrangements as are agreed to by the Parties with respect to the activities to be performed under such SOW. The Initial SOW Plan is an SOW. An exemplary form SOW is attached hereto as Exhibit A.

1.89 "**Supplier Indemnified Parties**" shall have the meaning defined in Section 9.8(b).

1.90"**Supplier Intellectual Property Rights**" means all Intellectual Property Rights Controlled by Supplier or its Affiliates as of the Effective Date or during the Term that are used by Supplier to Manufacture the Products or are necessary for the exploitation of Products.

1.91 "**Supplier-Owned Inventions**" means any and all inventions, discoveries and improvements and Intellectual Property Rights therein that are first conceived or made by or on behalf of one or both Parties under this Agreement that are not HMI-Owned Inventions and relate to Manufacturing of products generally.

1.92 "**Supplier-Sourced Materials Cost**" shall have the meaning defined in Section 3.4(b).

1.93 "**Supply Failure**" means, for any Product, that Supplier has failed to supply [***].

1.94 "**Technology Transfer**" shall have the meaning defined in Section 2.11.

1.95 "**Term**" shall have the meaning defined in Section 6.2.

1.96 "**Third Party**" means a Person other than (a) HMI or any of its Affiliates and (b) Supplier or any of its Affiliates.

1.97 "**Third Party Claims**" shall have the meaning defined in Section 9.8(a).

1.98 "**Trademarks**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, whether or not registered, including the goodwill and activities associated with each of the foregoing.

1.99 "**Transferred Assets**" shall have the meaning defined in the Contribution Agreement.

1.100 "**Transition Services Agreement**" means that certain transition services agreement to be entered into by and between the Parties and effective on the date herewith.

1.101 "[*****] Forecast**" shall have the meaning defined in Section 3.1(b).

ARTICLE 2
SUPPLY OF PRODUCTS AND RELATED SERVICES

2.1 Manufacture and Supply. Subject to the terms and conditions of this Agreement, HMI hereby agrees to purchase from Supplier its requirements of Products and Supplier shall Manufacture and supply such Products to HMI in accordance with the terms and conditions set forth in this Agreement and in a professional manner, in conformance with the level of care

and skill ordinarily exercised by other professionals in similar circumstances, and with respect to cGMP Products, in accordance with the Product Specifications, Quality Agreement, and Applicable Law.

2.2 Services. In addition to the Manufacture and supply of Products hereunder, Supplier shall provide the Services in accordance with SOWs and with the terms and conditions set forth in this Agreement. No SOW will be effective unless signed by authorized representatives of both Parties. Each fully signed SOW will be subject to the terms of this Agreement and will be incorporated herein and form part of this Agreement.

(a) Supplier will carry out the activities for Services in accordance with the estimated timeline set forth in such SOW. The Parties acknowledge that certain of the Services set forth in an SOW (including the Initial SOW Plan) will involve performance of activities that are developmental or explorative by nature (the "**Explorative Activities**") which, by their nature, are expected to be unpredictable until Supplier has successfully established a standard process or routine for performing such activities. For Services involving activities that are Explorative Activities, [***]. The Parties shall designate in each SOW whether and the extent to which an activity or set of activities governed thereby will include or involve Explorative Activities.

(b) Supplier shall promptly inform HMI in writing, after becoming aware, if it is unable to perform the activities under an SOW or if it cannot, or cannot continue to, provide the Services set forth in an SOW or cannot meet the timeline set forth in an SOW. Upon such notice, the Project Managers shall meet to discuss the reasons for Supplier's inability to perform under such SOW and propose appropriate amendments to the SOW that are reasonably acceptable to both Parties. Any such amendment to an SOW shall be signed by authorized representatives of both Parties. HMI shall have the right to terminate any individual SOW without penalty if at any time during the term of an SOW, Supplier provides such written notice that it is unable to perform the activities under such SOW, including if it is not able to meet the timeline set forth in such SOW; *provided* that HMI may not exercise such termination right if Supplier's discontinuation or delay of Services is caused by HMI's material breach of this Agreement or failure to timely provide HMI Raw Materials. Notwithstanding the foregoing, HMI will pay Supplier for any completed task under a partially performed SOW in accordance with the agreed upon scope and pricing for such task as set forth in the applicable SOW.

2.3 Exclusivity and Preferred Supplier.

(a) Clinical Supply and Development Exclusivity.

(i) During the Term, Supplier shall not Manufacture or supply [***] or provide Services in connection with the [***] to any entity other than HMI or its Affiliates or their licensees. Notwithstanding the foregoing sentence, nothing in this Agreement shall preclude Supplier from Manufacturing any product for any Third Party for so long as Supplier does not use (A) any HMI Intellectual Property Rights or Process or (B) any Contributed NewCo Know-How or Contributed NewCo Patent Rights (as such terms are defined in the License and Patent Management

Agreement) in the Manufacture of such Third-Party product, in each case ((A) and (B)) with respect to any Know-How, but solely to the extent such Know-How is not commonly known to a person skilled in the art in the viral vector industry.

(ii) HMI shall purchase from Supplier at least (x) [***] of HMI's actual requirements for clinical supplies of Drug Substance [***] and (y) [***] of HMI's actual requirements for clinical supplies of Drug Substance [***], it being acknowledged and agreed by the Parties that HMI's compliance with the minimum purchase obligations in this Section 2.3(a)(ii) shall be determined [***] (as specified below in Section 2.3(a)(v)), taking into account the aggregate purchases made by HMI during the relevant period for all Drug Substance.

(iii) During the Initial Term, HMI will pay Supplier (A) [***] covering [***], excluding [***], as directed by the Joint Steering Committee pursuant to Section 2.7(a) and as set forth in the Initial SOW Plan, and (B) at least [***] covering [***]; it being acknowledged and agreed by the Parties that HMI's compliance with the minimum purchase obligations in this Section 2.3(a)(iii) shall be determined after [***] in accordance with Section 2.3(a)(v). Reasonably in advance of the end of the Initial Term, the Parties shall negotiate with each other in good faith regarding the minimum amount of Services to be purchased by HMI from Supplier during the remainder of the Term after the Initial Term; *provided*, *however*, that neither Party shall be obligated to commit to a minimum amount of Services for the remainder of the Term after the Initial Term.

(iv) The minimum purchase requirements set forth in Section 2.3(a)(ii) shall be adjusted if a Supply Failure occurs as follows: if HMI believes a Supply Failure has occurred at any time after [***], HMI shall provide written notice thereof to Supplier and to the Joint Steering Committee; and if either the Supply Failure cannot be cured or, in the event such Supply Failure can be cured but is not cured within a commercially reasonable period of time under the circumstances, in no case exceeding [***] following Supplier's receipt of HMI's written notice of such alleged Supply Failure, then HMI will have the right to [***] Batches of the Drug Substance (or the Drug Product containing such Drug Substance) so affected.

(v) HMI agrees to purchase for each of the first [***] of the Initial Term [***] the following minimum number of Batches of Drug Substance: [***] Batches of Drug Substance ([***]) and [***] Batches of Drug Product for the remaining period of calendar year 2022; and [***] Batches of Drug Substance and [***] Batches of Drug Product for [***] (such minimums and the annual Services minimums set forth in Section 2.3(a)(iii), the initial "**Annual Purchase Minimums**"). No later than [***] during the Term (i.e., [***]), HMI shall notify Supplier of its Annual Purchase Minimum for [***] each calendar year thereafter during the Term (in the case this Agreement does not terminate at the end of the calendar year and, in the event of extension of the Initial Term pursuant to Section 6.2, such portion of the calendar year ending on the [***]). Promptly following the end of each calendar year, HMI shall provide Supplier with a written report in reasonable detail setting forth [***] in order for Supplier to determine whether HMI

has met its Drug Substance and Service purchase minimums, as set forth in Sections 2.3(a)(ii) and 2.3(a)(iii), respectively, during the applicable period (the "**Demand Based Purchase Minimums**"). If within [***] following receipt of such report or if thereafter, Supplier obtains new information indicating that the information contained in such report is inaccurate, Supplier believes that information contained in such report is inaccurate in material respects, it shall so notify HMI in writing. Unless HMI timely provides an updated report reasonably satisfactory to Supplier, Supplier may engage a Third Party auditor reasonably acceptable to HMI to access and review HMI's records and confirm HMI's [***] purchased by HMI from Supplier during the applicable period; provided that such auditor may not share with Supplier any Confidential Information of HMI and may only disclose information to Supplier to the extent necessary for Supplier to determine whether HMI has met its applicable Annual Purchase Minimum or Demand Based Purchase Minimum. If, based on the report provided by HMI or based on the findings of such auditor, Supplier reasonably determines that an Annual Purchase Minimum or Demand Based Purchase Minimum shortfall has occurred, then Supplier shall promptly submit an invoice to HMI detailing the shortfall between the number of Batches of the Drug Substance and/or value of Services actually supplied or provided, as applicable, by Supplier and the higher of the applicable Annual Purchase Minimum or Demand Based Purchase Minimum. HMI shall cure such shortfall by paying Supplier within [***] after Supplier's delivery of such invoice for an amount equal to, (i) with respect to Drug Substance, [***], (ii) with respect to Drug Product, [***], (iii) with respect to Services, [***], and (iv) [***]. Further, in the event of such a shortfall for a calendar year exceeds [***].

(b) Commercial Supply.

(i) No later than [***] (the "**Commercial Product**"), HMI shall notify Supplier in writing that HMI intends to negotiate the terms of a commercial supply agreement for such Commercial Product, and provide [***]. Supplier shall respond in writing within [***] after receiving such notice from HMI whether Supplier believes it can meet such capacity to produce commercial supplies of such Commercial Product, including any documentation reasonably substantiating Supplier's capabilities and capacity to produce such commercial supplies, [***]. If Supplier's written response states that Supplier does not believe it can provide such capacity or capabilities, then Section 2.3(b)(iii) shall apply.

(ii) If Supplier's written response states that Supplier believes it can provide such capacity and capabilities, then the Parties shall exclusively negotiate with each other in good faith for a period of no less than [***] (or such longer period as mutually agreed upon in writing by the Parties) to enter into a commercial supply agreement for such Commercial Product ("**Commercial Supply Agreement**"). For avoidance of doubt, neither Party shall be obligated to enter into a Commercial Supply Agreement and subject to subsection (iii) below, HMI shall be free to negotiate and enter into with any Third Party a commercial supply agreement for such Commercial Product after the expiration of such exclusive negotiation period.

(iii) If Supplier's written response pursuant to Section 2.3(b)(i) states that Supplier does not believe it has the capacity or capability to Manufacture such Product for commercial use, HMI shall notify OXB in writing that HMI intends to negotiate the terms of a Commercial Supply Agreement for such Commercial Product, and that Supplier has stated it does not have the capacity or capabilities required for commercial supply of such Commercial Product. HMI will provide to OXB then-available information regarding the capacity HMI believes in good faith is required for such commercial supply of such Commercial Product, and any special capabilities that HMI believes are required for commercial supply of such Product. OXB shall respond in writing within [***] after receiving such notice from HMI whether OXB believes it can meet such capacity to produce commercial supplies of such Commercial Product, [***]. If OXB's written response states that OXB believes it can provide such capacity or capabilities, then HMI shall negotiate exclusively in good faith with OXB for a period of no less than [***] (or such longer period as mutually agreed upon by the HMI and OXB) to enter into a Commercial Supply Agreement for such Commercial Product. If HMI and OXB do not agree on the terms of such Commercial Supply Agreement within such period, HMI shall be entitled to negotiate and enter into a Commercial Supply Agreement with any other Third Party for such Commercial Product without any further obligations owed under this Section 2.3(b). For clarity, this subsection (iii) shall not apply if the Parties commenced negotiations but did not enter into a Commercial Supply Agreement pursuant to subsection (ii).

