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, 2025

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

Q32 Bio 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.)**
830 Winter Street Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 999-0232

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, par value $0.0001 per share	QTTB	The Nasdaq Capital 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 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, 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	☒	Smaller 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Capital Market on June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $10.4 million.

The number of shares of Registrant's common stock, par value $0.0001 per share, outstanding as of March 1, 2026 was 14,629,463.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the information required to be furnished pursuant to Part III of this Annual Report on Form 10-K will be set forth in, and incorporated by reference from, the Registrant's definitive proxy statement for the annual meeting of stockholders or an amendment to this Annual Report on Form 10-K which will be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended December 31, 2025.

Auditor Firm Id: 42 Auditor Name: Ernst & Young LLP Auditor Location: Boston, Massachusetts, USA

Table of Contents

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains statements that are not historical facts and are considered forward-looking within the meaning of 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"). These forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Annual Report on Form 10-K may include, for example, statements about:

- our ability to achieve and sustain profitability in the future;
- our strategies, prospects, plans, expectations or objectives of management for our future operations;
- estimates of our future expenses, revenues, capital requirements, cash runway, and our needs for additional financing;
- our estimates of and anticipated use of our existing cash, cash equivalents and marketable securities;
- the progress, scope or timing of the development of our product candidates;
- our expectations surrounding the potential safety, efficacy, and regulatory and clinical progress of our product candidates, including bempikibart, and our anticipated milestones and timing therefor;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to achieve and maintain market acceptance and adoption of our product candidates;
- the benefits that may be derived from any of our future products or the commercial or market opportunity with respect to any of our future products;
- our ability to maintain patent protection for our product candidates and protect our intellectual property rights;
- our ability to successfully compete against other companies developing similar products to ours;
- our anticipated operations, financial position, ability to raise capital to fund our operations, revenues, costs or expenses;
- our ability to continue to achieve benefits and improvements in connection with the strategic restructuring plan, including the reduction in force;
- our ability to retain our key executives and to attract and retain highly qualified personnel;
- our ability to successfully protect against cyber-attacks, security breaches and other disruptions to our information technology systems;
- our ability to establish and maintain an effective system of internal controls over financial reporting;
- the effect of unfavorable macroeconomic conditions or market volatility resulting from global economic conditions or geopolitical developments, including fluctuating interest rates and inflation and capital market disruptions, changes in governmental agencies, government shutdowns, international tariffs, trade protection measures, public health crises, economic sanctions and potential economic slowdowns or recessions, or similar events;
- our reliance on third parties in the supply and manufacture of our product candidates;
- the impact of applicable laws and regulations, whether in the U.S. or foreign jurisdictions, and any changes thereto;
- the statements regarding our future economic conditions or performance, statements of belief and any statement of assumptions underlying any of the foregoing; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

These forward-looking statements are based on information available to us at the time of this Annual Report on Form 10-K and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and except as otherwise required by applicable law, we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties, and other factors. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements, including those set forth in this Annual Report on Form 10-K in the section titled "Risk Factors" and in our periodic filings with the U.S. Securities and Exchange Commission (the "SEC"). Our SEC filings are available publicly on the SEC's website at www.sec.gov. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Should one or more of the risks or uncertainties described in this Annual Report on Form 10-K, or should underlying

assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Annual Report on Form 10-K, and we believe these industry publications and third-party research, surveys and studies are reliable.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks include the following, among others:

- We have incurred significant operating losses since inception, expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts.
- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We face competition from entities that have developed or may develop programs for the diseases we plan to address with bempikibart or other product candidates.
- Bempikibart and the rest of our pipeline are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on the success of our most advanced product candidate, bempikibart, and our clinical trials of our lead candidate may not be successful.
- Our rights to develop and commercialize our product candidates are, and in the future may be, subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or these agreements are terminated, or we otherwise experience disruption to our business relationships with our licensors, we could lose license rights that are important to our business.
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.
- Our business could be adversely affected by economic downturns, inflation, changes in interest rates, natural disasters, public health crises, political crises, government shutdowns, geopolitical events or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.
- We rely on third parties in the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our product candidates.
- Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability, as well as negatively impact our ability to exist as a standalone company.
- If we are unable to attract and retain qualified key management and scientists, staff, consultants and advisors, our ability to implement our business plan may be adversely affected.
- Our failure to meet the continued listing requirements of the Nasdaq Capital Market ("Nasdaq") could result in a delisting of our securities.

The summary risk factors described above should be read together with the text of the full risk factors below in the section titled "Risk Factors" and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

PART I

Item 1. Business.

Overview

We are a clinical stage biotechnology company focused on developing novel biologics to effectively and safely restore healthy immune balance in patients with alopecia areata ("AA") and other autoimmune and inflammatory diseases driven by pathological immune dysfunction.

Bempikibart (ADX-914)

Bempikibart (ADX-914), our most advanced product candidate, is a fully human anti–interleukin-7 receptor alpha ("IL-7Rα"), antagonist monoclonal antibody designed to re-regulate adaptive immune function by potently blocking signaling mediated by interleukin-7 ("IL-7"), and thymic stromal lymphopoietin ("TSLP"). We have completed two Phase 2a clinical trials evaluating bempikibart, SIGNAL-AA Part A, for the treatment of AA, and SIGNAL-AD, for the treatment of atopic dermatitis ("AD").

In December 2024, we announced topline results from both of these trials, as well as our intention to advance bempikibart for the treatment of AA. In April 2025, we announced dosing of the first patients in both the Part A open-label extension and Part B of the SIGNAL-AA Phase 2a clinical trial and in October 2025, we announced completion of enrollment in SIGNAL-AA Part B. Bempikibart is being evaluated for the treatment of AA in the ongoing Part B of the SIGNAL-AA Phase 2a clinical trial. Enrollment has been completed in the Part B portion of the clinical trial, with 33 patients enrolled, and dosing remains ongoing. We expect to report 36-week topline data from the SIGNAL-AA Part B trial in mid-2026.

Patients in the SIGNAL-AA Part A and the SIGNAL-AD Phase 2a clinical trials were dosed with 200mg subcutaneous ("SC") bempikibart every two weeks. In SIGNAL-AA Part A, 44 patients with severe and very severe AA were enrolled. Patients were dosed for 24 weeks and followed for an additional 12 weeks following the end of treatment. At the 24-week endpoint, we observed more hair regrowth in treated patients compared to placebo and evidence of durable responses in patients. The average hair regrowth across patients in the trial continued to improve from week 24 to week 36 despite patients being off therapy during the 12-week follow-up period. In AD, bempikibart was evaluated in two parts, Part A (15 patients) and Part B (106 patients). While encouraging results were seen in Part A, the primary endpoint was not met in Part B.

Across the trials, at the 200mg Phase 2a dose, we achieved our desired receptor occupancy ("RO") and observed favorable pharmacokinetics ("PK") / pharmacodynamic ("PD") properties, consistent with those from the Phase 1 clinical trial. Minimal anti-drug antibodies ("ADAs") were observed in the trials.

In addition, across the two trials, we observed changes in biomarkers consistent with the IL-7Rα mechanism and activity mediated by both the TSLP and IL-7 receptors. In the SIGNAL-AD trial, we observed meaningful decreases in key Th2 biomarkers of TARC, IgE, and eosinophils, each of which were statistically significant at multiple timepoints suggestive of potent TSLP inhibition. In the SIGNAL-AA trial, we observed a CD3+ T cell decrease, which was also statistically significant at multiple timepoints, suggestive of potent IL-7 inhibition. These findings were consistent with expected target engagement and IL-7Rα blockade. Across all clinical trials, bempikibart has been dosed in over 150 participants to-date and has demonstrated a favorable safety and tolerability profile, with no Grade 3 or higher related adverse events.

The Part B portion of SIGNAL-AA is an open-label clinical trial dosing severe or very severe AA patients with a maximum duration of current episode of four years. Patients will be treated with bempikibart for 36 weeks, with follow-up out to 52 weeks. Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, followed by a maintenance dose of 200mg every-other-week over a 32-week period for a total dosing period of 36 weeks. Efficacy will be evaluated on the basis of mean percentage change from baseline in Severity of Alopecia Tool ("SALT") scores as well as the proportion of subjects achieving various relative and absolute SALT score improvements at week 36, with follow-up through week 52. The trial is intended to support advancement into pivotal trials upon completion, pending review of the results. We expect to report 36-week topline data from the SIGNAL-AA Part B trial in mid-2026.

In April 2025, we announced that the U.S. Food and Drug Administration (the "FDA") has granted Fast Track designation ("FTD") to bempikibart for the treatment of AA. FTD is a process designed to facilitate the development and expedite the review of new drugs to treat serious diseases and fill an unmet medical need with the purpose of getting important new drugs to patients earlier. A drug that receives FTD may be eligible for more frequent meetings and communications with the FDA to

discuss development plans and ensure the collection of appropriate data needed to support approval and for a rolling review of an application for marketing approval.

ADX-097

In addition to bempikibart, our strategy has been focused on the advancement of our proprietary tissue-targeted complement inhibitor platform. ADX-097, a Phase 2 asset from this platform, is a humanized anti-C3d monoclonal antibody ("mAb") fusion protein that completed Phase 1 clinical trials. However, in February 2025, we announced a corporate restructuring to focus on the advancement of bempikibart for the treatment of patients with AA. On November 28, 2025, we entered into an Asset Purchase Agreement with Akebia Therapeutics, Inc. ("Akebia") pursuant to which we sold to Akebia substantially all of our assets related to the research, development, manufacture and commercialization of ADX-097 (the "ADX-097 Asset Sale"). Following the ADX-097 Asset Sale, Akebia is now responsible for the future development and commercialization of ADX-097. As consideration for the ADX-097 Asset Sale, we received an upfront payment of $7.0 million and will receive a payment of $3.0 million on the six-month anniversary of the transaction. We will also receive a near-term milestone payment of $2.0 million upon the earlier of achievement of the first milestone under the Asset Purchase Agreement or December 31, 2026. In addition to these payments, we are eligible to receive up to $580 million upon the achievement of specified milestones, including up to $92.5 million related to development and regulatory milestones and up to $487.5 million related to commercial milestones. We are also eligible to receive tiered royalties on potential future sales of ADX-097 ranging from low single-digit to mid-teen percentages of annual net sales. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

Development Pipeline

Our development pipeline is shown in the figure below.

Figure 1: Our Development Pipeline.

Bempikibart (ADX-914)

Our most advanced product candidate, bempikibart, is a fully human antibody designed to potently block IL-7- and TSLP-mediated signaling via their cognate receptors. Increased levels of IL-7 and TSLP are associated with inflammatory and autoimmune diseases.

T cell pathology has been strongly implicated in AA. TH1 has long been implicated in the pathogenesis of AA supporting the potential for bempikibart to directly address the underlying driver of follicle damage and hair loss. In addition, given that AA is a disease often diagnosed in young adults, there is a critical need for effective novel treatments with a safety profile suitable for long-term, chronic treatment.

We own and have in-licensed various patents, patent applications, know-how and trade secrets relating to the development and commercialization of our IL-7Rα -targeted antagonistic antibody therapy candidates and platform technologies. Patents that

have issued or may issue in the future protect composition of the bempikibart product candidate to the beginning of 2040, and protect methods of use to 2044, excluding any patent term adjustments and/or any patent term extensions.

We have completed two Phase 2a clinical trials and are advancing bempikibart for the treatment of AA in the ongoing Phase 2a Part B clinical trial and Phase 2a Part A open-label extension trial.

ADX-096/Complement Inhibitor Platform

In addition to ADX-097, we developed a proprietary tissue-targeted complement platform, which is designed to inhibit complement activation in the tissue while minimizing systemic complement blockade, a key differentiator versus current complement therapeutics. Other assets developed from our proprietary platform include ADX-096, a C3d mAb – $CR1_{1-10}$ fusion protein with preclinical data supportive of its use in ophthalmologic indications as well as potential utility in a broad range of other indications, and C3d mAb fusions and nanobodies designed for tissue-targeted complement inhibition. We retain the rights to our wholly owned tissue-targeted complement inhibitor platform, including ADX-096 and other remaining early-stage assets, and are continuing to evaluate strategic options for these programs.

We believe that the tissue-directed approach to addressing complement dysregulation has the potential to drive improved efficacy and better safety across indications. This tissue-directed complement inhibiting approach also has the potential to avoid the additive infection risk associated with systemic complement treatments, which is of significant importance to patients where the underlying condition is marked by high mortality due to infection.

Complement activation is an essential part of innate and humoral immunity, and uncontrolled and sustained tissue complement activity plays a significant role in the pathogenesis of multiple human inflammatory and autoimmune diseases. The first approved complement inhibitor, eculizumab, targets C5 systemically, one of the effector arms of the complement pathway. The next generation of marketed and development stage complement therapeutics continue to rely on systemic complement blockade. While commercial and clinical success provide validation of complement as a therapeutic target, clinical experience reveals the inherent drawbacks of systemic inhibition as a therapeutic approach, including:

- **limited activity** due to reliance on systemic blockade for control of complement dysregulation at the tissue level;
- **high treatment burden**, including high doses and/or frequent administration due to high abundance and rapid turnover of most target complement proteins; and
- **infection risk** due to systemic blockade.