(iv) If for a given Product, HMI has complied with all of the provisions of subsection (i) and (ii) above and thereafter enters into a commercial supply arrangement with a Third Party or OXB for commercial supply of such Product, Supplier shall, at HMI's written request, promptly initiate Technology Transfer for such Product to such Third Party or OXB, as applicable. Such Technology Transfer shall be [***].

(v) The Parties agree that the Commercial Supply Agreement may include provisions addressing contingencies in the event that [***].

(c) Preferred Supplier. HMI acknowledges that Supplier [***] any Third Party supplier in the Manufacture of any Product, *provided* that [***].

(i) In connection therewith, HMI will provide Supplier with written notice of any future Manufacture and supply opportunities for any Product being considered by HMI, for which HMI intends to seek bids or proposals from Third Parties ("**Opportunities**"). HMI will at all times have the right to solicit and consider bids and proposals for such Opportunities from Third Parties.

(ii) If HMI notifies Supplier in writing of any Opportunities, then Supplier may submit a bid or proposal in respect thereof within [***] after receiving such written notice of an Opportunity from HMI. In the event Supplier makes such submission to HMI, HMI shall take into consideration all relevant terms for such

bids or proposals provided by Supplier, as well as any bids or proposals from Third Parties, [***].

(iii) HMI shall have the right to determine, in its sole discretion, whether Supplier's bid or proposal is competitive with those of Third Parties. If HMI so determines such bid or proposal is competitive, HMI shall reasonably consider awarding such opportunity to Supplier. Nothing in this Section 2.3(c) shall be construed as to prohibit HMI from (A) Manufacturing Product directly; or (B) purchasing Product from other Third Party suppliers.

2.4 Manufacturing Changes. Unless otherwise agreed by the Parties in writing, Supplier's Manufacture of Products will take place at the Facility(ies) and use the same [***], or as specified in an SOW, to the extent [***]. If there is any material change to the Facility(ies) or any change in [***], Processes, [***] relied upon by HMI to Manufacture Products at the Facility(ies) before the Effective Date ("**Manufacturing Change**"), then (a) Supplier shall reasonably assist HMI with complying with any necessary modifications or variations to regulatory approvals, filings or submissions required under Applicable Law as a result of such changes, (b) Supplier will not commence Manufacturing at a facility other than the Facility(ies) or use different Manufacturing [***], Process, or [***] until HMI has consented in writing to such Manufacturing Change (such consent not to be unreasonably withheld) and HMI and Supplier have received all applicable Licenses and Permits thereto, and (c) any such Manufacturing Change shall be implemented by Supplier in accordance with the Quality Agreement.

(i) If a Manufacturing Change is due to Supplier's request or a Governmental Authority's requirement to change one or more Facility(ies) which requirement is not specifically or solely relating to any particular Product, [***], unless such Manufacturing Change is related to [***].

(ii) If a Governmental Authority requires any Manufacturing Change with respect to a particular Product or set of Products for use for clinical purposes, then the Parties will meet and discuss in good faith an action plan for such required Manufacturing Change, and Supplier shall be required to implement such required Manufacturing Change and assist HMI with regulatory filings or submissions required under Applicable Law as a result of such required Manufacturing Change, in each case [***].

(iii) Supplier shall make all Manufacturing Changes imposed by a Governmental Authority within a reasonable time after first learning of such requirement.

2.5 Subcontracting. Supplier may not subcontract the Manufacture of Products or provision of Services or any portion thereof to a Third Party (other than Permitted Subcontractor) without HMI's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed. [***]. Supplier will be responsible for ensuring compliance by such subcontractors with the applicable terms of this Agreement, as if such subcontractors are Supplier hereunder. Each subcontract shall be in writing and shall contain obligations, on the part of the applicable subcontractor, consistent with this Agreement, including with respect to confidentiality and non-use and the assignment of, or the grant of substantially equivalent

rights under, all Intellectual Property Rights that such subcontractor may develop or acquire by reason of work performed under this Agreement. Supplier will conduct, and will cause [***].

2.6 Key Positions. Supplier acknowledges that the [***] to the Manufacture of Products. Supplier shall submit to HMI for prior review and approval [***], such approval not to be unreasonably withheld, delayed, or conditioned by HMI, *provided* that such prior review and approval shall not be required for [***].

2.7 Joint Steering Committee. Each Party shall name a mutually agreed upon number of representatives for the joint steering committee (the "**Joint Steering Committee**," and each such representative, a "**Member**"), each of whom shall be a senior employee of the applicable Party and knowledgeable in an appropriate discipline, such as the head of manufacturing/operations for each Party or his or her designee and the relevant discipline experts.

(a) Within [***] following the Effective Date, the Joint Steering Committee shall mutually agree upon (i) the Key Performance Indicators that will apply to the Manufacturing and supply obligations of Supplier for the applicable Product for the remainder of the calendar year in which the Effective Date occurs, based on [***] with respect to Products [***] prior to the Effective Date, (ii) objective criteria that will serve as the basis for the Key Performance Indicators applicable for each calendar year thereafter, and (iii) (x) the anticipated Services to be covered under the Initial SOW Plan (as defined below), which Services will include Explorative Activities as well as other activities based on equivalent activities that were being performed by HMI as of the Effective Date, and (y) a description of deliverables and specified timelines for such Services, as may be amended from time to time by the Parties (the "**Initial SOW Plan**"), in each case such Services shall be aligned with the overall agreed-upon budget for Services for such period. Within [***] prior to the end of each calendar year, the Joint Steering Committee shall mutually agree upon the SOWs for Services for the following calendar year.

(b) From time to time after the Effective Date, the Joint Steering Committee shall (i) establish the Key Performance Indicators that will apply to the Manufacturing and supply obligations of Supplier for any Product that is not a Product as of the Effective Date as promptly as practicable following the [***] becomes available, and (ii) as requested in writing by HMI, discuss and agree upon any improvement plan that is reasonably necessary and appropriate to address any failure to meet or satisfy the Key Performance Indicators as promptly as reasonably practicable (an "**Improvement Plan**").

(c) In addition to the specific tasks set forth in Sections 2.7(a) and 2.7(b), the Joint Steering Committee shall be responsible for (i) providing a forum for strategic decision-making; (ii) coordinating and reviewing each Party's performance of its obligations hereunder, including [***], Technology Transfer, and disclosure of HMI-Owned Inventions made by Supplier; (iii) resolving any disputes referred to it by the Project Team; and (iv) making such other determinations as are expressly delegated to it under this Agreement (including establishing the Key Performance Indicators and developing any Improvement Plan).

(d) The Joint Steering Committee shall, at a minimum, consist of at least [***] from each Party. The Joint Steering Committee shall meet in-person, telephonically or by videoconference once per calendar quarter during the Term, or as otherwise mutually agreed by the Parties. The Joint Steering Committee will make decisions by consensus with each Party having [***] vote. If the Joint Steering Committee is unable to reach unanimous decision on a particular matter within a reasonable period (not to exceed [***], unless extended by mutual agreement of the Parties) following the Joint Steering Committee meeting, then the matter will be referred to the Party representatives under Section 11.15, who will use good faith efforts to resolve such matter within [***] after the matter is submitted to them for resolution.

2.8 Project Team.

(a) Within [***] after the Effective Date, the Parties will establish a project team ("**Project Team**"), which shall consist of each Party's project manager who will oversee their respective obligations under this Agreement (each, a "**Project Manager**") and such other employees, or, subject to the approval of the other Party, representatives or consultants of a Party as considered necessary to attend by such Party's Project Manager. Prior to attendance of any Project Team meeting all such employees, representatives and consultants of a Party must be bound by confidentiality obligations at least as protective to the other Party's Confidential Information as the terms set out in Article 10. The Project Team shall:

(i) provide a forum for, and facilitate, communications between the Parties with respect to the Manufacture and supply of Products and provision of Services by the Supplier hereunder;

(ii) have operational responsibility for coordinating the performance of SOWs or Purchase Orders;

(iii) discuss and propose, but not approve, the content and budget of SOWs and amendments thereto; and

(iv) be responsible for initial dispute resolution and if the Project Team is unable to resolve any dispute within [***] after initiating dispute resolution, either Project Manager may refer such dispute to the Joint Steering Committee for resolution.

(b) The Project Team shall hold meetings as often as the Project Managers agree is necessary during the Term. Project Team meetings may be held in person, or by tele- or video-conference, at such times and places as are agreed to by the Parties. All decisions of the Project Team will be made by consensus of the Project Managers, and any failure to agree will be referred to the Joint Steering Committee for resolution.

2.9 Limitations on Authority. Notwithstanding any provision to the contrary, neither the Joint Steering Committee nor the Project Team shall have any power (a) to amend or modify the provisions of this Agreement (which may only be amended or modified as provided in Section 11.8), (b) to waive compliance with this Agreement or (c) to make determination as

to whether a Party is in breach of this Agreement; and each Party shall retain the rights, powers and discretion granted to it under this Agreement, and no such rights, powers or discretion shall be delegated to or vested in the Joint Steering Committee or the Project Team.

2.10 Technical Support. Both Parties acknowledge that during the Term, Supplier may need temporary technical assistance or support by HMI to facilitate Supplier's Manufacturing of the Products. [***].

2.11 Technology Transfer. Upon the occurrence of any of the events set forth under Section 2.11(a), the Joint Steering Committee shall promptly agree upon a plan and timeline for a customary manufacturing technology transfer ("**Technology Transfer Plan**") within [***] following the occurrence of the applicable event. Without limiting the foregoing, such an event shall be deemed to have occurred upon delivery of any written notice of termination under Section 6.3.

(a) Supplier shall promptly, in accordance with the Technology Transfer Plan, transfer all Know-How under Supplier's Control (and that is not already in HMI's possession) that is necessary or actually used by Supplier to Manufacture and supply the Products, for enabling, with respect to events set forth in clauses (i), (ii) and (iv) below, collectively [***] Alternate Manufacturer [***] per Product (for purposes of this Section 2.11(a), an applicable [***] unless otherwise agreed by the Parties in writing), and with respect to event set forth in clauses (iii) and (v), up to [***] Alternate Manufacturers per Product, to Manufacture or have Manufactured the Product(s) by such Alternate Manufacturer ("**Technology Transfer**"), if one or more of the following events has occurred: [***]. If a Technology Transfer is effected in the case of clause (ii) or (iii) or (v), [***] pursuant to Sections 2.3(a) and 3.1 on an aggregate basis, shall continue to apply; for clarity, if a Technology Transfer is effected in the case of clause (i) with respect to a given Product, the [***] no longer apply to such Product, and the Joint Steering Committee shall promptly discuss and agree on the [***] for the unaffected Products; and, for clarity, if a Technology Transfer is effected in the case of clause (iv), [***].

(b) The Alternate Manufacturer(s), regardless of cause for the Technology Transfer, shall be bound by confidentiality obligations in writing no less stringent than those set forth in ARTICLE 10 and have sufficient process and safeguard in place to protect Supplier's Confidential Information and manufacturing technologies.

(c) Notwithstanding the foregoing, the Technology Transfer Plan shall set forth the maximum number of full time employee ("**FTE**") hours that Supplier's personnel shall be required to provide in the performance of such transfer activities. [***].