Our aim is to solve for these inherent drawbacks with our proprietary approach designed to generate tissue targeted inhibitors of complement activation, which have the following advantages:

- **enhanced activity** through tissue targeted inactivation of convertases directly at the site of destruction;
- **convenient dosing** with a subcutaneous route and weekly dosing, with potential for every 2 week dosing; and
- **improved risk/benefit profile** by maximizing therapeutic index while maintaining intact systemic immune surveillance.

We retain the rights to our wholly owned tissue-targeted complement inhibitor platform, including ADX-096 and other remaining early-stage assets and are continuing to evaluate strategic options for these programs.

Our Team

We have assembled a team of industry-leading research, drug development, and operational experts, who have deep experience in advancing drug candidates in autoimmune and inflammatory diseases. The team is led by Jodie Morrison, our Chief Executive Officer, who brings extensive biopharma leadership experience from early stage through mid-size public biotech and pharmaceutical companies; Shelia Violette, Ph.D., Founder and Chief Scientific Officer, has more than 30 years of biotech experience in inflammatory and autoimmune diseases and served as an Entrepreneur in Residence at Atlas Venture; Lee Kalowski, President and Chief Financial Officer, has 20 years of life science industry experience and has previously served as CFO at multiple biotech companies and in equity research; Maria Marzilli, Chief Business Officer, has over 20 years of industry experience across strategy, corporate development, and program and alliance management.

Our company was built upon the discoveries and findings from renowned researchers in immunology: Michael Holers, M.D. and Joshua Thurman, M.D., from the University of Colorado and Stephen Tomlinson, Ph.D. from the Medical University

of South Carolina. They are pioneers in the field of tissue targeted regulation of complement system. The portfolio was expanded in 2019 with the in-licensing of bempikibart, currently our most advanced product candidate.

Since our inception, we have been supported by leading biotechnology investors and pharmaceutical companies including OrbiMed, Atlas Venture, Abingworth, Bristol-Myers Squibb, Acorn Bioventures, Osage University Partners, CU Healthcare Innovation Fund and Sanofi Ventures.

Our Strategy

Our mission is to develop therapeutics that restore healthy immune regulation for patients with severe autoimmune and inflammatory diseases. Our strategic initiatives are to:

- ***Advance bempikibart for the treatment of AA in the SIGNAL-AA Phase 2a Part B clinical trial.*** In Part B, we enrolled 33 patients for 36 weeks of treatment, with follow-up through 52 weeks. We expect to report 36-week topline data from the SIGNAL-AA Part B trial in mid-2026. The trial is intended to support advancement into pivotal trials upon completion, pending review of the results;
- ***Advance bempikibart for the treatment of AA in the SIGNAL-AA Phase 2a Part A open-label extension (OLE)***. We initiated an open-label extension (OLE) following the same bempikibart dosing regimen leveraged in Part A to enable longer-term follow-up of patients and to further elucidate the durability of response and potential remittive effect;
- ***Maximize value of our tissue-targeted complement inhibitor platform.*** We believe that the tissue-directed approach to addressing complement dysregulation has the potential to drive improved efficacy and better safety across indications and we intend to maximize the value of ADX-096 and our tissue-targeted complement inhibitor platform as we evaluate our strategic options.

Our Programs

Bempikibart

Bempikibart blocks both IL-7 and TSLP cytokine signaling pathways. IL-7 lowers the threshold needed for T cells to respond in low antigen microenvironments promoting pathogenic T-effector cell function, induces TH2 cell-mediated antibody production, and inhibits the immunosuppressive properties of T regulatory cells. When uncontrolled, IL-7 can promote inflammation and autoimmune disease. By blocking IL-7 signaling, we believe bempikibart has the potential to re-regulate immunity by rebalancing the T-effector / T-regulatory ratio to inhibit inflammation and invoke tolerance, and mitigating T-cell dependent autoantibody responses. TSLP is a cytokine that promotes TH2 cell differentiation and production of TH2 cytokines, such as IL-4, IL-5, and IL-13, and promotes inflammation, particularly at the epidermis, in response to environmental stimuli. IL-7 and TSLP signaling have been biologically linked to numerous inflammatory and autoimmune diseases including our initial target diseases of AA and AD. The figure below illustrates the mechanistic rationale for bempikibart.

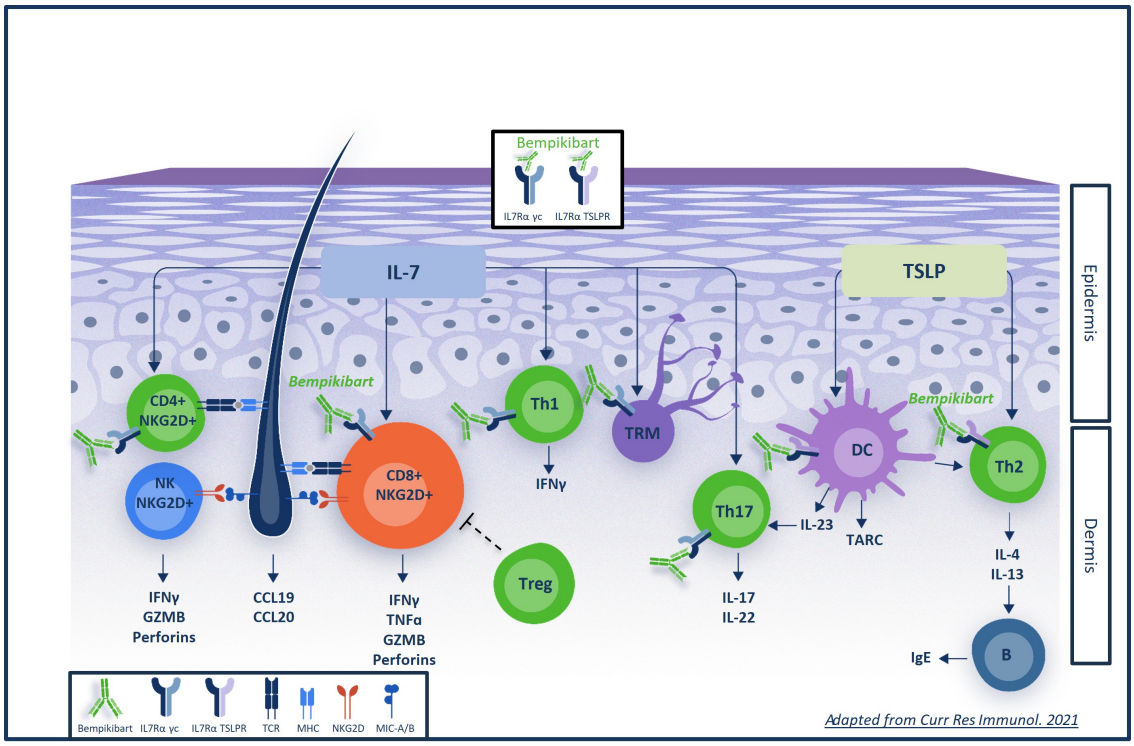

Figure 2: Bempikibart Has the Potential to Inhibit Pathogenic T-cells That Directly Drive Hair Follicle Destruction and Suppress the Function of T-regulatory Cells.

Rights to Bempikibart

In October 2023, Amgen Inc. ("Amgen") completed the acquisition of Horizon Therapeutics public limited company ("Horizon plc"). Following the acquisition, Legacy Q32 agreed with Amgen to mutually terminate the Collaboration and Option Agreement (the "Horizon Collaboration Agreement") and the Asset Purchase Agreement (the "Purchase Agreement", and together with the Horizon Collaboration Agreement, the "Horizon Agreements"), each between Legacy Q32 and Horizon Therapeutics Ireland DAC ("Horizon").

In November 2023, Legacy Q32 entered into a termination agreement with Horizon (the "Horizon Termination Agreement"), pursuant to which Horizon's option to acquire the bempikibart program was terminated. As a result, Legacy Q32 retained the initial consideration and development funding received under the Horizon Collaboration Agreement and regained full development and commercial rights to bempikibart. In consideration for the Horizon Termination Agreement, Legacy Q32 agreed to pay Horizon regulatory and sales milestones payments of up to an aggregate amount of $75.1 million upon the first achievement of certain regulatory and sales milestones with respect to bempikibart.

In November 2025, we entered into an amendment to the Horizon Termination Agreement (the "Amgen Amendment") with Amgen, pursuant to which we issued Horizon a one-time equity grant of 553,695 shares of our common stock as full

consideration of the milestone payments under the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, we have no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. For more information, see the section titled "Business—Collaboration and License Agreements" in this Annual Report on Form 10-K.

Bempikibart Preclinical and Clinical Data

Bempikibart was evaluated in a series of in vitro assays and demonstrated potent inhibition of IL-7-and TSLP-mediated intracellular signaling.

Bempikibart, or a mouse surrogate, SB14, was evaluated in vivo in animal models of inflammation and autoimmunity. Activity was observed as determined by various endpoints, including disease activity measures, body weight, inflammatory cytokine production and tissue damage.

Preclinical studies evaluating bempikibart PK, PD and toxicology were carried out in non-Good Laboratory Practice ("GLP") single dose and GLP repeat dose studies of 6 weeks, 3-months, and 6-months duration in cynomolgus monkeys. Bempikibart exposure was maintained above the desired PK threshold throughout the dosing phase in most animals despite detectable ADAs. PD evaluations included T cell receptor occupancy ("RO") inhibition of IL-7–induced phosphorylation of STAT5 ("pSTAT5") an immediate proximal marker of IL-7R intracellular signaling, and keyhole limpet hemocyanin ("KLH") induced T cell dependent antibody response. There was a favorable PK/PD relationship, with bempikibart demonstrating >95% RO, ≥90% inhibition of pSTAT5 and up to 80% suppression of a KLH-induced IgG response.

Bempikibart was generally well tolerated in all preclinical studies described above. The no-observed-adverse-effect level ("NOAEL") in the 6-month GLP study was 150 mg/kg, the highest dose tested, with exposure >50x the anticipated area under the curve at the dose presently being utilized for the ongoing Phase 2 studies.

Phase 1 Clinical Trial Results

We completed a Phase 1 trial to assess the safety, PK, and PD of bempikibart after subcutaneous ("SC") administration in healthy volunteers. Pharmacodynamic analyses showed bempikibart treatment at SC doses achieving desired RO and inhibition of IL-7 mediated intracellular signaling, as demonstrated by phosphorylation of STAT5 ("pSTAT5") in T-cells. At doses greater than 1 mg/kg, bempikibart demonstrated sustained full RO for at least 2 weeks. In addition, a separate analysis of overall numbers of lymphocytes and lymphocyte subsets demonstrated modest, dose-dependent effects consistent with the expected and desired bempikibart pharmacology.

Safety data showed that bempikibart demonstrated a favorable safety profile at single doses up to the highest evaluated dose of 4 mg/kg and repeat doses of 1 mg/kg every 2 weeks in healthy subjects. There were no safety-related treatment discontinuations, no serious or severe AEs reported, and no deaths.

The Role of IL-7 and TSLP in AA

AA is an immune-mediated disorder that results in hair loss and shares some similarity in pathophysiology with AD. Studies have indicated that multiple immunomodulators are involved in the development of AA, with hair follicle immune privilege collapse being a key marker in the course of the disease. Immune system activation in lesional skin contributes to the progression of disease.

IL-7 has been shown to be involved in the pathogenesis of AA. IL-7 expression is upregulated at the site of AA lesions and animal studies demonstrated IL-7–dependent acceleration of disease progression and beneficial effects with IL-7Rα inhibition. Cumulatively, substantial evidence suggests that inhibition of IL-7Rα may be an effective modulator of the T-cell response that could act to reverse alopecia.

Current Treatment Landscape and Unmet Need in AA

AA is an autoimmune condition that affects hair follicles and leads to hair loss. This condition may develop at any age and in both sexes, and the incidence of this disease has been estimated to be 2% of the population worldwide. The disease most commonly affects scalp and facial hair and although some patients recover spontaneously, many patients progress to alopecia totalis (total scalp hair loss) or alopecia universalis (total body hair loss). The disease is associated with significant quality of life impairment and is associated with a high burden of psychosocial comorbidities, such as depression. Although pathophysiology

has not been fully delineated, development of the condition is mediated by inflammatory mechanisms, and it is thought to have genetic and environmental components. IL-7 upregulation has been shown to be involved in the pathogenesis of AA, and evidence suggests that inhibition of IL-7Rα may be an effective modulator of the T-cell response driving injury in the disease.

Janus kinase ("JAK") inhibitors are the only current FDA-approved treatments for severe and very severe AA. Although JAK inhibitors have demonstrated hair regrowth in patients with severe disease (≥50% hair loss), responsiveness is often not durable after treatment cessation and the drug class carries increased risk of serious side effects that may preclude this option for some patient populations. Other standard-of-care approaches for AA include topical corticosteroids, immunotherapy, and light therapy, as well as the off-label use of other therapies. Because hair loss can affect such disparate body locations, these treatments often have limited usefulness across the patient population.

Further Clinical Development of Bempikibart: Clinical Trial Plan

For patients with a wide range of autoimmune diseases, we believe the blockade of IL-7 and/or TSLP signaling may offer a new therapeutic approach to modulate the autoimmune response. A high unmet medical need exists for more broadly effective therapies in these conditions, and we are developing bempikibart with the goal of addressing this need. Based on the totality of data to date, bempikibart has shown a favorable safety profile and has not been associated with clinically meaningful ADA. At exposures that can be achieved via SC administration, bempikibart has shown full receptor occupancy and signaling inhibition.

Overall, the available clinical and nonclinical data for bempikibart support the continued clinical development of bempikibart. To this end, we are continuing to advance bempikibart into Part B of the SIGNAL-AA Phase 2a Clinical Trial.

SIGNAL-AA Phase 2a Clinical Trial

SIGNAL-AA is a Phase 2a, randomized, double-blind, placebo-controlled, proof-of-concept clinical trial evaluating the efficacy, safety and tolerability of bempikibart in participants with severe and very severe AA, as defined by a baseline Severity of Alopecia Tool ("SALT") score of 50-100. In Part A of the trial, bempikibart or placebo was dosed SC for 24 weeks, with a follow-up period of 12 weeks. Following completion of the SIGNAL-AA Part A clinical trial, eligible patients were allowed to enroll in the SIGNAL-AA Part A open label extension ("OLE") to enable longer-term follow-up. The SIGNAL-AA Part A OLE clinical trial remains ongoing.

The study recruited adults with a current episode of severe hair loss with no spontaneous improvement over the past six months, along with the investigator's assessment that hair loss had been stable for at least three months and regrowth was possible.

Forty-four participants were enrolled and randomly assigned (3:1) to receive 200 mg bempikibart or placebo administered SC every two weeks for 24 weeks. The primary efficacy endpoint was the mean relative percent change in SALT score at 24 weeks compared with baseline. A key secondary endpoint was the percentage of patients achieving a SALT score of less than or equal to 20 (SALT-20) compared to placebo. Patients were followed for an additional 12 weeks after end of treatment.

Compared to placebo, the average hair regrowth and achievement of SALT-20 was greater in patients on bempikibart compared to patients on placebo. Average hair re-growth continued to improve in the 12-week period through week 36, despite patients being off therapy. Bempikibart was observed to be generally well tolerated in the SIGNAL-AA trial. There were no serious adverse events ("SAEs") or Grade 3 or higher adverse events related to treatment.

SIGNAL-AA Part B is an open-label clinical trial that enrolled 33 severe or very severe AA patients with a maximum duration of current episode of four years. Patients are treated with bempikibart for 36 weeks, with follow-up out to 52 weeks. Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, followed by a maintenance dose of 200mg every-other-week over a 32-week period for a total of 36 weeks. Efficacy will be evaluated on the basis of mean percentage change from baseline in SALT scores as well as the proportion of subjects achieving various relative and absolute SALT improvements at week 36, with follow-up through week 52. The trial is intended to enable advancement into pivotal trials upon completion, pending review of the results. We expect to report 36-week topline data from the SIGNAL-AA Part B trial in mid-2026.

Collaboration and License Agreements

Bempikibart—License Agreement – Bristol-Myers Squibb Company

In September 2019, we entered into a license agreement, as amended in August 2021 and July 2022 (the "BMS License Agreement") with Bristol-Myers Squibb Company ("BMS"), pursuant to which we obtained sublicensable licenses from BMS to research, develop and commercialize licensed products, including bempikibart, for any and all uses worldwide. The licenses granted to us are exclusive with respect to BMS's patent rights and know-how relating to certain antibody fragments (including certain fragments of bempikibart) and non-exclusive with respect to BMS's patent rights and know-how relating to the composition of matter and use of a specific region of bempikibart. BMS retained the right for it and its affiliates to use the exclusively licensed patents and know-how for internal, preclinical research purposes. Under the BMS License Agreement, we are prohibited from engaging in certain clinical development or commercialization of any antibody other than a licensed compound with the same mechanism of action until the earlier of the expiration of our obligation to pay BMS royalties or September 2029.

In consideration for the license, we made an upfront payment to BMS of $8 million, issued 6,628,788 Series A preferred shares to BMS and agreed to use commercially reasonable efforts to develop and commercialize at least one licensed product in key geographic markets. In addition, we agreed to pay BMS (i) development and regulatory milestone payments in aggregate amounts ranging from $32 million to $49 million per indication for the first three indications and commercial milestone payments in an aggregate amount of up to $215 million on net sales of licensed products, (ii) tiered royalties ranging from rates in the mid-single digit percentages to up to 10% of net sales, with increasing rates depending on the cumulative net sales, (iii) up to 60% of sublicense income, which percentage decreases based on the development stage of bempikibart at the time of the sublicensing event, and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents.

Our obligation to pay BMS royalties under subsection (ii) above commences, on a licensed product-by-licensed product and country-by-country basis, on the first commercial sale of a licensed product in a country and expires on the later of (x) 12 years from the first commercial sale of such licensed product in such country, (y) the last to expire licensed patent right covering bempikibart or such licensed product in such country, and (z) the expiration or regulatory or marketing exclusivity for such licensed product in such country (the "Royalty Term"). If we undergo a change of control prior to certain specified phase of development, the development and milestone payments are subject to increase by a low double-digit percentage and the royalty rates are subject to increase by a low sub-single-digit percentage.

Unless terminated earlier by either party pursuant to its terms, the BMS License Agreement will expire on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last to expire Royalty Term with respect to such licensed product in such country. Either party may terminate the BMS License Agreement for the other party's material breach, subject to a specified notice and cure period. BMS may terminate the BMS License Agreement if we fail to meet its diligence obligations under the BMS License Agreement, for our insolvency, or if we or our affiliates challenges the validity, scope, enforceability, or patentability of any of the licensed patents. We may terminate the BMS License Agreement for any reason upon prior written notice to BMS, with a longer notice period if a licensed product has received regulatory approval. If the BMS Agreement is terminated for our material breach, BMS will regain rights to bempikibart and we must grant BMS an exclusive license under our patent rights covering bempikibart, subject to a low single-digit percentage royalty on net sales of bempikibart payable to us by BMS.

Bempikibart – Collaboration and Option Agreement, Asset Purchase Agreement and Termination Agreement – Horizon Therapeutics Ireland DAC

From August 2022 until November 2023, Legacy Q32 was a party to the Horizon Agreements with Horizon, pursuant to which Legacy Q32 received $55.0 million in initial consideration and staged development funding to complete two ongoing Phase 2 trials for bempikibart, and granted Horizon an option to acquire the bempikibart program at a prespecified price, subject to certain adjustments.

In October 2023, Amgen completed the acquisition of Horizon plc. Following the acquisition of Horizon plc, Legacy Q32 agreed with Amgen to mutually terminate the Horizon Agreements and in November 2023, Legacy Q32 entered into the Horizon Termination Agreement, pursuant to which Horizon's option to acquire the bempikibart program was terminated. As a result, Legacy Q32 retained all initial consideration and development funding received under the Horizon Collaboration Agreement and regained full development and commercial rights to bempikibart. In consideration for the Horizon Termination Agreement, Legacy Q32 agreed to pay Horizon regulatory and sales milestones payments of up to an aggregate amount of $75.1 million upon the first achievement of certain regulatory and sales milestones with respect to bempikibart.

On November 7, 2025, we entered into the Amgen Amendment pursuant to which we issued Horizon a one-time equity grant of 553,695 shares of our common stock as full consideration of the milestone payments outlined in the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, we have no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. Therefore, we derecognized the refund liability previously recorded for the $55.0 million of cash received under the Horizon Collaboration Agreement and recognized collaboration arrangement revenue for the difference between the equity issuance, and the refund liability as the consideration was no longer constrained.

ADX-097—License Agreement – The Regents of the University of Colorado

In August 2017, we entered into an exclusive license agreement, as amended in February 2018, September 2018, and April 2019 (the "Colorado License Agreement") with The Regents of the University of Colorado ("Colorado"), pursuant to which we obtained worldwide, royalty-bearing, sublicensable licenses under certain patents and know-how owned by Colorado and Medical University of South Carolina ("MUSC") relating to the research, development and commercialization of ADX-097. The licenses granted to us are exclusive with respect to certain patent families and know-how and non-exclusive with certain other patent families and know-how. The licenses granted to us are also subject to certain customary retained rights of Colorado and MUSC and rights of the United States government owing to federal funding giving rise to inventions covered by the licensed patents. We agreed to use commercially reasonable efforts to develop, manufacture and commercialize ADX-097, including by using commercially reasonable efforts to achieve specified development and regulatory milestones by specified dates.

In addition, we agreed to pay Colorado (i) development and sales milestone payments in an aggregate amount of up to $2.2 million per licensed product for the first three products, (ii) tiered royalty rates on cumulative net sales of licensed products in the low single digit percentages, (iii) 15% of sublicense income and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents. Our obligation to pay royalties to Colorado commences, on a licensed product-by-licensed product and country-by-country basis, from the first commercial sale of a licensed product in any country and expires on the later of (i) the last to expire valid claim within the licensed patents covering such licensed product in such country, and (ii) 20 years following the effective date of the Colorado License Agreement, or April 2037 (the "Royalty Term").

On November 28, 2025, in connection with the ADX-097 Asset Sale, the Colorado License Agreement was amended and restated and all of our rights and obligations thereunder were transferred to Akebia.

Competition

We expect to face intense competition from other biopharmaceutical companies that are developing agents for the treatment of autoimmune and inflammatory diseases. Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors. Accordingly, competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for any of our targeted indications by a competitor could render our product candidate non-competitive or obsolete, or reduce the demand for our product candidate before we can recover its development and commercialization expenses.

Manufacturing

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We contract with third parties for the manufacture, storage and distribution of our product candidates. Because we rely on contract manufacturers, we employ and contract with personnel with extensive technical, manufacturing, analytical and quality experience. Our staff has strong knowledge and understanding of the extensive regulations that govern manufacturing, documentation, quality assurance, and quality control of drug supply that are required to support our regulatory filings.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing technological innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of autoimmune and inflammatory diseases. Our future success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for our commercially important technology, inventions, and know-how, defend and enforce our intellectual property rights (in particular our patent rights), preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating, or violating the valid and enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing products identical or similar to ours may depend on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent position of biotechnology and pharmaceutical companies are generally uncertain and can involve complex legal, scientific, and factual issues. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. We also cannot ensure that patents will issue with respect to any patent applications that we or our licensors may file in the future, nor can we ensure that any of our owned or licensed patents or future patents will be commercially useful in protecting our product candidates and methods of manufacturing. In addition, the coverage claimed in a patent application may be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by valid and enforceable patents. Moreover, any of our patents may be challenged, circumvented, or invalidated by third parties.

Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office ("USPTO") may be significantly narrowed before issuance, if issued at all. We expect this may be the case with respect to some of our pending patent applications referred to below.