(d) To effect a Technology Transfer, Supplier shall transfer to HMI, to the extent not already in HMI's possession, copies of any physical embodiment of any and all such Know-How (including without limitation quality control documents, quality assurance documents and testing and release documents, equipment specifications and detailed drawings for equipment), that are necessary for or used by Supplier to Manufacture the Product(s). Such transfer shall be achieved by the delivery of material documents, to the extent such Know-How is embodied in such documents, and to the extent that such Know-How is not fully embodied in such documents, to effect the foregoing, Supplier shall make available its and its Affiliates'

appropriately qualified employees and agents, and appropriately qualified employees and agents of its Third Party suppliers/vendors, to the extent Supplier has the right to make such Third Party supplier/vendor employees and agents available, in each case who have sufficient knowledge of such Know-How in addition to that embodied in documents available to HMI, for interviews and discussions with, demonstrations to and training of HMI's employees at Supplier's Facility(ies). If HMI engages an Alternate Manufacturer to Manufacture a Product, subject to the Technology Transfer Plan, Supplier shall use commercially reasonable efforts to effect the transfer of Know-How applicable to such Product to such Alternate Manufacturer. Supplier shall reasonably respond to HMI's questions via telephone or e-mail raised from time to time with respect to the Know-How and its use thereof that is necessary to effect the intent of the Technology Transfer.

2.12 Alternate Manufacturer. Prior to selecting a Third Party as an Alternate Manufacturer, HMI will confer with Supplier and reasonably consider Supplier's comments with respect thereto, including with respect to any concerns regarding protection of Know-How to be transferred to such Third Party for manufacturing the relevant Product(s). Following a Technology Transfer to the applicable Alternate Manufacturer(s), HMI shall not, and shall not permit the applicable Alternate Manufacturer(s) to, further transfer to any other CMO the transferred Know-How so as to enable such other CMO to Manufacture any applicable Product(s), *provided* that the foregoing restriction on transfer of Know-How shall not apply to CMO(s) that HMI may engage to Manufacture a Commercial Product pursuant to Section 2.3(b) or Section 2.3(c).

ARTICLE 3
PURCHASE TERMS - DELIVERY - QUALITY CONTROL

3.1 Forecasts.

(a) On the Effective Date, HMI shall provide a [***] forecast to Supplier for [***] consistent with the Annual Purchase Minimums and the Demand Based Purchase Minimums in a form substantially similar to the exemplary forecast in Exhibit B, specifying the [***] forecasted number of Batches of Drug Substance and number of Batches of Drug Product and the [***] forecast for Services, subject to and consistent with the Initial SOW Plan and the Joint Steering Committee's initial direction for Services to be provided prior to final agreement on the Initial SOW Plan.

(b) No later than [***], HMI shall provide a [***] forecast for the next [***] (the "[*****] Forecast**"), *provided* that such [***] forecast shall not in any event include any time period beyond [***] and shall not be binding or otherwise relied upon by either Party beyond the expiration of the Term. The [***] of each [***] Forecast (except for Services that are forecasted to first commence in [***]) shall be binding on both Parties (the "**Binding Forecast**"), and the [***] of each [***] Forecast will be consistent with the Annual Purchase Minimums and the Demand Based Minimums or up to [***] higher than the Annual Purchase Minimums (or in the case of Drug Product Batches, [***] higher than what was forecast for such [***] in the [***]) in which case Supplier would use commercially reasonable efforts to meet such excess demand. To calculate the foregoing deviation, any forecasted number of Batches of Drug Substance and number of Batches of

Drug Product shall be based on whole Batches (as no partial Batches would be supplied), and if such updated [***] Forecast would exceed the [***] upper limit due to the requirement that HMI purchase whole Batches, the Supplier would use commercially reasonable efforts to supply such additional whole Batch if requested by HMI.

(c) If HMI's Purchase Order or SOW calls for a lesser number of Batches of Drug Substance or Drug Product or value of Services, as applicable, than set forth in the Binding Forecast, then Supplier shall use commercially reasonable efforts to utilize the unused capacity that would have been used to Manufacture Products or provide Services, as applicable, to Manufacture other products or provide services for other customers of Supplier, and HMI shall only be liable to Supplier for, [***] that are actually incurred by Supplier in reliance on the Binding Forecast but are not used in the Manufacture of products or performance of services to HMI or other customers.

3.2 Purchase Orders and SOWs.

(a) All orders for Products must be received in writing and include (i) the number of Batches of the Drug Substance, (ii) the number of Batches of the Drug Product, (iii) for each Batch of Drug Product ordered, the number and identity of Batches of the applicable Drug Substance to be used, (iv) delivery terms, (v) type and amount of HMI Raw Materials to be provided to Supplier, and (vi) the applicable Drug Substance Batch Price and Filling Price, as applicable (each a "**Purchase Order**"). The first Purchase Order shall be submitted within [***] after the Effective Date and cover the Products to be supplied to HMI over the first [***] of the first [***] Forecast. All subsequent Purchase Orders shall be sent by HMI in writing to Supplier monthly at least [***] before the date upon which Manufacture of the applicable Batch of Drug Substance or Drug Product is expected to be initiated. Any terms or conditions in a Purchase Order that conflicts with this Agreement shall be null and void. Supplier shall confirm in writing within [***] after receipt of each Purchase Order that is consistent with Section 3.1 its acceptance of such Purchase Order, which shall be then considered a firm order ("**Firm Order**"). [***] period, the Purchase Order shall be deemed accepted by Supplier and thereby a Firm Order, *provided* that it is consistent with Section 3.1.

(b) Supplier shall provide the Services in accordance with the Initial SOW Plan and individual SOWs. Any Services not covered by the Initial SOW Plan will be performed under individual SOWs. For individual SOWs, upon HMI's request, Supplier will prepare and provide HMI with a draft SOW for review and comment, and such SOW will be binding if the Parties agree upon and sign the SOW, *provided* that Supplier will not be obligated to begin providing Services under any such SOW any sooner than [***] after the last signature date of such SOW. In the event a Party wishes to amend an SOW, such Party will identify the work under such SOW it wishes to be amended, added or terminated in writing and Supplier will provide a draft change order to HMI for review. Once the Parties have agreed on the draft change order, such change order will be signed by both Parties and the applicable SOW shall be deemed amended in accordance with such change order.

3.3 Orders. Supplier will accept and supply the number of Batches of Drug Substance and/or Drug Product ordered by HMI in Purchase Orders (and which will therefore be Firm Orders) that comply with the number of Batches of Drug Substance and the number of Batches

of Drug Product, as applicable, stated in the applicable Binding Forecast and other terms of this Agreement. With respect to a Drug Substance or a Drug Product, Supplier [***] additional number of Batches of such Drug Substance or Drug Product that exceeds no more than [***] of the number of Batches of such Drug Substance or Drug Product stated in the applicable Binding Forecast for the applicable period; *provided* that Supplier then has available resources and capacity to supply such excess number of Batches of Drug Substance or Drug Product. To the extent HMI's Purchase Order exceeds such forecasted number of Batches of the applicable Drug Substance or Drug Product by more than [***] for the applicable period, Supplier shall have no obligation to accept the Purchase Order for such excess number of Batches of such Drug Substance or Drug Product. It is understood that Supplier shall not be obliged to deliver such excess number of Batches of Drug Substance or Drug Product until Supplier has agreed to do so in writing by its acceptance of Purchase Orders specifying such excess number of Batches of Drug Substance or Drug Product. Subject to the foregoing, Supplier shall meet the delivery dates and the number of Batches of the applicable Drug Substance or Drug Product indicated in HMI's Firm Order. Subject to Section 3.8(b), if any circumstances occur that could reasonably result in any delivery delay or variation in the number of Batches of any Drug Substance or Drug Product supplied, Supplier shall immediately inform HMI thereof in sufficient detail for HMI to assess the likelihood that such delivery delay or variation in the number of Batches of Drug Substance or Drug Product will [***]. The Joint Steering Committee will discuss and identify appropriate measures to address the shortage and/or delay and Supplier will [***]. Notwithstanding the foregoing two sentences, Supplier [***] the number of Batches of Drug Substance and/or Drug Product order in Purchase Orders in the event the potential shortage and/or delay is the result of HMI's failure to provide the HMI Raw Materials necessary for the initiation or completion of the applicable Purchase Order in accordance with Section 3.4. If HMI reasonably anticipates a failure to timely provide HMI Raw Materials necessary for the initiation or completion of a Purchase Order, it shall promptly notify Supplier via the Project Team, and the Parties shall discuss in good faith and agree on appropriate solutions, and if the solutions mutually agreed upon require Supplier to obtain alternative sources of HMI Raw Materials, [***].

3.4 Raw Materials.

(a) On a Product-by-Product, Purchase Order-by-Purchase Order and/or SOW-by-SOW basis, HMI shall provide to Supplier certain HMI Raw Materials that are necessary for the Manufacture of Products or the performance of Services. In the event where HMI specifies in a Purchase Order or an SOW that a Product shall be made or that certain Services shall be performed using certain HMI Raw Materials (as applicable), HMI will deliver the amount of HMI Raw Materials that is reasonably expected to be necessary for the initiation of such Purchase Order or SOW at least (a) [***] before the expected production start date for the relevant Product Batch or (b) [***] before the expected start date for the relevant Services, and HMI shall further deliver any remaining amount of the HMI Raw Materials that is necessary for the completion of such Purchase Order (including in connection with any replacement of Products in accordance with the terms hereof) or such SOW. HMI shall be responsible for sourcing and qualifying the suppliers for all HMI Raw Materials, and HMI will provide Supplier with access to written confirmation of release for each item of the HMI Raw Materials, and upon Supplier's request in writing,

Certificates of Analysis if applicable. [***]. Supplier may not use the HMI Raw Materials for any purpose other than to Manufacture Products and to perform Services for HMI.

(b) Any raw material necessary for the Manufacture of Product or the performance of Services that is not provided by HMI to Supplier as HMI Raw Material is the responsibility of Supplier. Unless otherwise specified herein, all Supplier-sourced materials and consumables shall be [***]. It is acknowledged that pursuant to the Contribution Agreement, HMI shall have contributed certain assets, including certain raw materials necessary for the Manufacture of Product, to Supplier at or prior to the Effective Date. With respect to up to [***] Batches (i.e., [***]) of Drug Substance of Named HMI Product(s) supplied hereunder, if the raw materials contributed by HMI under the Contribution Agreement are of sufficient quantity and suitable for the Manufacture of such Batches of Drug Substance of Named HMI Products, [***]. For purposes of this Section 3.4(b), raw materials are "suitable" if as of the time of initiation of the Manufacture of the applicable Batch of Drug Substance, such raw materials conform in all material respects to the applicable specifications and quality standards for each item of such raw materials set forth in the Quality Agreement (as applicable), and with cGMP. For clarity, for any subsequent Batches of Drug Substance after [***], (i.e., [***]) supplied hereunder, [***] in accordance with Section 5.1 regardless of Supplier's utilization of any amount of suitable raw materials or other assets contributed to Supplier pursuant to the Contribution Agreement.

(c) All HMI Raw Materials will be provided [***] to Supplier.

(d) For clarity, the Drug Substance Batch Price and the Filling Price shall exclude [***].

(e) It is understood and agreed that Supplier-sourced materials may require a longer time period to acquire or procure the supply thereof and accordingly will be purchased by Supplier based on the applicable [***] Forecast; and in the event the number of Batches of any Drug Substance or Drug Product set forth in a Binding Forecast is lower than the number of Batches for such Drug Substance or Drug Product set forth in the applicable [***] Forecast that was first submitted by HMI for the applicable period, HMI shall reimburse Supplier for the non-cancellable portion of the Supplier-Sourced Material [***] directly attributable to such deviation; *provided* that Supplier shall use its commercially reasonable efforts to utilize or store for later use the excessive portion of the Supplier-sourced materials to mitigate such costs to HMI.