With respect to bempikibart, as of December 31, 2025, we exclusively licensed from BMS one patent family relating to antibodies against the IL-7R alpha subunit and uses thereof comprising two issued U.S. patents, two issued patents in Japan, one issued patent in each of Australia, China (with extension to Macao), Chile, Indonesia, Malaysia, Russia, Saudi Arabia, Singapore, South Africa, South Korea and Taiwan, one pending U.S. patent application, and 23 pending patent applications in Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, South Korea, Mexico, New Zealand, Peru, Philippines, Singapore, Thailand, United Arab Emirates, Qatar, Bahrain, Egypt, Kuwait, and Oman. The issued patents are expected to expire in January 2040 and any patents that issue from these pending patent applications are expected to expire in 2040, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

We also own one international PCT patent application relating to the use of bempikibart for the treatment of hair-loss disorders such as AA, and another international PCT patent application relating to the use of bempikibart for the treatment of AD, both beginning to enter national stage in the United States, Europe, Japan, Brazil, China, India, Russia (via Eurasia Patent Office), Australia, Canada, Israel, South Korea, Mexico, New Zealand, Philippines, Singapore, and South Africa. Any patents that issue from patent applications derived from or claiming priority to these pending PCT applications are expected to expire in 2044, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

We also own one international PCT patent application relating to the use of bempikibart for the treatment of certain difficult to treat hair-loss disorders, such as severe or very severe AA, or patients having had AA for a long duration; and another international PCT patent application relating to the use of bempikibart for the treatment of certain T-cell mediated inflammatory and/or autoimmune diseases. Any patents that issue from patent applications derived from or claiming priority to these pending PCT applications are expected to expire in 2046, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

Under the Asset Purchase Agreement entered into with Akebia Therapeutics, Inc., we retain rights under certain patents and applications solely to research, develop, manufacture, commercialize, and otherwise exploit any ADX-096 molecule or product, including, as of December 31, 2025, one patent family relating to ADX-096 and the underlying anti-C3d antibodies. This family includes two relevant issued U.S. patents, one pending U.S. patent application, one issued patent in each of Australia, Canada, South Korea, Malaysia, Russia and Japan, two pending Japanese patent applications, and 19 other pending applications in Australia, China, Europe, Hong Kong, India, Indonesia, Israel, South Korea, Mexico, New Zealand, Philippines, Saudi Arabia, Singapore, South Africa, United Arab Emirates, Qatar, Bahrain, Kuwait, and Oman. The issued patent that covers ADX-096, and any patents that issue from these pending patent applications are expected to expire in December 2039, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

As of December 31, 2025, our retained rights also include a pending international Patent Cooperation Treaty, or PCT, patent application that covers the use of ADX-096 for targeted treatment of complement-media disease through local complement inhibition based on detection of a urinary biomarker. Any patents that issue from patent applications derived from or claiming priority to this PCT application are expected to expire in 2044, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

While we believe that the specific and generic claims contained in our patents provide protection for the claimed compounds, pharmaceutical compositions and methods of use, third parties may nevertheless challenge such claims. If any such claims are invalidated or rendered unenforceable for any reason, we could lose valuable intellectual property rights and our ability to prevent others from competing with our products and technology would be impaired.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we pursue patent protection, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent covering an FDA-approved drug may, in certain cases, be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years, but the remaining term of a patent cannot be extended beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. We intend to seek patent term extension for patents covering our products if available.

In addition to patent protection, we may also rely, in some circumstances, on trade secrets to protect our technology. To that end, we also enter into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators and advisors. We also enter into agreements requiring assignment of inventions with selected consultants, scientific advisors, and collaborators. However, trade secrets are difficult to protect. These agreements may not provide meaningful protection and may be breached without an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information and know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Our success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our strategies, obtain licenses, or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we need may have an adverse impact on our business.

For more information and comprehensive risks related to our proprietary technology, inventions, improvements and product candidates, see the section titled “Risk Factors—Risks Relating to Our Intellectual Property” in this Annual Report on Form 10-K.

Government Regulation

The FDA, and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. 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 are currently conducting and in the future may conduct studies or seek approval or licensure of our product candidates. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and the Public Health Service Act (the "PHSA") and their implementing regulations, as well as other federal, state, local, and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practices ("GLP");
- submission to the FDA of an investigational new drug application ("IND") which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or independent ethics committee at each clinical site before the trial may commence;
- manufacture of the proposed biologic candidate in accordance with current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practice ("GCP") requirements and other clinical-trial related regulations to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application ("BLA") after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and potential audit of selected clinical investigation sites to assess compliance with GCPs and cGMPs;
- payment of user fees for FDA review of the BLA, unless a waiver is applicable; and
- FDA review and approval of a BLA to permit commercial marketing of the product for a particular indication(s) for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research participants provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

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, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may recommend halting 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 preclinical studies and clinical trials and clinical study results to public registries. Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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 be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the safety, purity and potency of the final product. Additionally, appropriate packaging must be selected and tested and long-term stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical study investigators. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected suspected adverse events, any findings from other studies, 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.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources,

including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("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 Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan ("PSP") within sixty days after an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews the 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. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facilities in which it is manufactured, processed, packed or stored meet standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. 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 typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and 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 compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a complete response letter (a "Complete Response Letter"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter 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 Complete Response Letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response Letter, 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. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. 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 ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product 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. 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. The FDA may require one or more Phase 4 post-market studies and 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.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track designation is intended to expedite or facilitate the process for development and review of new products that meet certain criteria. Specifically, new product candidates 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 fast track product candidate has opportunities for more frequent interactions with the 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.

A 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 product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, 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, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on 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 accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies with due diligence to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA") the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. 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.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, 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.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United

States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same approved use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. 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.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. 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. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits batch data from 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 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 biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors 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 cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. Such products can only be promoted in a manner that is consistent with 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 by the sponsor 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.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved 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, is generally 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. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. FDA-approved interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state pharmacy laws, which differ by state. The BPCIA is complex and continues to be interpreted and implemented by the FDA.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

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: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which impose criminal and civil penalties and can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that "caused" the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements or representations relating to healthcare matters. Similar to the 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value made to various healthcare professionals including physicians, certain other licensed health care practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

If any of our product candidates are approved, we will also be subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Further, we are subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, it may be subject to penalties, including, without limitation, 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, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of its operations.

Data Privacy and Security

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. As our operations and business grow, we may become subject to or affected by U.S. federal and state laws and regulations, including HIPAA and its implementing regulations, as amended, that govern the collection, use, disclosure, and protection of health-related and other personal information. At the federal level, in addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission ("FTC") Act, 15 U.S.C § 45(a). 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. Regulators and legislators in the U.S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

In addition, numerous U.S. states have introduced comprehensive privacy laws which govern the privacy and security of personal information. For example, in California the California Consumer Protection Act ("CCPA"), as amended by the California Privacy Rights Act ("CPRA") established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, establishing data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope. In addition, the CPRA imposed additional obligations on companies covered by the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information and by establishing the California Privacy Protection Agency to enforce the CCPA.

Other states have passed similar privacy legislation and more states may do so in the future. Such legislation adds additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs. These laws may impact our strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating consumer health information. For example, Washington's My Health My Data Act regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have

proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states, including Illinois and Texas, have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there have been discussions in the U.S. Congress of new comprehensive federal data privacy laws to which we could become subject to, if enacted.

Non-U.S. laws, including for example the European data protection laws, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. The collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the EEA and UK, including personal health data, is subject to the EU General Data Protection Regulation ("EU GDPR") with respect to the EEA and the UK General Data Protection Regulation and UK Data Protection Act 2018 with respect to the UK ("UK GDPR") and collectively with the EU GDPR referred to as the "GDPR" in this document unless specified otherwise. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal information, including requirements relating to processing of special categories of personal information (such as health data), relying on a legal basis or condition for processing personal information, where required obtaining consent of the individuals to whom the personal information relates, providing information to individuals regarding data processing activities, conducting privacy impact assessments for "high risk" processing, implementing safeguards to protect the security and confidentiality of personal information, implementing limitations on the retention of personal information, providing mandatory notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal information to countries outside the EEA and UK to non-adequate territories, including the United States in certain circumstances unless derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses ("SCCs") and the UK International Data Transfer Agreement/Addendum ("UK IDTA")) have been put in place. Where relying on the SCCs /UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal information. Failure to comply with the GDPR, and any supplemental EEA Member State or UK national data protection laws which may apply by virtue of the location of the individuals whose personal information we collect, may result in substantial penalties, including potential fines of up to €20 million (£17.5 million for the UK GDPR) or 4% of annual global revenues for the preceding financial year, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increases our responsibility and liability in relation to personal information that we process where such processing is subject to the GDPR, and requires us to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Failure, or perceived failure, to comply with these laws, where applicable, can result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties as well as the imposition of significant civil and/or criminal penalties and private class action 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, 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, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require it 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. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. 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 that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

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. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that it commercializes and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union ("EU") provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Also, the U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may otherwise affect the price we can obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. Under the One Big Beautiful Bill Act of 2025 ("OBBBA"), this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. Although the effects of the IRA on our business and the healthcare industry in general are not yet known, we are taking into consideration the potential impact of the IRA on our development and commercialization activities.

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 federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Further, 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. The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or

condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

President Trump has also issued multiple executive orders that have sought to reduce prescription drug costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Trump administration may reverse or otherwise change these measures, both the Trump administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation ("MFN") price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the MFN lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Notwithstanding the IRA and President Trump's executive orders, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

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 drug access and marketing cost disclosure and transparency measures, and 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, financial condition, results of operations 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 its drugs or put pressure on its drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients,

marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits ("UPIs") on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

Regulation Outside of the United States

EU Drug Development

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing clinical studies, commercial sales, and distribution of our products. Most countries outside of the United States require that clinical trial applications be approved by the local regulatory authority for each clinical study. In the EU, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the new Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System for clinical trial authorization in up to 30 EU/EEA countries at the same time and with a single set of documentation.

The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States Concerned), based on a draft assessment report prepared by a Reporting Member State. Part II is assessed separately by each Member State Concerned. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the Member State Concerned, however overall related timelines are defined by the Clinical Trials Regulation. The new Clinical Trials Regulation also provides for simplified reporting procedures for clinical trial sponsors.

EU Drug Review and Approval

In addition, whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of countries outside the United States before we can commence marketing of the product in those countries. The approval process and requirements vary from country to country, so the number and type of nonclinical, clinical, and manufacturing studies needed may differ, and the time may be longer or shorter than that required for FDA approval.

To obtain regulatory approval for our medicinal products under the EU regulatory system, a marketing authorization application ("MAA") needs to be submitted. There are a number of potential routes open to obtain a marketing authorization ("MA"). The centralized procedure allows applicants to obtain a MA that is valid throughout the EU, and the additional Member States of the European Economic Area, such as Iceland, Liechtenstein and Norway (collectively, the "EEA"). It is compulsory for medicinal products manufactured using biotechnological processes, orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and human products containing a new active substance which is not authorized in the EU and which is intended for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, auto-immune and other immune dysfunctions, viral diseases or diabetes. The centralized procedure is optional for any other products containing new active substances not authorized in the EU or for products which constitute a significant therapeutic, scientific, or technical innovation or for which a centralized authorization is in the interests of patients at EU level. When a company wishes to place on the market a medicinal product that is eligible for the centralized procedure, it sends an application directly to the European Medicines Agency ("EMA"), to be assessed by the Committee for Medicinal Products for Human Use ("CHMP"). The CHMP is responsible for conducting the assessment of whether a medicine meets the required quality, safety, and efficacy requirements, and whether the product has a positive risk/benefit profile. The procedure results in a European Commission decision, which is valid in all EU Member States. The centralized procedure is as follows: full copies of the MAA are sent to a rapporteur and a co-rapporteur designated by the competent EMA scientific committee. They coordinate the EMA's scientific assessment of the medicinal product and prepare draft reports. Once the draft reports are prepared (other experts might be called upon for this purpose), they are sent to the CHMP, whose comments or objections are communicated to the applicant. The rapporteur acts as an EMA contact person for the applicant and continues to play this role, even after the MA has been granted.

The rapporteur and co-rapporteur then assess the applicant's replies, submit them for discussion to the CHMP, and taking into account the conclusions of this debate, prepare a final assessment report. Once the evaluation is completed, the CHMP gives a favorable or unfavorable opinion as to whether to grant the authorization. When the opinion is favorable, it shall include the draft summary of product characteristics ("SmPC"), the package leaflet, and the texts proposed for the various packaging materials. The time limit for the evaluation procedure is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). The EMA then has fifteen days to forward its opinion to the European Commission, which will make a binding decision on the grant of an MA within 67 days of the receipt of the CHMP opinion.

There are two other procedures in the EU for the grant of an MA in multiple EU Member States. The decentralized procedure provides for approval by one or more concerned Member States, of an assessment of an application performed by one Member State, known as the Reference Member State. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft SmPC, and draft labeling and package leaflet, to the Reference Member State and concerned Member States. The Reference Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the Reference Member State's assessment report, each concerned Member State must decide whether to approve the assessment report and related materials. If a Member State cannot approve the assessment report and related materials on the grounds of potential serious risk to the public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all Member States. Where a product has already been authorized for marketing in a EU Member State, this national MA can be recognized in other Member States through the mutual recognition procedure.

EU New Chemical Entity Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's 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. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, however, another company could nevertheless also market another version of the product if such company obtained an MA based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

EU Orphan Designation and Exclusivity

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 persons in the EU when the application is made. In addition, orphan designation can be granted if the product is intended for a life threatening, seriously debilitating, or serious and chronic condition in the EU and, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in its development. Orphan designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the applicable orphan condition, or if such a method exists, the proposed orphan medicinal product will be of significant benefit to patients affected by such condition, as defined in Regulation (EC) 847/2000.

Orphan designation provides opportunities for fee reductions, protocol assistance, and access to the centralized procedure. Fee reductions are limited to the first year after an MA, except for small and medium enterprises. In addition, if a product which has an orphan designation subsequently receives a centralized MA for the indication for which it has such designation, the product is entitled to orphan market exclusivity, which means the EMA may not approve any other application to market a similar medicinal product for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The exclusivity period may be reduced to six years if, at the end of the fifth year, it is shown that the designation criteria are no longer met, including where it is shown that the product is sufficiently

profitable not to justify maintenance of market exclusivity. Additionally, an MA may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior;
- the MA holder of the authorized product consents to a second orphan medicinal product application; or
- the MA holder of the authorized product cannot supply enough orphan medicinal product.

EU Pediatric Investigation Plan

A pediatric investigation plan ("PIP") in the EU is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All applications for MAs for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when an MA holder wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the EU. Medicines authorized across the EU with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate ("SPC") by six months (provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires). This is the case even when the studies' results are negative. For orphan medicinal products, the incentive is an additional two years of market exclusivity. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use MA ("PUMA"). If a PUMA is granted, the product will benefit from ten years of market protection as an incentive.

PRIME Scheme

In March 2016, the EMA launched an initiative, the PRIority Medicines ("PRIME") scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. 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 potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact and rapporteur from the CHMP or from the Committee for Advanced Therapies ("CAT") are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's committee level. An initial meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

The aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the EU

The European Commission introduced legislative proposals in April 2023, that if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text has been agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted, and are not expected to become applicable before 2028.

Brexit and the Regulatory Framework in the United Kingdom

Now that the United Kingdom ("U.K.") has left the EU, the U.K. is no longer covered by the EU procedures for the grant of marketing authorizations under the centralized EU procedure and a separate marketing authorization is therefore required to

market drugs in the U.K.. As a result of the Northern Ireland protocol, following Brexit, the EMA remained responsible for approving novel medicines for supply in Northern Ireland under the EU centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and placed medicinal products supplied to Northern Ireland under the regulatory authority of the MHRA. The Windsor Framework removes EU licensing processes and certain EU labeling and serialization requirements for medicines supplied to Northern Ireland and introduces a U.K.-wide licensing process for medicines. A single U.K.-wide marketing authorization will be granted by the MHRA for all novel medicinal products to be sold in the U.K., enabling products to be sold in a single pack and under a single authorization throughout the U.K. In addition, the new arrangements require, for packs placed on the U.K. market on or after January 1, 2025, a "U.K. Only" label, indicating they are not for sale in the EU.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. All existing EU MAs for centrally authorized products were automatically converted (grandfathered) into United Kingdom MAs free of charge on January 1, 2021. On January 1, 2024, the MHRA put in place a new international recognition framework under which the MHRA may have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new U.K. MA. There is no pre-MA orphan designation in the U.K. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the U.K. market, i.e., the prevalence of the condition in the U.K. rather than the EU must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the U.K.

Human Capital

As of December 31, 2025, we had 24 full-time employees, of which 3 have M.D. or Ph.D. degrees. Within our workforce, 13 employees are engaged in research and development and 11 are engaged in general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our principal office is located at 830 Winter Street, Waltham, Massachusetts 02451, where we lease approximately 15,771 square feet of office space. The lease term began in January 2022 and will end in December 2031. We believe that this facility will be adequate to meet our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on commercially reasonable terms to accommodate any such expansion our operations.

Corporate Information

We were incorporated under the laws of the State of Delaware on April 10, 2017. Our principal executive office is located at 830 Winter Street, Waltham, Massachusetts 02451, and our telephone number is (781) 999-0232. Our website address is www.q32bio.com. References to our website address to not constitute incorporation by reference of the information contained on the website, and the information on the website is not part of this document.

On March 25, 2024, Merger Sub, a wholly-owned subsidiary of Homology, completed its merger with and into Q32 Bio Operations Inc. (previously named Q32 Bio Inc. and referred to herein as Legacy Q32), with Legacy Q32 continuing as the surviving entity as a wholly-owned subsidiary of Homology. This transaction is referred to as the Merger. Homology changed its name to Q32 Bio Inc., and Legacy Q32, which remains as a wholly-owned subsidiary of ours, changed its name to Q32 Bio Operations, Inc. The Merger was effected pursuant to the Merger Agreement dated as of November 16, 2023, by and among Homology, Legacy Q32, and Merger Sub. Effective March 26, 2024, our common stock is listed on the Nasdaq Global Market, under the trading symbol "QTTB."

Available Information

We file electronically with the 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.q32bio.com, under "Investors & Media," free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Research and Development Committee of our Board of Directors are posted on our website, www.q32bio.com, under "Investors & Media". The information contained in the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk Factors.

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the "SEC"). We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this Annual Report on Form 10-K.

Risks Related to Our Business

Risks Related to Our Limited Operating History, Financial Position and Need for Capital

We have incurred significant losses since inception, expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable.

Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront expenditures and significant risks that any program will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale nor have we generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until it successfully completes clinical development and obtains regulatory approval of, and then successfully commercializes, at least one product candidate. We may never succeed in these activities and, even if it does, may never generate product revenue or revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of any approved products, it may be unable to continue operations without additional funding.

We have incurred recurring operating losses since inception. During the year ended December 31, 2025, we had net income of $29.8 million as a result of the collaboration revenue recognized upon the execution of the Amgen Amendment. Our net loss for the year ended December 31, 2024, was $47.7 million. We expect to continue to incur significant losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance our existing and future programs through preclinical and clinical development, including expansion into additional indications;
- seek to identify additional programs and additional product candidates;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek regulatory and marketing approvals for product candidates;
- seek to identify, establish and maintain additional collaborations and license agreements;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which we may obtain marketing approval, either by ourselves or in collaboration with others;
- commence commercial sales of products for which we receive marketing approval;
- hire additional personnel including research and development, clinical and commercial;

- add operational, financial and management information systems and personnel, including personnel to support product development;
- acquire or in-licenses products, intellectual property and technologies; and
- establish commercial-scale current good manufacturing practices ("cGMP") capabilities through a third-party or our own manufacturing facility.

In addition, our expenses will increase if, among other things, we are required by the U.S. Food and Drug Administration (the "FDA"), or other regulatory authorities to perform trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in completing our clinical trials or the development of any product candidates, or there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for, and are successful in commercializing, one or more product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional programs and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Our failure to become profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in our value could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts.

Developing biotechnology products is a very long, time-consuming, expensive and uncertain process that takes years to complete. Since inception, we have funded our operations primarily through private equity and debt financings and have incurred significant recurring losses. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our clinical trials for bempikibart, initiate additional clinical trials, and continue to research, develop and conduct preclinical studies of our other potential product candidates, and continue to operate as a public company. In addition, if we obtain regulatory approval for any product candidate for commercial sale, we anticipate incurring significant commercialization expenses related to product manufacturing, marketing, sales and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our current, planned and anticipated clinical trials are highly uncertain, and many of our near-term plans are subject to regulatory feedback, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Our future capital requirements depend on many factors, including factors that are not within our control.

We will continue to incur costs associated with operating as a public company. We will require substantial additional funding to continue our operations. Based on our current operating plan, we believe that our existing cash and cash equivalents, combined with gross proceeds from our registered direct offering completed in February 2026 and guaranteed near-term milestone payments from the ADX-097 Asset Sale, should be sufficient to fund our operations into the fourth quarter of 2027. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the timing and progress of preclinical and clinical development activities, including our ongoing Phase 2 clinical trial for bempikibart in alopecia areata ("AA");
- the number and scope of preclinical and clinical programs we pursue;
- our ability to establish an acceptable safety profile with IND-enabling toxicology studies to enable clinical trials;
- successful patient enrollment in, and the initiation and completion of, larger and later-stage clinical trials;
- per subject trial costs;
- the number and extent of trials required for regulatory approval;
- the countries in which the trials are conducted;

- the length of time required to enroll eligible subjects in clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the extent to which we encounter any serious adverse events in our clinical trials;
- the timing of receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish or maintain collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third parties in connection therewith;
- hiring and retaining research and development personnel;
- our arrangements with our contract development and manufacturing organizations ("CDMOs"), and contract research organizations ("CROs");
- development and timely delivery of clinical and commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch, respectfully;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Adequate additional financing may not be available to us on acceptable terms, or at all, and we may be required to seek additional funds sooner than planned through public equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing or refinancing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to product development programs, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by global macroeconomic conditions and volatility in the credit and financial markets in the U.S. and worldwide, over which we may have no or little control. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate clinical trials, product development programs or future commercialization efforts.

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biotechnology company with limited operating history. Since our inception in 2017, we have incurred significant operating losses and have utilized substantially all of our resources to conduct research and development activities (including with respect to our bempikibart program) and undertake preclinical studies of product candidates, as well as for conducting clinical trials of our most advanced product candidates and the manufacturing of such product candidates, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. We have limited significant experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and planned clinical trials will begin or be completed on time, if at all. We have not yet demonstrated our ability to successfully complete Phase 3 or other pivotal clinical trials, obtain regulatory or marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition.

Risks Related to Discovery, Development and Commercialization

We face competition from entities that have developed or may develop programs for the diseases we plan to address with bempikibart or other product candidates.

The development and commercialization of drugs and biologics is highly competitive. Our product candidates may compete with other product candidates in development for similar indications, and if approved, bempikibart or other product candidates will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future 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 and biotechnology industry 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, establishing clinical trial sites, patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, bempikibart or other product candidates.

Our competitors have developed, are developing or may develop programs and processes competitive with bempikibart or other product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than any products we may develop, if any, or if competitors develop competing products or if generic products or biosimilars enter the market more quickly than we are able to, if at all, and are able to gain market acceptance.

Bempikibart and the rest of our pipeline are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and bempikibart and the rest of our pipeline are in the early stages of development. As a result, we expect it will be many years before we commercialize any product candidate, if any. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, bempikibart or other product candidates either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any product candidates. We have limited experience as a company in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or comparable foreign regulatory authorities. We have also not yet demonstrated our ability to obtain regulatory approvals, 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. Before obtaining regulatory approval for the commercial distribution of product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of such product candidates.

We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize bempikibart or any other product candidates, including:

- regulators or Institutional Review Boards ("IRBs"), the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any our product candidates may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials compared to approved products, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up 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, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators, or expand the scope of our planned clinical trials to accrue sufficient data from such trials;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other therapies in the same class as our product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

Commencing clinical trials in the U.S. is subject to the FDA allowing an Investigational New Drug Application ("IND") to proceed after an evaluation of the proposed clinical trial design. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from the FDA, the FDA could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are comparable processes and risks applicable to clinical trial applications needed to initiate clinical trials in other countries, including countries in the European Union ("EU").

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, bempikibart or any other product candidates. We or our current or future collaborators' inability to complete development of, or commercialize, bempikibart or any other product candidates or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the success of our most advanced product candidate, bempikibart, and our clinical trials of our lead candidate may not be successful.

Our future success is substantially dependent on our, or our current or future strategic partners', ability to timely obtain marketing approval for, and then successfully commercialize, our most advanced product candidate, bempikibart. We are investing a majority of our efforts and financial resources into the research and development of bempikibart. We are developing bempikibart to treat autoimmune and inflammatory diseases, with the aim of achieving the optimal balance of efficacy,

tolerability and convenience for patients via infrequently administered subcutaneous doses. We have completed a Phase 1 double-blind, placebo-controlled, single ascending dose and multiple dose study to assess the safety, pharmacokinetic ("PK") and pharmacodynamic ("PD") of bempikibart after subcutaneous administration in healthy subjects. This study supported further evaluation of bempikibart, including through demonstration of a PK/PD profile supporting evaluation of every two-week subcutaneous dosing in clinical trials. Subsequent to this study, we advanced bempikibart into two Phase 2a clinical trials. The Phase 2a SIGNAL-AD trial evaluated the use of bempikibart for the treatment of atopic dermatitis ("AD") and the Phase 2a SIGNAL-AA trial is evaluating bempikibart for the treatment of alopecia areata ("AA"). We completed enrollment and dosing through the 12-week and 24-week periods for the SIGNAL-AD and SIGNAL-AA trials, respectively, and in December 2024, we announced topline data from both clinical trials, as well as our intention to advance bempikibart for the treatment of AA. In April 2025, we announced dosing of the first patients in both the Part A open-label extension and Part B of the SIGNAL-AA Phase 2a clinical trials and in October 2025, we announced completion of enrollment in Part B of the SIGNAL-AA Phase 2a clinical trial. The success of bempikibart may depend on having a comparable safety and efficacy profile and a more favorable dosing schedule (i.e., less frequent dosing) with patient-friendly administration (i.e., S.C. self-administration) to products currently approved or in development for the indications we plan to pursue.

We previously completed a Phase 1 clinical trial of ADX-097 in healthy volunteers and initiated a Phase 2 clinical trial of this candidate. However, in November 2025, we sold to Akebia substantially all of our assets related to the research, development, manufacture and commercialization of ADX-097. Following the sale, Akebia will be responsible for any future development and commercialization of ADX-097.

Bempikibart will require additional clinical development, evaluation of clinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales, if any. We are not permitted to market or promote any product candidates, before we receive marketing approval from the FDA and/or comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of bempikibart will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any current or future collaborator or other third party. Accordingly, we cannot guarantee that we will ever be able to generate revenue through the sale of any of our product candidates, even if approved. If we are not successful in commercializing bempikibart, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of bempikibart or any other product candidates may be delayed.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies, preclinical studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of bempikibart or any other product candidates may be delayed or never achieved.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value.