3.5 Delivery.

(a) All Batches of Drug Product shall be delivered by Supplier [***] or delivered to the applicable warehouse or storage location at the Facility or such other location as is agreed by the Parties in writing and set forth in the applicable Purchase Order. [***]. Each delivery of the Drug Product shall be accompanied by a Certificate of Analysis and any other documentation set forth in Section 4.5 of the Quality Agreement. Risk of loss or damage to Drug Product shall pass to HMI [***].

(b) A Batch of Drug Substance shall be deemed to have been delivered by Supplier [***] or delivered to the applicable warehouse or storage location at the Facility or such other location as is agreed by the Parties in writing and set forth in the applicable Purchase Order upon the Manufacturer's Release thereof. [***] risk of loss or damage shall pass from Supplier to HMI [***].

(c) The Project Team shall discuss and determine the logistics and procedures for the Manufacturer's Release of Drug Substance and the delivery of Drug Product for the period when the manufacturing Facility is physically located in the same building as HMI.

3.6 Supply Capacity. [***] pursuant to this Agreement at [***], as necessary, to Manufacture Products for HMI in accordance with the [***] and to provide Services as set forth in the [***]. The Joint Steering Committee will periodically discuss [***] Manufacture of Products and provision of Services for HMI.

3.7 Storage. During the Term, HMI is entitled to request the Supplier to store an inventory of up to [***] supply of each Product in the form designated by HMI (e.g., as Drug Substance or Drug Product, on a Product-by-Product basis), [***], based on the then-current Binding Forecast, on a first-expiry first-out basis and if so requested, the Parties will negotiate in good faith and enter into an SOW covering such storage. Subject to the applicable SOW, [***] of the applicable Drug Substance or delivery of the applicable Drug Product and Supplier will provide to HMI, upon written request, an inventory status report setting forth the number of Batches of the Drug Substance and Drug Product and dating of each Batch of such Drug Substance and Drug Product stored by Supplier.

3.8 Supply Shortage.

(a) In the event the Joint Steering Committee has mutually agreed upon an Improvement Plan with respect to a Product pursuant to Section 2.7(b), Supplier shall use its commercially reasonable efforts to implement such Improvement Plan.

(b) The Parties acknowledge and agree that the yield on any Batch of Product may vary based on the nature of the Product and Manufacturing technology used therefor. With respect to a Product, promptly after the Manufacture of the [***] Batch of Drug Substance or the [***] Batch of Drug Product, in each case at the Facility whether Manufactured by HMI prior to the Effective Date or by Supplier after the Effective Date, the Parties shall discuss (via the Joint Steering Committee) in good faith [***] by the Joint Steering Committee [***].

(i) [***].

(ii) [***].

(iii) [***].

(c) [***]. If Supplier experiences capacity constraints for any reason, including due to a Force Majeure Event or shortage of a Supplier-sourced materials, Supplier shall [***].

ARTICLE 4
QUALITY

4.1 Quality Agreement. The Parties shall enter into a Quality Agreement on or before the closing date under the Contribution Agreement.

4.2 Non-Conformance with Product Specifications and Defects.

(a) Without limiting Sections 2.3(a)(iv) and 2.11, [***].

(b) HMI shall notify Supplier in writing of any Patent Defects in a Batch of cGMP Product (including by way of inspection or examination of the Certificate of Analysis, batch records or any other documentation required to be provided with each delivery of the Products) within [***] of delivery of the relevant Batch of cGMP Product.

(c) HMI shall notify Supplier of any Latent Defects in a Batch of cGMP Product within [***] after becoming aware of such Latent Defect.

(d) Subject to Section 4.2(e), (i) solely with respect to Defect(s) [***], Supplier shall replace the Defective Product(s) [***] as promptly as practical and in any case initiate the replacement within [***] after notice is provided under Section 4.2(b), and if Supplier does not, or is unable to initiate a replacement within such period, then [***]; and (ii) if the Defect(s) are not caused by [***], Supplier shall replace the Defective Product(s) upon HMI's request and [***] within a timeline reasonably agreed to between the Parties; *provided* that Supplier shall have the capacity to Manufacture such replacement.

(e) In the event of an alleged Defect, Supplier will investigate the cause for such Defect in accordance with the Quality Agreement. If Supplier disputes that there is a Defect or that the Defect [***] based on its investigation, the Parties shall investigate the dispute in accordance with the Quality Agreement, including any quality assurance and compliance activities that have been established and mutually agreed upon by the Parties to detect or measure parameters of such Defect(s). A copy of the investigation report delivered in accordance with the Quality Agreement (if applicable) shall be provided to the Project Team concurrently. If within [***] following the conclusion of such investigation, the Parties through the Project Team are unable to reach an agreement regarding (i) whether there is a Defect or (ii) the cause of the Defect, the matter may be referred by either Party to the Joint Steering Committee in accordance with Section 2.7. If the Joint Steering Committee is not able to resolve such dispute within [***], then, the Parties shall engage [***] to determine whether there is Defect and/or the cause of Defect, if applicable, [***]. The determination of [***] shall be final and binding on both Parties. [***]. If [***] determines that the Batch (or portion thereof) of cGMP Product is [***] Supplier shall replace the Defective Products as promptly as practical and in any case initiate the replacement within [***] of [***] determination, and if Supplier is unable to, or does not, initiate a replacement within such period, then [***]. HMI will be responsible for the destruction of the relevant Batch(es) (or portions thereof) of Products found to be Defective that are in HMI's possession.

(f) If Supplier has [***] implement such remediation plan in a timely manner.

ARTICLE 5
PRICES – INVOICING - PAYMENTS

5.1 Drug Substance Supply Price. With respect to a Drug Substance, the price for each cGMP Batch of such Drug Substance will be the sum of [***] (collectively, the "**Drug Substance Supply Price**"). The Parties agree to negotiate in good faith a reasonable discount to the Drug Substance Batch Price for engineering/reference Batches of Drug Substance that are not intended to be or required to be cGMP compliant.

5.2 Drug Product Filling Price. With respect to a Drug Product, the price for each Batch of such Drug Product will be the sum of [***]. For clarity, the Filling Price for a Drug Product shall not include the cost of the Drug Substance that is used or consumed in the Drug Product Manufacturing process.

5.3 Supply Price Determination and Adjustments.

(a) Prior to HMI's submission of the first Purchase Order for a Drug Substance that is an Other HMI Product, HMI shall provide reasonable advance notice to Supplier with description of the applicable Process and materials required for the Manufacture of such Drug Substance in sufficient detail for Supplier to determine the applicable Drug Substance Batch Price. Subject to Section 5.3(c), Supplier shall, at its sole discretion, determine and notify HMI of the Drug Substance Batch Price for such Drug Substance; *provided* that such Drug Substance Batch Price shall be [***]. For avoidance of doubt, neither Party is obligated under this Agreement to accept the price proposed by the other Party for any Other HMI Product.

(b) No later than [***] prior to the beginning of each calendar year after the Effective Date, Supplier shall be permitted, on an annual basis, to increase the Drug Substance Batch Prices or Filling Price by written notice to HMI, which price increase shall become effective as of [***]; *provided* that such year-to-year increase in Drug Substance Batch Price for a Drug Substance or the Filling Price for a Drug Product shall not exceed [***]; *provided further*, that such price increase shall not apply to any Firm Orders, whether outstanding or fulfilled as of the effective date of such increase.

(c) Notwithstanding the foregoing, Supplier shall review the prices for Products charged to HMI as soon as [***].

5.4 Development Services Prices.

(a) The prices for the Services for calendar year 2022 shall be the Services fees set out in the Initial SOW Plan, which shall be paid in equal monthly installments. The prices for all Services set out in individual SOWs will be paid based on [***], in each case incurred in connection with the performance of the applicable Services.

(b) For calendar year 2023, the FTE Rate for the Services to be provided shall be [***] (which is calculated based on an hourly rate of [***] and [***] per year per FTE). No later than [***] prior to the beginning of calendar year 2024 and each calendar year thereafter, Supplier shall be permitted, on an annual basis, to increase the then-current FTE

Rate by written notice to HMI, which price increase shall become effective as of January 1 of such calendar year; *provided* that such year-to-year increase in FTE Rate shall not exceed [***].

(c) Notwithstanding the foregoing, the FTE Rate paid by HMI for the Services [***].

5.5 Invoices. For all payments due under this Agreement, Supplier shall provide HMI with an invoice for the amount due.

(a) Unless otherwise agreed by the Parties, (i) during the term of the Initial SOW Plan, HMI shall pay the [***] Services fees set forth in Section 5.4(a) on a monthly basis, upon receipt of the applicable invoice; and (ii) with respect to any Services performed under an individual SOW, in accordance with the payment schedule set out in the applicable SOW.

(b) The Drug Substance Batch Price for each Batch of the Drug Substance Manufactured under this Agreement shall be due as follows: (i) [***]; (ii) [***]; and (iii) [***].

(c) The Filling Price for each Batch of the Drug Product Manufactured under this Agreement shall be due as follows: (i) [***]; and (ii) [***].

(d) Supplier shall issue invoices for any fees and charges when due under Sections 5.5(a) through 5.5(c), and shall issue monthly invoices to HMI for any other cost and additional charges due under this Agreement [***] payments under Sections 5.5(a) through 5.5(c). Invoices shall be sent to the HMI invoice mailbox as outlined in the Purchase Order or SOW. Each invoice shall set forth in reasonable detail the amounts payable by HMI under this Agreement and contain the following information, as applicable: Supplier's name, associated Purchase Order or SOW reference number, HMI contact name, the applicable Drug Substance Batch Price, Filling Price or Service fees, [***] in connection therewith. HMI shall promptly notify the Supplier if it determines that any invoice or related document is inaccurate or incorrectly submitted to HMI, but in any event no later than the payment due date of the invoice. HMI may withhold from an invoice any portion of the invoiced amount that is disputed in good faith, but shall pay the undisputed portion before the payment deadline for such invoice. Other than disputes resolved under Section 4.2, the Parties shall seek to resolve any invoice disputes expeditiously and in good faith in accordance with the dispute resolution provisions set forth in Section 11.15. Any payment by HMI of an invoice is not an acceptance of the terms of said invoice to the extent it is inconsistent with the terms and conditions of this Agreement, or any nonconforming element of the related Batch of Product.

5.6 Payment. Except for any amounts disputed by HMI in good faith, Supplier's accurate and correctly submitted invoices will be payable within [***] following HMI's receipt of Supplier's invoice. Any payment by HMI will not be deemed acceptance of the Products or waive HMI's right to inspect the delivered Products. HMI shall make all payments under this

Agreement in United States dollars by check, wire transfer or automated clearing house in accordance with the instructions as stated on the applicable invoice.

5.7 [***].

5.8 Late Payments. Any late payments due hereunder shall bear interest at an annual rate equal to the [***] of (a) [***] and (b) the highest rate permitted by Applicable Law, in each case, calculated based on the number of days such payment is delinquent from the date originally due as provided in Section 5.6, [***].

5.9 No Setoff. All payments required to be made by either Party hereunder shall be calculated without reference to any set off or counterclaim and shall be made free and clear of and without any deduction for or on account of any set off or counterclaim.