Our approach to the discovery and/or development of bempikibart leverages the understanding of cytokine and complement biology in diverse tissues and indications. Bempikibart is directed at target pathways, IL-7 and thymic stromal lymphopoietin ("TSLP") signaling, that have been implicated in several inflammatory and autoimmune diseases. However, the scientific research that forms the basis of efforts to develop bempikibart is ongoing and has not been successfully proven in clinical trials. The long-term safety and exposure profile of bempikibart is also unknown.

We may ultimately discover that our technologies for our specific targets and indications and bempikibart and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. For our lead candidate, we currently have only data from our Phase 1 clinical trial and our Phase 2 Part A AA and AD clinical trials, and the same data or results may not be seen in larger, later-stage clinical trials. In addition, product candidates using investigational technologies and approaches may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies and bempikibart may interact with human biological systems in unforeseen, ineffective or possibly harmful ways.

In addition, we may in the future seek to discover and develop product candidates that are based on novel targets and technologies that are unproven. If our discovery activities fail to identify novel targets or technologies for drug discovery, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional product candidates. We and our existing or future collaborators may never receive approval to market and commercialize bempikibart or future product candidates. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of non-human primates ("NHPs") to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of certain types of NHPs available for Good Laboratory Practice ("GLP") testing for drug development. This could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly, and if the shortage continues, and could result in delays to our development timelines. Furthermore, a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

Additionally, we are currently conducting an "open-label" clinical trial. An open-label trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate. Such trials may test only the investigational product candidate and sometimes may do so at different dose levels. Open-label trials are subject to various limitations that may exaggerate any therapeutic effect as patients in such trials are aware when they are receiving treatment. Open-label trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with our product candidates when studied in a controlled environment with a placebo or active control. In addition, we expect to rely on patients to provide feedback on measures which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and from site to site within a clinical trial.

Although we plan to seek regulatory guidance in designing and conducting our development plans, we cannot be sure that the FDA or comparable foreign regulatory authorities will agree with these plans. If the FDA or comparable regulatory authorities requires us to revise or amend a clinical trial, generate additional pre-clinical data in support of clinical conduct (e.g., toxicology studies), conduct additional trials or enroll additional patients, our development timelines may be delayed. We cannot be sure that submission of an IND, clinical trial application ("CTA") or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB or ethics committee approval at each clinical trial site;

- difficulties in patient enrollment in our clinical trials for a variety of reasons;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's Good Clinical Practices ("GCPs"), or regulations or applicable regulations or regulatory guidelines in other countries;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a CDMO, and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing processes; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is placed on clinical hold, suspended or terminated by us, the FDA, the competent authorities of the EU Member States or other regulatory authorities or the IRBs or ethics committees of the institutions in which such trials are being conducted, if a clinical trial is recommended for suspension or termination by the data safety monitoring board ("DSMB"), or equivalent body for such trial, or on account of changes to federal, state, or local laws. If we are required to conduct additional clinical trials or other testing of bempikibart or any other product candidates beyond those that we contemplate, if we are unable to successfully complete clinical trials of bempikibart or any other product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

A key part of our long-term business strategy is to identify and develop additional product candidates. Our preclinical research and clinical trials may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development for a number of reasons. For example, we may be unable to identify or design additional product candidates with the pharmacological and pharmacokinetic drug properties that we desire, including, but not limited to, adequate tissue targeting, acceptable safety profile or the potential for the product candidate to be delivered in a convenient formulation. Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify suitable complement targeting strategies for preclinical and clinical development, we may not be able to successfully implement our business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts, which would negatively impact our financial condition.

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

We may experience difficulties in patient enrollment in our future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients in future trials for bempikibart or any other product candidates will depend on many factors, including if patients choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients instead enroll in such clinical trials. Additionally, the number of patients required for clinical trials of bempikibart or any other product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non-inferiority or superiority trials compared to approved products. Even if we are able to enroll a sufficient number of patients for our future clinical trials, we may have difficulty maintaining patients in our clinical trials. Our inability to enroll or maintain a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether.

Preliminary, "topline" or interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline 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 or subsequently made subject to audit and verification procedures. Any preliminary or topline data should be viewed with caution until the final data is available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data 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 or as patients from our clinical trials continue other treatments.

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 product candidate, the approvability or commercialization of a particular product candidate and us in general. In addition, the information we choose to publicly disclose regarding a particular preclinical 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 preliminary, topline or interim 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, bempikibart or any other product candidate may be harmed, which could harm our business, operating results, prospects or financial condition.

Our current or future clinical trials or those of our future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical and/or early clinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of bempikibart or any other product candidates or result in potential product liability claims.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our completed preclinical studies and our completed and ongoing clinical trials in humans have not shown any such characteristics to date, significant further evaluation must be done of each of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, patients may be harmed, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA, the European Medicines Agency (the "EMA"), or other applicable regulatory authorities, or an IRB or ethics committee, may suspend any clinical trials of bempikibart or any other product candidates at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude a product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of an approved product due to its tolerability versus other therapies. Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with bempikibart or any other product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from bempikibart or any other product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

In addition, even if we successfully advance bempikibart or any other product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to such product candidates. As a result, we cannot be assured that adverse effects of bempikibart or any other product candidates will not be uncovered when a significantly larger number of patients are exposed to such product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidate over a multi-year period.

If any of the foregoing events occur or if bempikibart or any other product candidates prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Because we have limited financial and managerial resources, we intend to focus our research and development efforts on certain selected product candidates. For example, we initially focused on our most advanced product candidates, bempikibart and ADX-097, and in November 2025, we sold to Akebia substantially all of our assets related to the research, development, manufacture and commercialization of ADX-097. As a result, we may forgo or delay pursuit of opportunities with other potential candidates that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that 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 candidate.

Even if regulatory approval is obtained, any approved products may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for bempikibart or any other product candidates, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. There are several approved products and product candidates in later stages of development for the treatment of AA. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a drug or biologic with a target product profile such as that of bempikibart for its targeted indications, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of bempikibart or any other product candidates will depend on many factors, including factors that are not within our control.

Sales of products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that any of our approved products are safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If bempikibart or any other product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product and may not become or remain profitable.

We have never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize a product candidate on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we may rely on the assistance and guidance of those collaborators. For a product candidate for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize a product candidate, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidate, ensuring regulatory compliance of us, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of a product candidate upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of an approved product candidate, we may not generate revenues from them or be able to reach or sustain profitability.

We have never completed any late-stage clinical trials and we may not be able to submit applications for regulatory authorizations to commence additional clinical trials on the timelines we expect, and, even if we are able to, the FDA, EMA or comparable foreign regulatory authorities may not permit us to proceed and could also suspend/terminate the trial after it has been initiated.

We are early in our development efforts and will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA, EMA or comparable foreign regulatory approval to market our product candidates. Carrying out clinical trials and the submission of a successful IND or CTA is a complicated process. As an organization, we have limited experience

as a company in preparing, submitting and prosecuting regulatory filings. We may not be able to initiate or complete our planned clinical trials in accordance with our desired timelines. For example, we may experience manufacturing delays or other delays with IND-or CTA-enabling studies, including with suppliers, trial sites, or third-party contractors and vendors on whom we depend. Moreover, we cannot be sure that submission of an IND or a CTA or submission of a trial to an IND or a CTA will result in the FDA or EMA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that lead us to suspend or terminate clinical trials. Upon submission of an IND or CTA, the FDA or EMA may recommend changes to the proposed trial designs, which may impact the number and size of registrational clinical trials required to be conducted in such development programs and may change predicted timelines for clinical development. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of our product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a CTA, such regulatory authorities may change their requirements in the future. The FDA, EMA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to file INDs or CTAs, initiate clinical trials, or obtain regulatory authorizations for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

Risks Related to our Intellectual Property

Our ability to protect our patents and other proprietary rights is uncertain, exposing it to the possible loss of competitive advantage.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and to prevent third parties from infringing on our patents and trademarks or misappropriating or violating our other intellectual property rights, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their uses, components, formulations, methods of manufacturing and methods of treatment, as well as our ability to operate without infringing on or violating the proprietary rights of others. We have licensed know-how and patent families that pertain to, among other things, composition of matter and certain methods of use relating to our leading product candidate, bempikibart. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and novel discoveries that are important to our business. Our intellectual property strategy is, where appropriate, to file new patent applications on inventions, including improvements to existing products candidates and processes to improve our competitive edge or to improve business opportunities. We continue to assess and refine our intellectual property strategy to ensure appropriate protection and rights are secured. However, our pending and future patent applications may not result in patents being issued. We cannot assure you that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our product candidates.

Composition of matter patents for biotechnology and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign jurisdictions, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign jurisdictions. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our current or future patent applications may not result in patents being issued which protect our technology or drug candidates or which do not effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of our claims or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

The issuance of a patent does not ensure that it is valid or enforceable, nor does it give us the right to practice the patented invention. Issued patents may be challenged, narrowed, invalidated or circumvented and third parties may have blocking patents that could prevent us from commercializing our product candidates or technologies. While we endeavor to identify and circumvent third-party patents and patent applications which may block our product candidates or technologies to minimize this risk, relevant documents may be overlooked or missed, which may in turn impact our ability to commercialize the relevant asset. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by pharmaceutical and biotechnology companies. Thus, any of our issued patents, including patents that we may rely on to protect our market for approved drugs, may be held invalid or unenforceable by a court of final jurisdiction.

A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

Because patent applications in the U.S., Europe and many other jurisdictions are typically not published until 18 months after filing, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or future patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our future patents in the U.S., Europe and in many other jurisdictions cannot be predicted with certainty and, as a result, any future patents that we own, or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our patent applications that we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are dependent on patents rights, know-how and proprietary technology licensed from third parties. In particular, we depend substantially on our license agreement with Bristol Myers Squibb Company ("BMS"), under which we in-license patent rights and know-how that cover bempikibart (the "BMS Agreement"). For more information regarding the BMS Agreement, please see the section titled "*Business–Collaboration and License Agreements*" in this Annual Report on Form 10-K. We may also enter into additional agreements with third parties in the future.

Our current and future license agreements may impose diligence, development and commercialization timelines, milestone payments, royalties, indemnification, insurance, or other obligations on us. For example, under the BMS License Agreement, the counterparty may terminate the agreement if we fail to meet our diligence obligations, including using commercially reasonable efforts to meet diligence milestones by specified dates. If we fail to comply with our obligations to our licensors or collaborators, our counterparty may have the right to terminate this agreement. Termination of this agreement or reduction or elimination of our rights under this agreement may result in us having to negotiate a new or reinstated agreement with less favorable terms, or cause us to lose our rights under this agreement, including our rights to important intellectual property or technology that are necessary for our business.

Certain patent filings relating to our product candidates may be subject to step-in rights of certain of our licensors. We may have limited control over our licensor's activities or use or licensing of any other intellectual property that may be related to our in-licensed intellectual property. If any of our licensors or licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors or other third parties from making, using or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with our licensors, such licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of such patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors or, in some cases, other necessary parties, such as any co-owners of patents or other intellectual property from which we have not yet obtained a license. We cannot be certain that our licensors, and in some cases, their co-owners, will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after assuming control.

Our current or future license agreements may not provide exclusive or sufficient rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future. Some licenses granted to us may be subject to certain preexisting rights held by the licensors or certain third parties. As a result, we may not be able to prevent third parties from developing and commercializing competitive products in certain territories or fields.

In the event that our third party licensors determine that, in spite of our efforts, we have materially breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the license agreement or, in some cases, one or more license(s) under the applicable license agreement. Such termination could result in us losing the ability to develop and commercialize product candidates and technology covered by the licensed intellectual property. In the event of such termination of a third-party in-license, or if the underlying patent rights under a third-party in-license fail to provide the intended exclusivity, third parties may be able to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If our current or future license agreements are terminated, or if the underlying patent rights fail to provide the intended exclusivity, competitors or other third parties may be able to seek regulatory approval of, and to market, products identical to ours and we may be required to cease the development and commercialization of our product candidates. Any of the foregoing

could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent rights to third parties under our license agreements or collaborative development relationships;
- our diligence obligations under the license agreement with respect to the use of the licensed technology in relation to the development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensor and us and our partners; or
- the priority of invention of patented technology.

Our current or future license agreements may be subject to certain rights retained by third parties.

Our current or future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions. In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"), including a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development that are subject to the Bayh-Dole Act. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our current or future licensors pending patent applications will issue or that patents based on us or any of our current future licensors patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any potential future licensors or collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have several pending United States and foreign patent applications in our portfolio. We cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;

- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our or any future licensors' pending patent applications directed to our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our or any future licensors' inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or any future licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or any future licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our or any future licensors' portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

We may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Patents are of national or regional effect, and although we currently have issued patents and pending applications in the United States, filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or any of our licensors' inventions in all countries outside the United States, even in jurisdictions where we or any of our current or future licensors do pursue patent protection, or from selling or importing products made using our or any of our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or any of our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or any future licensors have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our or any of our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our or our licensors' patents or marketing of competing products in violation of our proprietary rights.

In addition, some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also 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 is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected. 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.

Certain countries outside the United States have laws that may impact a patent owner's right to claim priority or require a patent applicant to obtain a foreign filing license or first file patent applications in a foreign jurisdiction to the extent that foreign nationals are involved in the development of the claimed subject matter of the resulting patent. our pending and future patent applications may not result in patents being issued that comply with the law of each foreign jurisdiction. Pending applications and issued patents may be challenged in various jurisdictions for failure to comply with local foreign laws, which could result in the rejection of pending applications or invalidation of issued patents. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future

protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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 if we fail to comply with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office (the "USPTO") and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance 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, and 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 drug candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable.

Any issued patents that we may license or own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad, including the USPTO. Patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position with respect to our product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, enforceability of our patents and/or other intellectual property. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO or the European Patent Office or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates.

Patent terms may be inadequate to protect our competitive position with respect to our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Once patents covering our product candidates have expired, we may be open to competition from competitive products, including generics or biosimilars. 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.

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

In the U.S., the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. However, a patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extension on patents covering such product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extension should be granted, and even if granted, the length of such extension. we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (the "Purple Book"), a searchable, online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service Act. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Purple Book. Even if we submit a patent for listing in the Purple Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If any of our product candidates are approved and patents covering such product candidates not listed in the Purple Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidates.

Changes to patent laws in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our intellectual property.

Changes in either the patent laws or interpretation of patent laws in the U.S., including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), could increase the uncertainties and costs surrounding the prosecution of our future owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of

whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and altered the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future legislation by the U.S. Congress, decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. For example, in the case Amgen v. Sanofi, the Supreme Court held broad functional antibody claims invalid for lack of enablement. Similarly, in the case Juno v. Kite, the Federal Circuit held genus claims directed to CAR-T cells invalid for lack of written description for failing to provide disclosure commensurate with the scope of the claims. While we do not believe that any of the patents licensed or owned by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

Moreover, in 2012, the European Union Patent Package ("EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent ("UP"), covering all participating European Union member states, and a new European Unified Patent Court, UPC, for litigation involving European patents including all UPs. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC if not opted out. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC before the prescribed deadlines, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke its European patents that have not been opted out, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

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 and market our product candidates, if approved.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant third party patents, the scope of said patent claims or the expiration of relevant patents, are complete, accurate or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our product candidates, if approved, in any jurisdiction. The scope of a patent claim is 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. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such product candidates or technologies.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or any future licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from

conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that these licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

In addition, while it is our policy to require our employees, consultants, and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, it may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached or challenged, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could adversely affect our business, financial condition, results of operations, and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, it may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our patents or patent applications. An adverse determination in any such submission or proceeding 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 technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents or trademarks or misappropriate or violate our other intellectual property rights. To counter infringement, misappropriation or unauthorized use, we or any future licensors may be required to file infringement or misappropriation claims, which can be expensive and time consuming and divert the time and

attention of our management and scientific personnel. We or any future licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed their patents, in addition to counterclaims asserting that our patents or any future licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description, obviousness-type double patenting, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of our or any future licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or any future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any future licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or any future licensors' patents could limit our ability to assert our or any future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, we cannot assure you that it will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may become involved in third-party claims of intellectual property infringement, misappropriation or violation, which may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on us avoiding infringement of the patents or trademarks and misappropriation or violation of other proprietary rights of third parties. There is a substantial amount of litigation involving the infringement of patents or trademarks and misappropriation or violation of other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent, trademark or other intellectual property rights and who allege that our product candidates, uses and/or other proprietary technologies infringe their patents or trademarks or misappropriate or violate their other intellectual property rights. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk that our product candidates may give rise to claims of infringement of the patent rights of others increases. Moreover, it is not always clear to industry participants, including us, which patents exist which may be found to cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications currently pending in our fields, there may be a risk that third parties may allege they have patent rights which are infringed by our product candidates, technologies or methods.

If a third party alleges that we infringed its patents or trademarks or misappropriate or violate its other intellectual property rights, we may face a number of issues, including, but not limited to:

- patent and trademark infringement and other intellectual property misappropriation or violation which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, misappropriation or violation, which we may have to pay if a court decides that the product candidate or technology at issue infringes on, misappropriates or violates the third-party's rights;

- an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights protecting our product candidates or processes; and
- we may be forced to try to redesign our product candidates or processes so they do not infringe third-party patents or trademarks or misappropriate or violate other third party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. While we may believe that patent claims or other intellectual property rights of a third party would not have a materially adverse effect on the commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by its activities. If any third-party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtain a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or which we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of its proprietary know-how. If a competitor independently develops a technology that we protect as a

trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use its own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our products, including confidential aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

We may be subject to damages resulting from claims that we or our employees or consultants have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors. These claims may be costly to defend and if we do not successfully do so, it may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for or are concurrently employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and commercialize, or prevent us from developing and commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against such claims, 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, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding 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. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be able to effectively secure first-tier technologies when competing against other companies or investors.

Our future success may require that we acquire patent rights and know-how to new or complementary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

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.

Our future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

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 or other third parties 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 registered or unregistered trademarks or trade names. Over the long term, if we are unable to 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 names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we may file or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and

- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the U.S. and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the U.S. without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our most advanced product candidate, bempikibart, we must demonstrate through lengthy, complex and expensive preclinical and clinical trials that such product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, a product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. A product candidate could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to a product candidate, which may result in inquiries from or actions by regulatory authorities to address such events;
- we may be unable to demonstrate that a candidate's clinical and other benefits outweigh our safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of a product candidate may not be acceptable or sufficient to support the submission of a Biologics License Application ("BLA"), a new drug application ("NDA"), or similar marketing application to obtain regulatory approval in the U.S. or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of a product candidate;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we may contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs 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 us failing to obtain regulatory approval to market bempikibart or other product candidates, which would significantly harm our business, results of operations and prospects. 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. For example, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' decisions and interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act (the "APA"). Decisions such as this could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations. 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 lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

If we were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, 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. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue may be materially impaired.

Changes in funding for, or other disruptions to the operations of, the FDA, the SEC, the National Institute of Health ("NIH"), and other government agencies, including from government shutdowns could hinder our ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The current U.S. administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees at various federal agencies, including the FDA. Currently, most federal agencies in the U.S. are funded through September 30, 2026. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve regulatory submissions and NIH's ability to conduct and partner with industry on important research can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, layoffs and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved, which would harm our business. Changes and cuts in FDA staffing have been reported by some within the pharmaceutical industry as creating instances of delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion.

If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

With the change in the U.S. presidential administration in 2025, there have been numerous legislative changes and there continues to be substantial uncertainty as to the extent and manner in which the Trump administration will continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the current administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates. Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug and biologic products safely and in accordance with regulatory requirements. This includes synthesizing the active ingredient, developing an acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process and demonstrating that our products meet stability requirements. Meeting these chemistry, manufacturing and control ("CMC") requirements is a complex task that requires specialized expertise. If we are not able to meet the CMC requirements, we may not be successful in advancing our clinical studies or obtaining regulatory approvals for our product candidates.

We have and may in the future conduct clinical trials for our product candidates at sites outside the U.S., and the FDA may not accept data from trials conducted in such locations.

We have conducted and may in the future choose to conduct clinical trials for our product candidates outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the U.S., it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the U.S. or to continue such trials once initiated. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

Other risks inherent in conducting international clinical trials include:

- the need to comply with foreign regulatory requirements, differences in healthcare services, and differences in cultural customs that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple sets of foreign regulations;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- political and economic risks relevant to foreign countries.

Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved 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 approved. 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.

Our investigational biological products, if approved, could be considered reference products entitled to the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. The approval of a biosimilar of any of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

Even if we receive regulatory approval of bempikibart or other product candidates, we will be subject to extensive 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 regulatory approvals that we may receive for bempikibart or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such 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 risk evaluation and mitigation strategy in order to approve a product candidate, 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, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug substances and products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize bempikibart or other product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of bempikibart or other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. See the section titled "*Business-Government Regulation-Healthcare Reform*" elsewhere in this Annual Report on Form 10-K for a more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize product candidates.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

For example, the OBBBA enacted significant Medicaid reforms, including approximately $1 trillion in federal spending reductions through 2034. Among other provisions, the legislation imposes work requirements for certain adult Medicaid enrollees, mandates more frequent eligibility redeterminations, and authorizes increased cost-sharing obligations for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and limit access to care. Although the precise impact on our business is not yet clear, any reduction in the number of covered patients or reimbursement levels for our products could adversely affect our future revenue and commercial prospects.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Recent CMS proposals, including the GLOBE, GUARD, and GENEROUS, could materially impact the Company's revenue. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Our business operations and current and future arrangements 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 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. See the section titled "*Business-Government Regulation-Other Healthcare Laws and Compliance Requirements*" elsewhere in this Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to it, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and 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.

Even if we are able to commercialize bempikibart or other product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such products at competitive prices which would seriously harm our business.

We intend to seek approval to market bempikibart and other product candidates in both the U.S. and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for such product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for medications. These entities may create preferential access policies for a competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off-label uses of those programs, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See the sections titled "*Business-Government Regulation-Coverage and Reimbursement*" and "*-Regulation in the EU*" elsewhere in this Annual Report on Form 10-K for a more detailed description of the government regulations and third-party payor practices that may affect our ability to commercialize our product candidates.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell products outside the U.S., to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly Member States of the EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various Member States and parallel distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of a product to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected.

We may seek one or more designations or expedited programs for our product candidates, but may not receive such designations or be allowed to proceed on expedited program pathways, and even with the fast track designation ("FTD") we received for bempikibart or may receive for another product candidate in the future, such designations or expedited programs may not lead to a faster development or regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the U.S.

In April 2025, we received FTD for bempikibart for the treatment of AA. In the future, we may seek FTD for other product candidates, where applicable. If a drug is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data for the drug demonstrates the potential to address an unmet medical need for such a condition, the drug sponsor may apply for FTD. The FDA has broad discretion whether to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot provide assurance that the FDA would decide to grant this designation. Even with the FTD granted to bempikibart or that may be granted to any other product candidate, as applicable, bempikibart or other product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw FTD if it believes that the designation is no longer supported by data from the clinical development program. FTD alone does not guarantee qualification for the FDA's priority review procedures.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug 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 drugs 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. 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 therapies considered for approval under conventional FDA 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 such product candidates no longer meet the conditions for qualification or decide that the time for FDA review or approval will not be shortened.

In the future, we may also seek approval of product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage 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 new drug 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 trials to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory trial or trials be underway prior to approval or within a specified time after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such trials, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such trials in a timely manner, send the necessary updates to the FDA, or if such post-approval trials fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory trial or submit timely reports to the agency on their progress. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of regulatory approval be submitted to the Agency for review during the pre-approval review period. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. Moreover, even if we received accelerated approval, any post-approval trials required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may pursue orphan drug designation for certain of our product candidates, but may not be able to obtain such designation, or obtain or maintain the benefits of such designation including orphan drug exclusivity, and even if we do obtain orphan designation for our product candidates, any orphan drug exclusivity it receives may not prevent regulatory authorities from approving other competing products.

We may seek orphan drug designation for some of our product candidates; however, we may never receive such designation. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population of 200,000 or more in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. Orphan drug designation must be requested before submitting an NDA or a BLA. A similar regulatory scheme governs orphan products in the EU.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. In addition, if a product candidate with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same product for the same therapeutic indication for seven years.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same approved use or condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same approved use or condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition. Further, even if we obtain orphan drug designation, we may not be the first to obtain regulatory approval for any indication due to the uncertainties associated with developing pharmaceutical products.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. Additionally, legislation has been proposed by the European Commission that, if implemented, has the potential in some cases to shorten the ten-year period of orphan marketing exclusivity. It is unclear if, when, or how the FDA or other regulatory authorities may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA or other regulatory authorities may make to their orphan drug regulations and policies, our business could be adversely impacted.

Risks Related to Our Third Party Relationships

We currently rely and expect to rely on third parties in the future to conduct our clinical trials and some aspects of our research, as well as some aspects of our delivery methods, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently, and expect to continue to, rely on third parties, such as but not limited to CROs, clinical data management organizations, medical institutions, preclinical laboratories and clinical investigators, to conduct some aspects of our research. For example, we may rely on a third party to supply components of our product candidates, or to conduct some of our preclinical animal experiments. Any of these third parties may terminate their engagements with us at any time under certain criteria. If we need to enter into alternative arrangements, it may delay our product research and development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols. Moreover, the FDA, the EMA and other regulatory authorities require us and the study sites and investigators we work with to comply with standards, commonly referred to as GLPs and GCPs for conducting, recording and reporting the results of preclinical studies and clinical trials to assure, amongst other things, that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

We have collaborations and license agreements with third parties, including our existing license agreements with BMS and Colorado and expect to collaborate with third parties in the future. We may not be successful in finding strategic collaborators for continuing development of certain of our future product candidates or successfully commercializing or competing in the market for certain indications.