5.10 Taxes. All amounts due to Supplier under this Agreement:

(a) are exclusive of any value added taxes, goods and services taxes, sales taxes, consumption taxes and other similar indirect taxes imposed with respect to, or as a result of, such amounts due to Supplier under this Agreement ("**Indirect Taxes**"). HMI (or its assignee) shall be responsible for the payment of any such Indirect Taxes and shall pay to the Supplier for remittance by the Supplier to the appropriate taxing authority (or, if required by Applicable Law, directly to the appropriate taxing authority) the amount of any such Indirect Taxes. Supplier shall provide to HMI all customary receipts for payment of such Indirect Taxes and reasonably cooperate with HMI in making applications for and securing any available exemptions or reductions of Indirect Taxes reasonably available;

(b) shall be made free and clear of, and without, any deduction or withholding on account of taxes, except to the extent such taxes are required to be withheld under Applicable Law. If Applicable Law requires withholding by HMI (or its assignee) with respect to any payments made to Supplier under this Agreement, such taxes shall be deducted by HMI (or its assignee, if applicable) as required by Applicable Law and timely remitted to the proper tax authorities, and if HMI changes its domicile to a country where withholding tax is required by Applicable Law or if HMI assigns this Agreement to any Person that resides in a country where withholding tax is required by Applicable Law, then HMI or its assignee, as applicable, or their respective assignee, shall make an additional payment to Supplier such that Supplier receives, after deduction and withholding of taxes from such payment, including any additional amount, an amount equal to the amount it would have received absent any such deduction and withholding. HMI (or its assignee) shall furnish official receipts of payment of any withholding tax to Supplier as evidence of its remittance of any amounts required to be withheld in respect of any payments (including additional amounts payable under this Section 5.10(b)). The Parties shall cooperate to ensure that any withholding taxes imposed are reduced to the extent legally permissible under the provisions of any relevant tax treaty or other Applicable Law, which cooperation shall include providing assistance with the completion of any required forms; and

(c) Supplier shall provide to HMI as properly executed, correct and complete Internal Revenue Service Form W-9 promptly after the Effective Date.

ARTICLE 6
TERM AND TERMINATION

6.1 Initial Term. This Agreement shall be effective from the Effective Date, and shall, unless terminated earlier under the provisions of Article 6, continue until [***].

6.2 Term Extension. The Initial Term may be renewed for [***] if HMI provides written notice of renewal to Supplier at least [***] prior to the expiration date of the Initial Term (the Initial Term and if applicable, such additional [***] term, the "**Term**"). If the Initial Term is renewed pursuant to this Section 6.2, the terms and conditions of this Agreement during the extended Term will be the same as the terms in effect during the Initial Term, including HMI's forecast obligations pursuant to Sections 2.3(a) and 3.1, respectively, unless otherwise agreed by Parties in writing; *provided*, *however*, that notwithstanding the foregoing, such same terms shall not include any obligation by HMI to commit to any Annual Purchase Minimums, Demand Based Purchase Minimums, or [***] Forecast, in each case, to the extent covering any period beyond expiration of such additional [***] term.

6.3 Termination.

(a) After the Initial Term, HMI may, at its option, terminate this Agreement in its entirety or on a Product-by-Product basis at any time and for any reason by giving prior written Notice of termination to Supplier. Termination will be effective [***] after the date Supplier receives such termination Notice. If such termination would become effective prior to the expiration of the Term, HMI shall pay to Supplier [***].

(b) Either Party may terminate this Agreement in its entirety for cause by providing written termination Notice to the other Party:

(i) subject to Section 4.2, if the other Party is in material breach of its representation, warranty or covenant under this Agreement and either the breach cannot be cured or, if the breach can be cured, it is not cured by the breaching Party within a commercially reasonable period of time under the circumstances, in no case exceeding [***] following breaching Party's receipt of the non-breaching's written notice of such breach, *provided* that if (1) such breach cannot be cured within the [***] period, (2) the breaching Party provides a notice to the non-breaching Party indicating the same, (3) delivers a plan to cure such breach to the non-breaching Party, and (4) cures the breach complained of within [***] following the expiration of the [***] period, then this Agreement shall continue in full force and effect; or

(ii) if the other Party becomes insolvent or is generally unable to pay, or fails to pay, its debts as they become due; files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law; makes or seeks to make a general assignment for the benefit of its creditors; or applies for or has appointed a receiver, trustee, custodian or similar agent appointed by order of any court

of competent jurisdiction to take charge of or sell any material portion of its property or business, in each case above, that is not discharged within [***] thereafter.

Any termination under this Section 6.3(b) will be effective on the other Party's receipt of the first Party's written termination Notice or such later date (if any) set forth in such termination Notice.

6.4 Change of Control of Supplier or HMI. In the event of Change of Control of either Party, the terms of this Agreement shall continue with both Parties being obligated to perform under the original terms of this Agreement. If modification of this Agreement is desired by either Party after the Change of Control, the Parties shall discuss in good faith to come to mutually agreed upon modified terms. If a written amendment is not reached by the Parties, the original terms of this Agreement shall continue to govern.

6.5 Effect of Expiration or Termination. Immediately upon the effective date of termination:

(a) Subject to performing any necessary wind-down activities Supplier shall promptly terminate all performance under this Agreement and under any outstanding Purchase Orders and SOWs unless directed otherwise by HMI, *provided* that HMI shall pay to Supplier (i) Supplier's costs actually incurred towards partially completed Services or unfinished Products or that will be incurred by Supplier during the remainder of the Term and are not cancellable, (ii) reasonable costs associated with necessary wind-down activities, and (iii) only in the event of a termination by Supplier pursuant to Section 6.3(b), [***].

(b) Supplier shall transfer title and deliver to HMI all Products Manufactured prior to the effective date of termination that were made in accordance with the Product Specifications, Purchase Order, the Quality Agreement and Applicable Law.

(c) Expiration or termination of this Agreement will not affect any rights or obligations of the Parties that come into effect as of or prior to termination of this Agreement or expiration of the Term; or otherwise survive the expiration or early termination of this Agreement, and were incurred by the Parties prior to such expiration or early termination.

(d) The licenses granted by HMI to Supplier under Section 8.2(a) shall terminate, and the licenses granted by Supplier to HMI under Section 8.2(b) shall become perpetual.

(e) Each Party shall:

(i) return to the other Party all documents and tangible materials (and any copies) containing, reflecting, incorporating or based on the other Party's Confidential Information;

(ii) permanently erase all of the other Party's Confidential Information from its computer systems, except for copies that are

maintained as archive copies on its disaster recovery and/or information technology backup systems or otherwise required to comply with cGMP or Applicable Law. Each Party shall destroy any such copies upon the normal expiration of its backup files; and

(iii) upon the other Party's written request, certify in writing to such other Party that it has complied with the requirements of this Section 6.5(e).

(f) Supplier shall be responsible for all cleanup and remediation of the Facility(ies) and removal and decommissioning of all materials and equipment therein used for Manufacturing Products, except for liabilities that are not assumed by Supplier pursuant to the Contribution Agreement, which shall remain as HMI's liabilities as between the Parties.

(g) Except as otherwise provided herein, neither Party, will be liable to the other Party for any damages of any kind (whether direct or indirect) incurred by the other Party solely arising out of the expiration or earlier termination of this Agreement. However, termination of this Agreement will not constitute a waiver of any of the terminating Party's rights or remedies under this Agreement, at law, in equity or otherwise.

6.6 Survival. In addition to the survivability of certain provisions of this Agreement as expressly set forth herein, the following provisions shall survive in the event of expiration or termination of this Agreement for any reason: Sections 4.2(a) through (e), 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 6.3, 6.5, 6.6, 7.3, 7.5, 7.6, 8.1, 8.2, 9.1, 9.2, 9.3, 9.4, 9.5(g), 9.6, 9.7, 9.8, 9.9, 9.10, and 9.11 and Articles 1, 8, 10 and 11 and such other provisions hereof as are required for the interpretation or enforcement of those Sections, and any other provisions that, as apparent from their terms in the context of this Agreement, are intended to survive termination or expiration of this Agreement.

ARTICLE 7
REGULATORY OBLIGATIONS - AUDITS

7.1 Subject to the terms of the Quality Agreement, Supplier shall Manufacture the Products in accordance with cGMP and all Applicable Law.

7.2 Supplier undertakes that the equipment and portion of the Facility(ies) under Supplier's ownership used to Manufacture the cGMP Products will meet the requirements of the Quality Agreement, cGMP appropriate to the phase of Product development and of all Applicable Law, except for liabilities that are not assumed by Supplier pursuant to the Contribution Agreement, which shall remain as HMI's liabilities.

7.3 Supplier shall provide access to Governmental Authorities and cooperate fully with such authorities for any matter involving the Products supplied to HMI. Such access will occur upon reasonable advance notice during normal business hours unless otherwise required by Governmental Authorities. Supplier shall also [***] provide such access to and cooperation with the Governmental Authorities [***] with the Governmental Authorities, [***]; *provided* that Supplier shall not be in breach of this Agreement or the Quality Agreement in the event that such [***]. Notwithstanding the foregoing two sentences, [***]. Supplier shall

immediately notify HMI upon receipt of notice from a Governmental Authority for an inspection of Supplier's Facilities where the Manufacturing of Products or Services are being performed, or in the event of an unannounced inspection, Supplier shall provide immediate notice if possible and permissible to the extent such inspection relates to the Manufacturing of Products or performance of Services. If permitted by the Governmental Authority, one Designee from HMI shall be permitted to be present on site where a Governmental Authority requests such attendance or where the audit or inspection is specific to a Product or Services but such Designee shall not participate in such audit or inspection. If Supplier receives any request by a Governmental Authority that requires a written response regarding the Products or Services, Supplier shall provide HMI a copy of such notice within [***] of Supplier's receipt of the notice. Supplier shall provide HMI a draft of the response prior to the response being submitted to the Governmental Authority so as to provide HMI with a reasonable period of time in which to review and comment on the response, which comments Supplier, in good faith, shall consider and incorporate into the response to the extent such comments are appropriate and specific to a Product or Services and in accordance with the Quality Agreement.

7.4 Upon HMI's prior request and upon at least [***] prior Notice and not more than [***], Supplier shall allow a maximum of [***] auditing Designees of HMI to inspect, during normal business hours, its facilities where the Products are Manufactured in order to observe operations related to Manufacture and testing thereof subject to Supplier's standard operating procedures, and to review such of Supplier's records relating to the Manufacture, safety, quality and regulatory control, release, storage, shipping and delivery of the Products as are relevant to confirm Supplier's compliance with the Quality Agreement, [***]. From time to time during the Term, Supplier shall also allow a Designee of HMI (or person in plant), to observe operations related to Manufacture and testing of the Product at mutually agreed times; *provided* that HMI shall provide reasonable advance notice to Supplier together with the stated purpose of the observation. HMI's Designee shall not have access to clean rooms during Manufacture but may view the Manufacture of the Product through video feed, viewing gallery or such other means of observation as Supplier may make available from time to time at the Facility. Any Designee attending the Facility pursuant this Section 7.4 may at Supplier's sole discretion be required to enter into an appropriate confidentiality agreement with Supplier. Notwithstanding the foregoing, to the extent any material breach of the Quality Agreement is found by HMI, Supplier shall [***] prior written notice. In the event of a critical quality issue identified by Supplier or a Governmental Authority, Supplier will notify HMI in accordance with the Quality Agreement, and all forecasts (including, as applicable, Binding Forecast and each [***] Forecast) and outstanding Purchase Orders shall be appropriately reduced to omit quantities of the affected Product during the pendency of any such critical issue until the full resolution thereof.

7.5 Supplier shall have in place systems and procedures to facilitate rapid recalls related to the Products and shall inform HMI where Supplier believes that such a recall of Products or product made with Products is necessary. In such circumstances, the Parties shall consult with each other as to what decisions or actions may be required. The cost of such recall shall be borne (i) by Supplier in the event that such recall has arisen or resulted from any breach or negligence or willful misconduct or violation of Applicable Law of Supplier and (ii) by HMI in all other cases. HMI shall retain exclusive responsibility for all decisions and actions with

respect to any complaint, recall, market withdrawal or other corrective action concerning the HMI's finished products unless otherwise appropriate or required by the relevant Governmental Authority.

7.6 If HMI is required to submit to a Governmental Authority information or data relating to a Product Manufactured by Supplier or to Services rendered by Supplier, for any reason including to seek or maintain marketing approval or to respond to an agency request for information, Supplier will promptly cooperate with HMI and provide to HMI all documentation, data and other information in Supplier's possession as HMI may reasonably require and request for such submission or response to Governmental Authority to the extent in Supplier's possession, custody or control. The cost of providing such information and cooperation shall be specified in an SOW and shall be borne by HMI.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 Ownership. HMI shall remain the sole owner of all right, title and interest in and to, or licensee of, as applicable, all HMI Intellectual Property Rights existing as of the Effective Date and shall solely own all HMI Intellectual Property Rights arising thereafter during the Term, and no right, title or interest therein is transferred or granted to Supplier except as expressly set forth in Section 8.2. Supplier shall remain the sole owner of all right, title and interest in and to, or licensee of, as applicable, all Supplier Intellectual Property Rights existing as of the Effective Date and shall solely own all Supplier Intellectual Property Rights arising thereafter during the Term, and no right, title or interest therein is transferred or granted to HMI except as expressly set forth in Section 8.2. Subject to the License and Patent Management Agreement, as between the Parties, HMI shall solely own all rights, title and interest in and to HMI-Owned Inventions and Supplier shall solely own all rights, title and interest in and to Supplier-Owned Inventions. Each Party shall cause its employees, consultants, agents, or independent contractors to so assign to such Party such person's entire right, title and interest in and to the foregoing, and all intellectual property rights therein, and to take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required, as is necessary to enable such Party to fully effect the ownership of the foregoing, and intellectual property rights therein, as provided in this Section 8.1.

8.2 Licenses.

(a) Subject to the terms and conditions of this Agreement, HMI hereby grants to Supplier a non-exclusive, non-transferable, non-sublicensable (except as set forth in Section 2.5), royalty-free, limited license to use HMI Intellectual Property Rights solely for the purpose of Manufacturing the Products and performing the Services pursuant to the terms and conditions of this Agreement.

(b) Subject to the terms and conditions of this Agreement, Supplier hereby grants to HMI [***].

8.3 Inventions. Supplier shall disclose promptly to HMI, in writing, any and all HMI-Owned Inventions conceived or created by or on behalf of Supplier. Supplier hereby assigns to HMI all of Supplier's right, title and interest in and to HMI-Owned Inventions without any additional consideration. At HMI's request and expense during and after the Term, Supplier shall provide HMI with reasonable assistance to perfect HMI's ownership interest in HMI-Owned Inventions and in obtaining, securing, maintaining, and enforcing patents and other Intellectual Property Rights covering such HMI-Owned Inventions. HMI shall disclose promptly to Supplier, in writing, any and all Supplier-Owned Inventions conceived or created by or on behalf of HMI. HMI hereby assigns to Supplier all of HMI's right, title and interest in and to Supplier-Owned Inventions without any additional consideration. At Supplier's request and expense during and after the Term, HMI shall provide Supplier with reasonable assistance to perfect Supplier's ownership interest in Supplier-Owned Inventions and in obtaining, securing, maintaining, and enforcing patents and other Intellectual Property Rights covering such Supplier-Owned Inventions. Each Party shall cause its employees, consultants, agents, or independent contractors to so assign to such Party such person's entire right, title and interest in and to the foregoing, and all intellectual property rights therein, and to take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required, as is necessary to enable such Party to fully effect the ownership of the foregoing, and intellectual property rights therein, as provided in this Section 8.3.

8.4 Relationship with the License and Patent Management Agreement. Notwithstanding the foregoing, the Parties acknowledge and agree that in the event certain HMI-Owned Inventions and Supplier-Owned Inventions constitute Jointly Managed Patents under the License and Patent Management Agreement, the ownership of such HMI-Owned Inventions and Supplier-Owned Inventions shall be governed by Section 8.3 hereunder except for [***], and such Jointly Managed Patents shall be prosecuted, maintained, enforced and otherwise managed pursuant to Articles 3, 4, 5, 6, 7, 8, and 9 of the License and Patent Management Agreement.

ARTICLE 9
REPRESENTATIONS, WARRANTIES, INDEMNIFICATION AND LIABILITY

9.1 Mutual Representations and Warranties. HMI and Supplier each represents and warrants as follows:

(a) it has all requisite corporate power and authority to enter into this Agreement and each Purchase Order and SOW and to carry out the transactions contemplated hereby and thereby;

(b) the execution, delivery and performance of this Agreement and each Purchase Order and SOW and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite corporate action on the part of such Party;

(c) this Agreement has been duly executed and delivered by such Party and (assuming the due authorization, execution and delivery hereof by the other party) is a valid

and binding obligation of such Party, enforceable against it in accordance with its terms; and

(d) its entry into this Agreement does not violate or constitute a breach of any of its existing contractual obligations with Third Parties as of the Effective Date.

9.2 Product Warranty. Assuming the accuracy of the representations and warranties in Section 9.3, Supplier warrants to HMI that:

(a) on the date of delivery in accordance with Section 3.5, each of the cGMP Product Manufactured and supplied hereunder will:

(i) conform in all material respects to the Product Specifications;

(ii) conform with the quality standards in the Quality Agreement; and

(iii) have been Manufactured in compliance with all Applicable Law, including without limitation 21 U.S.C. §§ 351(a)(2)(B); and

(b) each Batch of Product will be conveyed by Supplier to HMI with good title, free and clear of all liens, security interests, and other encumbrances;

(for each Product, the "**Product Warranty**").

9.3 Raw Materials Warranty. HMI warrants to Supplier that:

(a) on the date of delivery of HMI Raw Materials at the Facility(ies), the HMI Raw Materials will:

(i) conform in all material respects to the HMI Raw Materials specifications; and

(ii) conform with the quality standards for each item of HMI Raw Materials in the Quality Agreement, as applicable; and

(b) each HMI Raw Material will be conveyed by HMI to Supplier with good title, free and clear of all liens, security interests, and other encumbrances;

(the "**HMI Raw Materials Warranty**").

9.4 Additional Terms. The Products Warranty and the HMI Raw Materials Warranty (a) inures to the benefit of HMI or Supplier, as applicable, and their successors and permitted assigns, and (b) may not be limited or disclaimed by HMI or Supplier, as applicable. HMI's approval of Supplier supplied materials, consumables, Product Specifications or similar requirements will not be construed to relieve Supplier of any Product Warranties. Supplier's approval of HMI Raw Materials will not be construed to relieve HMI of any HMI Raw Materials Warranties.

9.5 Compliance. Supplier represents, warrants and covenants to HMI as follows:

(a) To Supplier's knowledge, all employees and individual consultants and contractors engaged by Supplier or its Affiliates in the Manufacture of the Products and the performance of the Services (collectively, "**Supplier Personnel**") are, and will continue to be, qualified and have, and will continue to have, sufficient technical expertise by directly applicable training, experience and supervision to perform Supplier's obligations under this Agreement;

(b) Supplier and its Affiliates are licensed and permitted as necessary to Manufacture the Products and perform the Services, including performing cGMP Manufacturing, under all Applicable Law;

(c) all performance of Services by Supplier, its Affiliates, and Supplier Personnel will be performed in accordance with: (i) all Applicable Law; (ii) the terms and conditions of this Agreement, the Quality Agreement (if applicable); (iii) generally prevailing industry standards; and (iv) HMI's written instructions, including without limitation SOWs;

(d) Supplier will [***];

(e) none of Supplier, its Affiliates, or to Supplier's knowledge, any Supplier Personnel has been debarred, disqualified or banned by any governmental or Governmental Authority or is subject to a debarment proceeding, and Supplier and its Affiliates will not knowingly employ or contract with any person or entity that has been so debarred, disqualified or banned to perform any Manufacturing of Products or Services;

(f) To Supplier's knowledge, all Supplier Personnel are, and will continue to be, under binding obligation (i) to assign to Supplier all inventions and Intellectual Property Rights therein that they develop or create in connection with this Agreement to Supplier and (ii) of confidentiality to Supplier that are substantially similar to or more stringent than the confidentiality obligations of Supplier to HMI under this Agreement;

(g) Supplier will maintain all records of Manufacture Products and performance of the Services under this Agreement and archive such records, if applicable, in accordance with cGMP, and Applicable Law, but in no case for less than a period of [***] following completion of a Purchase Order or SOW (completion period shall not include the period of any long-term stability study conducted by Supplier); and

(h) Supplier will [***] in providing Services, to the extent such equipment or materials are not provided or specified by HMI, in each case, under this Agreement.

9.6 Additional Representations and Warrants by HMI. HMI represents, warrants and covenants to Supplier as follows:

(a) To its knowledge, as of the Effective Date, there are no patents, trade secrets or other intellectual property or other proprietary rights of any Third Party related to the Manufacture of Products that would be violated, infringed, misappropriated or misused by Supplier's performance of this Agreement; and

(b) It and its Affiliates shall comply with all Applicable Law in its performance under this Agreement.

9.7 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT (INCLUDING THE PRODUCT WARRANTY), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NON-INFRINGEMENT OF ANY THIRD PARTY PATENT OR OTHER INTELLECTUAL PROPERTY RIGHT.

9.8 Indemnification.

(a) Subject to the terms and conditions of this Agreement, Supplier shall indemnify, defend and hold harmless HMI, its Affiliates, and their respective successors and assigns, and each of their respective Representatives (collectively, "**HMI Indemnified Parties**") against any and all losses, damages, liabilities, costs, or expenses, including reasonable attorneys' fees (collectively, "**Losses**") in connection with suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising out of or resulting from:

(i) a breach of any of Supplier's representations, warranties, obligations or covenants set forth in this Agreement (including the Product Warranty);

(ii) any bodily injury, the death of any Person, or damage to real or tangible personal property caused by the negligent acts or omissions of Supplier or any of its Representatives;

(iii) any grossly negligent or more culpable act or omission of Supplier or any of its Representatives (including any recklessness or willful misconduct) in connection with Supplier's performance under this Agreement;

(iv) [***] or

(v) any failure by Supplier or any of its Representatives to comply with any Applicable Law.

Notwithstanding the foregoing, Supplier's obligations under this Section 9.8(a) to indemnify the HMI Indemnified Parties will not apply to the extent any Losses of a HMI Indemnified Party arises out of any of the bases for indemnification described in Section 9.8(b).

(b) Subject to the terms and conditions of this Agreement, HMI shall indemnify, defend and hold harmless Supplier and its Affiliates, and their respective successors and assigns, and each of their respective Representatives (collectively, "**Supplier Indemnified**

Parties") against any and all Losses in connection with Third Party Claims arising out of or resulting from:

(i) breach of any of HMI's representations, warranties, or covenants set forth in this Agreement;

(ii) any grossly negligent or more culpable act or omission of HMI or any of its Representatives (including any recklessness or willful misconduct) in connection with HMI's performance under this Agreement;

(iii) any bodily injury, the death of any Person, or damage to real or tangible personal property caused by the negligent acts or omissions of HMI or any of its Representatives;

(iv) use of the Product Manufactured pursuant to this Agreement including in any clinical trials;

(v) the Manufacture of Products or provision of Services under HMI's instructions or directions under this Agreement;

(vi) any actual or alleged infringement, misappropriation or violation of any Third Party intellectual property by (A) use of the tangible materials that are provided by HMI (including HMI Raw Materials), (B) the practice of a Process specified by HMI to use in the Manufacture of Products, or (C) the conduct of any clinical trials utilizing the Product Manufactured pursuant to this Agreement, except to the extent arising from the use of any compositions or methods developed by Supplier and used to supply such Product that are not provided or specified by HMI; or

(vii) any failure by HMI or any of its Representatives to comply with any Applicable Law, including in the event HMI's instructions or directions to Supplier with respect to Manufacture of Products or Services provided violate Applicable Law.

Notwithstanding the foregoing, HMI's obligations under this Section 9.8(b) to indemnify the Supplier Indemnified Parties will not apply to the extent any Losses of a Supplier Indemnified Party arises out of any of the bases for indemnification described in Section 9.8(a).

9.9 Exceptions and Limitations on Indemnification. Notwithstanding anything to the contrary in this Agreement, an indemnifying Party is not obligated to indemnify or defend any indemnified Party against any Losses resulting directly from indemnified Party's:

(a) gross negligence or recklessness or willful misconduct; or

(b) bad faith failure to materially comply with any of its obligations set forth in this Agreement.

9.10 Indemnification Procedures. A Supplier Indemnified Party or a HMI Indemnified Party entitled to indemnification pursuant to either Section 9.8(a) or Section 9.8(b) will hereinafter be referred to as an "**Indemnitee**." A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an "**Indemnitor**." In the event an Indemnitee is seeking indemnification under either Section 9.8(a) or Section 9.8(b), the Indemnitee will inform the Indemnitor of a Third Party Claim as soon as reasonably practicable after it receives notice of the Third Party Claim, it being understood and agreed that the failure by an Indemnitee to give notice of a Third Party Claim as provided in this Section 9.10 will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is actually prejudiced as a result of such failure to give notice. The Indemnitee will permit the Indemnitor to assume direction and control of the defense of the Third Party Claim (including, subject to this Section 9.10, the right to settle the Third Party Claim solely for monetary consideration), and, at the Indemnitor's expense, will co-operate as reasonably requested in the defense of the Third Party Claim. The Indemnitee will have the right to retain its own counsel at its own expense; provided, that, if the Indemnitor assumes control of such defense and the Indemnitee reasonably concludes, based on advice from counsel, that the Indemnitor and the Indemnitee have conflicting interests with respect to such Third Party Claim, the Indemnitor will be responsible for the reasonable fees and expenses of counsel to the Indemnitee solely in connection therewith. The Indemnitor may not settle such Third Party Claim, or otherwise consent to an adverse judgment in such Third Party Claim, which would subject the Indemnitee to an injunction or if such settlement or judgment would materially diminish or limit or otherwise adversely affect the rights, activities or financial interests of the Indemnitee, without the express written consent of the Indemnitee. The Indemnitor will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of the Indemnitor, and Indemnitees shall not admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld. In the event that it is ultimately determined that the Indemnitor is not obligated to indemnify, defend or hold harmless the Indemnitee from and against the Third Party Claim, the Indemnitee will reimburse the Indemnitor for all costs and expenses (including attorneys' fees and costs of suit) and any Third Party Claims incurred by the Indemnitor in its defense of the Third Party Claim.

9.11 Limitations on Liability.

EXCEPT IN THE CASE OF [***], (A) IN NO EVENT SHALL EITHER PARTY OR ITS REPRESENTATIVES BE LIABLE FOR CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR ENHANCED DAMAGES ARISING OUT OF OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF (1) WHETHER SUCH DAMAGES WERE FORESEEABLE, (2) WHETHER OR NOT IT WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR (3) THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT OR OTHERWISE) UPON WHICH THE CLAIM IS BASED, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE; AND (B) SUPPLIER'S TOTAL LIABILITY

UNDER THIS AGREEMENT SHALL NOT EXCEED [***] (I) [***] AND (II) THE TOTAL OF THE AMOUNTS PAID AND AMOUNTS PAYABLE BY HMI TO SUPPLIER OVER THE [***] IMMEDIATELY PRIOR TO THE OCCURRENCE OF THE EVENT GIVING RISE TO THE LIABILITY, PROVIDED THAT FOR CLAIMS ARISING DURING THE [***] OF THE TERM, THE CAP SHALL BE NO LESS THAN THE DOLLAR AMOUNT THAT EQUALS [***].

9.12 Insurance. Each Party shall take all necessary steps, at its own cost and its own behalf to properly and adequately insure, with a reputable insurance company as far as reasonably possible, its entire legal liability to any Third Party which might be incurred, directly or indirectly, as a consequence of its activity relating to this Agreement. Supplier shall promptly inform HMI of any significant liability claim made by a Third Party or threat of a liability claim by a Third Party in connection with the Products and shall examine them in close consultation with HMI. For avoidance of doubt, such insurance will not create a limit to either Party's liability hereunder.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidential Information. From time to time during the Term, either Party (as the "**Disclosing Party**") may disclose or make available to the other Party (as the "**Receiving Party**") information about its business affairs, Products (including Product Specifications and HMI Raw Materials), and services (including any forecasts), confidential information and materials comprising or, relating to Intellectual Property Rights, Products, HMI's SOPs and quality management system, Third Party confidential information and other sensitive or proprietary information. Such information, whether provided orally or in written, electronic or other form or media, and whether or not marked, designated or otherwise identified as "confidential" constitutes "**Confidential Information**" hereunder. Confidential Information does not include information that at the time of disclosure and as established by contemporaneous documentary evidence:

(a) is or becomes generally available to and known by the public other than as a result of, directly or indirectly, any breach of this Section 10.1 by the Receiving Party or any of its representatives;

(b) is or becomes available to the Receiving Party on a non-confidential basis from a Third Party source, *provided* that such Third Party is not and was not prohibited from disclosing such Confidential Information;

(c) was known by or in the possession of the Receiving Party or its representatives prior to being disclosed by or on behalf of the Disclosing Party; provided that information known to representatives of Supplier who were representatives of HMI prior to the consummation of the transactions contemplated by the Contribution Agreement shall be treated as Confidential Information of HMI; provided further, that Know-How assigned by HMI to Supplier pursuant to the Contribution Agreement shall be Confidential Information of Supplier; or

(d) was or is independently developed by the Receiving Party without reference to or use of, in whole or in part, any of the Disclosing Party's Confidential Information.

Notwithstanding anything herein to the contrary, any HMI-Owned Inventions shall be Confidential Information of HMI and any Supplier-Owned Inventions shall be Confidential Information of Supplier.

10.2 Protection of Confidential Information. The Receiving Party shall, for [***] from receipt or disclosure of such Confidential Information:

(a) protect and safeguard the confidentiality of the Disclosing Party's Confidential Information with at least the same degree of care as the Receiving Party would protect its own Confidential Information, but in no event with less than a commercially reasonable degree of care;

(b) not use the Disclosing Party's Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement; and

(c) not disclose any such Confidential Information to any Person, except to the Receiving Party's representatives who need to know the Confidential Information to assist the Receiving Party, or act on its behalf, to exercise its rights or perform its obligations under this Agreement, and then only if each such representative is otherwise bound by obligations of confidentiality with respect to such information.

The Receiving Party shall be responsible for any breach of this Article 10 caused by any of its representatives.

10.3 Permitted Disclosure. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order to comply with Applicable Law (including any securities law or regulation or the rules of a securities exchange or as a requirement in filing for an International Nonproprietary Name (INN) or the like but excluding any regulatory inspections) or with a legal or administrative proceeding, or in connection with prosecuting or defending litigation;

(b) in connection with filings and other necessary disclosures and communications to Governmental Authorities and obligations pursuant to this Agreement; and

(c) in connection with exercising its rights hereunder, to its Affiliates, potential and future collaborators (including sublicensees), advisors, or independent contractors; permitted acquirers or assignees; and investment bankers, investors and lenders;

provided, however, that (i) with respect to Sections 10.3(a) and 10.3(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow

Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed; and (ii) with respect to Section 10.3(c), each of those named people and entities are bound by restrictions on use and disclosure consistent with Article 10 (other than advisors, investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality) and in any event, no disclosure of Know-How relating to the Manufacture of the Products shall be permitted. Notwithstanding the foregoing, unless consented to by HMI and Supplier in advance or as required by Law (in which case the Party required to make such disclosure will consult with the other Party a reasonable time prior to making such disclosure and will consider in good faith any comments made by the other Party to such disclosure), the Parties shall keep this Agreement strictly confidential and may not make any disclosure of this Agreement to any person or individual other than to their Affiliates. If either Party or any of its Affiliates, based on the advice of their counsel, determines that this Agreement must be publicly filed with a Governmental Authority, then such Party or its applicable Affiliate, prior to making such filing, shall provide the other Party and its counsel with a redacted version of this Agreement that it intends to file, and will consider in good faith any comments provided by the other Party or its counsel and use commercially reasonable efforts to ensure the confidential treatment by such Governmental Authority of those provisions specified by the other Party or its counsel for redaction and confidentiality.

ARTICLE 11
MISCELLANEOUS

11.1 Further Assurances. Upon a Party's reasonable request, the other Party shall, at its sole cost and expense, execute and deliver all such further documents and instruments, and take all such further acts, necessary to give full effect to this Agreement.

11.2 Relationship of the Parties. Without prejudice to the Contribution Agreement, the Transition Services Agreement or any other agreement between the Parties, the relationship between Supplier and HMI is solely that of vendor and vendee and they are independent contracting parties. Nothing in this Agreement creates any agency, joint venture, partnership or other form of joint enterprise, employment or fiduciary relationship between the Parties. Neither Party has any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

11.3 Entire Agreement. This Agreement, including and together with any related exhibits, schedules, the Quality Agreement, SOW, and any Purchase Orders, constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein and therein and shall collectively constitute the Agreement, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter. In case of a conflict between:

(a) the provisions of any schedule, Purchase Order, exhibit, or SOW and the provisions of the main body of this Agreement, the provisions of the main body of this Agreement shall prevail;

(b) the provisions of this Agreement and the provisions of the Contribution Agreement, unless otherwise expressly stated or the context otherwise requires, the provisions of the Contribution Agreement shall prevail;

(c) the provisions of this Agreement and the provisions of the Transition Services Agreement, unless otherwise expressly stated or the context otherwise requires, the provisions of this Agreement shall prevail; and

(d) the provisions of the Quality Agreement and the provisions of this Agreement, the provisions of this Agreement shall prevail, except that with respect to matters related to quality, the Quality Agreement shall prevail.

11.4 Notices. All notices, requests, consents, claims, demands, waivers and other communications under this Agreement (each, a "**Notice**") must be in writing and addressed to the other Party at its address set forth below (or to such other address that the receiving Party may designate from time to time in accordance with this Section 11.4). All Notices must be delivered by personal delivery, nationally recognized overnight courier or certified or registered mail (in each case, return receipt requested, postage prepaid). Notwithstanding the foregoing, notice by email (with confirmation of transmission) will satisfy the requirements of this Section 11.4 if acknowledged by the intended recipient upon receipt by replying to the original email message (except for any automated reply), such acknowledgement shall not be unreasonably withheld, delayed or conditioned. Except as otherwise provided in this Agreement, a Notice is effective only (a) on receipt by the receiving Party, and (b) if the Party giving the Notice has complied with the requirements of this Section 11.4.

Notice to Supplier:	Roadrunner Solutions LLC One Patriots Park Bedford, MA 01730 Attention: Chief Executive Officer Email: [***] with a copy (which shall not constitute notice) to: [***] with a copy (which shall not constitute notice) to: [***]
Notice to HMI:	HMI One Patriots Park Bedford, MA 01730 Attention: General Counsel Email: [***] with a copy (which shall not constitute notice) to: [***]
Notice to OXB:	[Oxford Biomedica UK Limited Windrush Court, Transport Way Oxford, OX4 6LT, UK] Attention: [***] Email: [***]

11.5 Interpretation. For purposes of this Agreement: (a) the words “include,” “includes” and “including” is deemed to be followed by the words “without limitation”; (b) the word “or” is not exclusive; (c) the words “herein,” “hereof,” “hereby,” “hereto” and “hereunder” refer to this Agreement as a whole; (d) words denoting the singular have a comparable meaning when used in the plural, and vice-versa; and (e) words denoting any gender include all genders. Unless the context otherwise requires, references in this Agreement: (x) to sections, exhibits, schedules, attachments, and appendices mean the sections of, and exhibits, schedules, attachments and appendices attached to, this Agreement; (y) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof; and (z) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. The Parties drafted this Agreement without regard to any presumption or rule requiring construction or interpretation against the Party drafting an instrument or causing any instrument to be drafted. The exhibits, schedules, attachments, and appendices referred to herein are an integral part of this Agreement to the same extent as if they were set forth verbatim herein.

11.6 Headings. The headings in this Agreement are for reference only and do not affect the interpretation of this Agreement.

11.7 Severability. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability does not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this Agreement to effect the original intent of the Parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

11.8 Amendment and Modification. No amendment to this Agreement is effective unless it is in writing, identified as an amendment to this Agreement and signed by an authorized representative of each Party.

11.9 Waiver. No waiver under this Agreement is effective unless it is in writing, identified as a waiver to this Agreement and signed by an authorized representative of the Party waiving its right. Any waiver authorized on one occasion is effective only in that instance and only for the purpose stated, and does not operate as a waiver on any future occasion. None of the following constitutes a waiver or estoppel of any right, remedy, power, privilege or condition arising from this Agreement: any failure or delay in exercising any right, remedy, power or privilege or in enforcing any condition under this Agreement; or any act, omission or course of dealing between the Parties.

11.10 Cumulative Remedies. All rights and remedies provided in this Agreement are cumulative and not exclusive, and the exercise by either Party of any right or remedy does not preclude the exercise of any other rights or remedies that may now or subsequently be available at law, in equity, by statute, in any other agreement between the Parties or otherwise.

11.11 Equitable Remedies. Each Party acknowledges and agrees that (a) a breach or threatened breach by such Party of any of its obligations under Article 9 or 10 would give rise to irreparable harm to the other Party for which monetary damages would not be an adequate remedy and (b) in the event of a breach or a threatened breach by such Party of any such obligations, the other Party shall, in addition to any and all other rights and remedies that may be available to such Party at law, at equity or otherwise in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction, without any requirement to post a bond or other security, and without any requirement to prove actual damages or that monetary damages will not afford an adequate remedy. Each Party agrees that such Party will not oppose or otherwise challenge the appropriateness of equitable relief or the entry by a court of competent jurisdiction of an order granting equitable relief, in either case, consistent with the terms of this Section 11.11.

11.12 Assignment. Neither Party may assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably delayed or withheld; *provided*, however, that (a) Supplier may assign its rights and obligations under this Agreement without HMI's prior written consent in connection with an assignment to an Affiliate or a Third Party acquirer of all or substantially all of the Transferred Assets constituting the Facility(ies) and the business of the Facility(ies)

and (b) HMI shall have right to assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of Supplier to its Affiliates or to any Third Party who acquires all or substantially all of the assets to which this Agreement relates. Any purported assignment or delegation in violation of this Section 11.12 is null and void *ab initio*. No assignment, delegation or transfer will relieve Supplier of the performance of any accrued obligation that Supplier may then have under this Agreement.

11.13 Successors and Assigns. This Agreement is binding on and inures to the benefit of the Parties and their respective permitted successors and permitted assigns.

11.14 No Third Party Beneficiaries. Except as expressly set forth in the second sentence of this Section 11.14, this Agreement benefits solely the Parties to this Agreement and their respective permitted successors and permitted assigns and nothing in this Agreement, express or implied, confers on any other Person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement. The Parties hereby designate each indemnified Person as a Third Party beneficiary of Section 9.8.

11.15 Dispute Resolution. Except as provided in Section 11.11, any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity hereof (each, a "**Dispute**"), shall be submitted for negotiation and resolution to the designated representative of Supplier (or to such other person of equivalent or superior position designated by Supplier in a written Notice to HMI) and an officer of HMI (or to such other person of equivalent or superior position designated by HMI in a written Notice to Supplier), by delivery of written Notice (each, a "**Dispute Notice**") from either of the Parties to the other Party. Such persons shall negotiate in good faith to resolve the Dispute. If the Parties are unable to resolve any Dispute within [***] after delivery of the applicable Dispute Notice, either Party may file suit in a court of competent jurisdiction in accordance with the provisions of Section 11.16 and Section 11.17 hereunder.

11.16 Governing Law. This Agreement, including all exhibits, schedules, attachments and appendices attached hereto and thereto, and all matters arising out of or relating to this Agreement, are governed by, and construed in accordance with, the Laws of the State of Delaware, without regard to the conflict of Laws provisions thereof. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement.

11.17 Choice of Forum. Each Party irrevocably and unconditionally agrees that it shall not commence any action, litigation or proceeding of any kind whatsoever against the other Party in any way arising from or relating to this Agreement, including all exhibits, schedules, attachments and appendices attached hereto and thereto, and all contemplated transactions, including contract, equity, tort, fraud, and statutory claims, in any forum other than the United States District Court for the District of Massachusetts or, if such court does not have subject-matter jurisdiction, the courts of the State of Massachusetts, and any appellate court from any thereof. Each Party irrevocably and unconditionally submits to the exclusive jurisdiction of such courts and agrees to bring any such action, litigation or proceeding only in the United States District Court for the District of Massachusetts or, if such court does not have subject-matter jurisdiction, the courts of the State of Massachusetts. Each Party agrees that a final

judgment in any such action, litigation or proceeding is conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law.

11.18 Waiver of Jury Trial. Each Party acknowledges and agrees that any controversy that may arise under this Agreement, including any exhibits, schedules, attachments, and appendices attached to this Agreement, is likely to involve complicated and difficult issues and, therefore, each such Party irrevocably and unconditionally waives any right it may have to a trial by jury in respect of any legal action arising out of or relating to this Agreement, including any exhibits, schedules, attachments, and appendices attached to this Agreement, or the transactions contemplated hereby. Each Party certifies and acknowledges that (a) no representative of the other Party has represented, expressly or otherwise, that such other Party would not seek to enforce the foregoing waiver in the event of a legal action, (b) such Party has considered the implications of this waiver, (c) such Party makes this waiver voluntarily, and (d) such Party has been induced to enter into this Agreement by, among other things, the mutual waivers and certifications in this Section 11.18.

11.19 Counterparts. This Agreement may be executed in counterparts, each of which is deemed an original, but all of which together is deemed to be one and the same agreement. A signed copy of this Agreement delivered by e-mail or other means of electronic transmission (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) is deemed to have the same legal effect as delivery of an original signed copy of this Agreement, if the party sending such e-mail or other means of electronic transmission has received express confirmation that the recipient party received the copy of this Agreement (not merely an automatic email reply).

11.20 Force Majeure. Any delay or failure of either Party to perform its obligations under this Agreement will be excused to the extent that the delay or failure was caused directly by an event beyond such Party's reasonable control, without such Party's fault or negligence (which events may include natural disasters, epidemics and pandemics, embargoes, explosions, riots, wars or acts of terrorism) (each, a "**Force Majeure Event**"). For the avoidance of doubt, the COVID-19 pandemic, including any variants of COVID-19 or any government restrictions or regulations relating thereto, will constitute a Force Majeure Event to the extent it causes the applicable delay or failure. Supplier's financial inability to perform, changes in costs that are within its control, or Supplier's legal actions or contract disputes will not excuse performance by Supplier under this Section 11.20. Supplier shall give HMI prompt written Notice of any event or circumstance that is reasonably likely to result in a Force Majeure Event and the anticipated duration of such Force Majeure Event. Supplier shall use all reasonable efforts to end the Force Majeure Event, ensure that the effects of any Force Majeure Event are minimized and resume full performance under this Agreement. During any Force Majeure Event, HMI may, at its option (a) [***]. The rights granted to Supplier with respect to excused delays under this Section 11.20 are intended to limit Supplier's rights under theories of force majeure, commercial impracticability, impracticability or impossibility of performance, or failure of presupposed conditions or otherwise. The Parties acknowledge and agree that HMI's [***].

11.21 No Public Announcements or Trademark Use. Unless expressly permitted under this Agreement or the Contribution Agreement, neither Party shall (a) make any statement (whether oral or in writing) in any press release, external advertising, marketing or promotion

materials regarding the subject matter of this Agreement, the other Party or its business unless (i) it has received the express written consent of the other Party, or (ii) it is required to do so by Law or under the rules of any stock exchange to which it is subject, or (b) use any of the other Party's Trademarks without the prior written consent of the other Party.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first set forth above.

HOMOLOGY MEDICINES, INC.

By: /s/ Arthur Tzianabos
Name: Arthur O. Tzianabos
Title: President and Chief Executive Officer

ROADRUNNER SOLUTIONS LLC

By: /s/ Tim Kelly
Name: Tim Kelly
Title: Chief Executive Officer

Solely for purposes of Section 2.3(b)(iii)

OXFORD BIOMEDICA UK LIMITED

By: /s/ Stuart Paynter
Name: Stuart Paynter
Title: Chief Financial Officer

Schedule 1.65

Named HMI Products

[***]

Schedule 2.6

Key Positions*

[***]

Exhibit A

Sample SOW

[***]

Exhibit B

Initial [***] Forecast

[***]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-237131 on Form S-3 and No. 333-224030 on Form S-8 of our report dated March 23, 2022, relating to the consolidated financial statements of Homology Medicines, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 23, 2022

Exhibit 31.1

CERTIFICATION

I, Arthur O. Tzianabos, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of Homology Medicines, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 23, 2022

By: /s/ Arthur O. Tzianabos, Ph.D.
Arthur O. Tzianabos, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, W. Bradford Smith, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2021 of Homology Medicines, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 23, 2022

By: /s/ W. Bradford Smith
W. Bradford Smith
Chief Financial and Business Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Arthur O. Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines, Inc. (the "Company") hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Report") fully complies with the requirements of Sections 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2022

By: /s/ Arthur O. Tzianabos, Ph.D.
Arthur O. Tzianabos, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, W. Bradford Smith, Chief Financial Officer of Homology Medicines, Inc. (the "Company") hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Report") fully complies with the requirements of Sections 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2022

By: /s/ W. Bradford Smith
W. Bradford Smith
Chief Financial and Business Officer and Treasurer
(Principal Financial Officer)