We currently collaborate with third-parties with respect to bempikibart. If any of our collaborators, licensors or licensees experience delays in performance of, or fail to perform their obligations under, their applicable agreements with us, disagree with our interpretation of the terms of such agreement or terminate their agreement with us, our pipeline of product candidates would be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators, licensors or licensees may have the right to terminate our agreements, in which event we may lose intellectual property rights, market or sell the products covered by such agreements or may face other penalties under such agreements. Our collaborators, licensors or licensees may also fail to properly maintain or defend the intellectual property we have licensed from them, or infringe upon other third party intellectual property rights, leading to the potential invalidation of such third party's intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive and could harm our ability to develop or commercialize our product candidates. Further, any of these relationships may require us to increase our near and long-term expenditures, issue securities that dilute our

existing stockholders or disrupt our management and business. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than under the agreements with us.

In the future, we may decide to collaborate with entities such as, but not limited to, non-profit organizations, universities, pharmaceutical and biotechnology companies for the development and potential commercialization of existing and new product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the U.S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, it may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to the market and generate product revenue.

The success of any potential collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions, include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with strategic partners because of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our company;

- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities, and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

We rely, and anticipate that we will rely, on third parties to assist in designing, conducting, supervising and monitoring our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely, and anticipate that we will rely, on third party clinical investigators, CROs, clinical data management organizations and consultants to help design, conduct, supervise and monitor preclinical studies and clinical trials of our product candidates. Because we rely on third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would if we conducted them on our own, including our inability to control whether sufficient resources are applied to our programs. If any of our CROs are acquired or consolidated, these concerns are likely to be exacerbated and our preclinical studies or clinical trials may be further impacted due to potential integration, streamlining, staffing and logistical changes. These investigators, CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. Further, these third parties may not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our preclinical and clinical development programs could be delayed and otherwise adversely affected. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA and other health authorities require certain preclinical studies to be conducted in accordance with GLP, and clinical trials to be conducted in accordance with GCP, including conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. If we or our CROs fail to comply with these requirements, the data generated in our clinical trials may be deemed unreliable or uninterpretable and the FDA and other health authorities may require us to perform additional clinical trials. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. In the U.S., we are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Any such event could adversely affect our business, financial condition, results of operations and prospects.

We rely on third parties in the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our product candidates.

We have not yet manufactured our product candidates on a commercial scale and may not be able to do so for any of our product candidates. We currently rely on third parties in the supply and manufacture of materials for our research, preclinical and clinical activities and may continue to do so for the foreseeable future, including if we received regulatory approval for any product candidate. We may do the same for the commercial supply of our drug product, if any. We use third parties to perform additional steps in the manufacturing process, such as the filling, finishing and labeling of vials and storage and shipping of our product candidates and we expect to do so for the foreseeable future. There can be no assurance that our supply of research, preclinical and clinical development drug candidates and other materials will not be limited, interrupted or restricted or will be of satisfactory quality or continue to be available at acceptable prices. Replacement of any of the third parties we may engage

could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, raw materials, reagents, and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available, may not be suitable or acceptable for use due to material or component defects, or may introduce variability into the supply of our product candidates. Furthermore, with the increase of companies developing fusion protein based antibodies and/or monoclonal antibodies, there may be increased competition for the supply of the raw materials that are necessary to make our fusion protein based antibodies and/or monoclonal antibodies, which could severely impact the manufacturing of our product candidates.

We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and they must be acceptable to the FDA or approved by foreign regulatory authorities. Suppliers and manufacturers, including us, must meet applicable manufacturing requirements, including compliance with cGMP regulations, and undergo rigorous facility and process validation tests required by regulatory authorities to comply with regulatory standards. In the event that any of our suppliers or manufacturers fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, some of which may be out of their or our control, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to increase the manufacturing of the materials ourselves, for which we currently have limited capabilities and resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. Any interruption of the development or operation of the manufacturing of our product candidates, such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility resulting from natural disasters, could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates or materials. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some cases of third parties on which we rely, depend on China-based suppliers or service producers for certain materials, products and services, or other activities. Our ability or the ability of the third parties we rely on to continue to engage these China-based suppliers or service providers for certain materials could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions.

In addition, we currently rely on foreign CROs and CDMOs, including WuXi Biologics, and will likely continue to rely on foreign CROs and CDMOs in the future. Foreign CDMOs may be subject to U.S. legislation, including, for example, legislation previously considered in the U.S. Congress (but not enacted) called the BIOSECURE Act, which would have prohibited the U.S. government from entering into contracts or providing grants or loans to procure biotechnology equipment and services provided or produced by so-called “biotechnology companies of concern.” It also would have prohibited the U.S. government from entering into contracts or providing grants or loans to entities that use biotechnology equipment or services provided or produced by “biotechnology companies of concern” in connection with such contracts, grants, or loans. An updated version of the BIOSECURE Act is currently being considered by Congress and, like the original version, this latest version includes a delayed implementation date to permit companies to wind down from impacted relationships. Any additional executive action, legislative action or potential sanctions with China could materially impact any Chinese vendor that we use and our agreements with them. In addition, foreign CDMOs may be subject to sanctions, tariffs, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to manufacture our product candidates.

We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties which could have a material adverse effect on our business prior to or after commercialization of any of our product candidates. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Failure to execute our manufacturing requirements, either by us or by one of our third-party vendors, could adversely affect our business.

Our relationships with healthcare providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, anti-bribery and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which it obtains marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations listed in the section above titled "Risk Factors—Risks Related to Government Regulation," including certain laws and regulations applicable only if we have marketed products.

Some state laws also require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Risks Related to Our Business, Personnel and Operations

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize bempikibart or other product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any product candidates before we receive regulatory approval from the applicable foreign regulatory authority and may never receive such regulatory approval for any product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of bempikibart or other product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of bempikibart or other product candidates will be harmed, and our business will be adversely affected. Moreover, even if we obtain approval of bempikibart or other product candidates and ultimately commercialize such product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. It is not always possible to identify and deter misconduct by these 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 these laws or regulations.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, third party service providers or consultants or potential future collaborators, may fail or suffer security incidents, data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, as well as other partners, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security incidents and data breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data including the theft, fraud, and subsequent misuse of employee credentials, wrongful conduct by insider employees or vendors, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, malicious codes, viruses, breakdown, wrongful intrusions, data breaches, and social engineering (including phishing attacks). Bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for us to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of bempikibart or other product candidates could be delayed.

As our employees work remotely and utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity threats, risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies or threats presented by malicious third parties.

We, like other organizations in our industry, have experienced and expect to experience cybersecurity incidents and threats to our infrastructure. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); increased investigation and compliance costs; financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our research and development activities, deter new customers from products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices or from disruptions in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We, and third parties with whom we work, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations. See the sections titled "*Business-Government Regulation-Data Privacy and Security*" and "*Other Regulatory Matters*" elsewhere in this Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.

Our use of new and evolving technologies, such as artificial intelligence ("AI"), may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate AI into our business processes both in our own development and implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain AI technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property and intellectual property infringement, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU began implementing the Artificial Intelligence Act (the "AI Act") on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high-risk AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The

scope of requirements depends on judicial interpretations and forthcoming legislative amendments, and non-compliance can lead to significant fines.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. If we develop or use AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. Bad actors around the world also use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we are unable to attract and retain qualified key management and scientists, staff, consultants and advisors, our ability to implement our business plan may be adversely affected.

We are highly dependent upon our senior management and our scientific, clinical and medical staff and advisors. The loss of the service of any of the members of our senior management or other key employees could delay our research and development programs and materially harm our business, financial condition, results of operations and prospects. In addition, we expect that we will continue to have an increased need to recruit and hire qualified personnel as we advance our programs and expand operations. Failure to successfully recruit and retain personnel could impact our anticipated development plans and timelines. We are dependent on the continued service of our technical personnel because of the highly technical and novel nature of our product candidates, platform and technologies and the specialized nature of the regulatory approval process. Replacing such personnel 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 successfully execute our business strategy, and we cannot assure you that we will be able to identify or employ qualified personnel for any such position on acceptable terms, if at all. Many of the biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. We do not maintain key person life insurance policies on any of our management team members or key employees. Our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in preclinical and clinical testing, manufacturing, governmental regulation and commercialization. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments may have a negative effect on our operating results. We face increased competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. If we are unable to attract and retain qualified personnel, the rate and success at which we may be able to discover and develop our product candidates and implement our business plan will be limited. Further, some of the qualified personnel that we hire and recruit are not U.S. citizens. Changes to U.S. immigration

policies, particularly to H-1B and other visa programs, could restrain the flow of technical and professional talent into the United States and may inhibit our ability to hire qualified personnel.

We expect to expand our research, development, delivery, manufacturing, commercialization, regulatory and future sales and marketing capabilities over time, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2025, we had 24 full-time employees, including 3 who hold Ph.D. degrees and 1 who holds an M.D. degree; 13 employees are engaged in research and development and 11 employees in management or general and administrative activities. In connection with the growth and advancement of our pipeline and operating as a public company, we expect to focus the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to retain qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our potential product candidates. If our management is unable to effectively manage the expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize any product candidates it may develop will depend in part on our ability to effectively manage the future development and our expansion.

General Risk Factors

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we believe we currently maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able

to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time, we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations with collaborators and intellectual property rights. Litigation to defend itself against claims by third parties, or to enforce any rights that we may have against third parties, may continue to be necessary, which could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, government shutdowns, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, international tariffs and uncertainty about economic stability. The Federal Reserve had raised interest rates multiple times in response to concerns about inflation until recently, and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. In addition, in early 2025, the U.S. imposed blanket 10% tariffs on virtually all imports to the U.S. and significantly higher tariffs applicable to imports from many countries, which have resulted in other countries imposing additional tariffs on imports from the U.S., and is likely to continue to result in more retaliatory tariffs. The U.S. Supreme Court invalidated the reciprocal tariffs on February 20, 2026; however, President Trump has stated that he intends to use other authorities to maintain historically elevated tariffs. Historically, increased tariffs have led to more trade and political tensions and the status of these agreements between the United States and the various countries, in light of the U.S. Supreme Court's February 20, 2026 decision, is not yet clear. While pharmaceutical end-products are currently excluded from certain tariffs, current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients ("APIs"), raw materials, laboratory equipment and research materials and components. In addition, the U.S. Department of Commerce is conducting a Section 232 investigation to assess the national security implications of pharmaceutical and API imports. The outcome of this investigation could result in additional trade restrictions, including tariffs, consistent with ongoing efforts to reshore pharmaceutical manufacturing. Further, the United States and the EU have announced the framework of a trade agreement that could impose a 15% tariff on most imports from the EU, including pharmaceutical products and inputs. However, the details of this trade agreement remain uncertain, including whether and to what extent such agreement may be impacted by the results of the Section 232 investigation. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. Similarly, global geopolitical disruptions, including civil or political unrest or military conflicts such as between Russia and Ukraine, in Israel and Gaza and U.S.'s rising tensions with China have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Since inception, we have incurred losses and may never achieve profitability. As of December 31, 2025 and December 31, 2024, we had federal and state net operating losses ("NOLs") of $423.3 million and $233.4 million, respectively. Under current law, our federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of its taxable income annually for tax years beginning after December 31, 2020. Federal NOLs generated in taxable years beginning before January 1, 2018, however, have a 20-year carryforward period, but are not subject to the 80% limitation. Our state NOLs expire at various dates from 2040 through 2045. As of December 31, 2025, we had federal research and development tax credit carryforwards of $6.3 million that expire at various

dates from 2041 through 2045. In addition, as of December 31, 2025, we had state research and development tax credit carryforwards of $2.4 million that expire at various dates from 2038 through 2045.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, or the Code, if a corporation undergoes an "ownership change," generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a rolling three-year period, the corporation's ability to use our pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset our post-change income or taxes may be limited. Similar rules may apply under state tax laws. Our prior equity offerings and other changes in our stock ownership may have resulted in such ownership changes in the past. We have not conducted a formal study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our inception. In addition, we may experience ownership changes in the future as a result of future securities offering or subsequent shifts in our stock ownership, some of which are outside of our control. As a result, even if we earn net taxable income in the future, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income or income taxes may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed by us. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. For example, the One Big Beautiful Bill Act ("OBBBA") was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and financial condition. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. In recent years, many changes to tax laws have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

In addition, since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U.S. Department of Treasury, the Federal Reserve Board (the "Federal Reserve"), and the FDIC released

a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, FDIC and Federal Reserve have announced a program to provide up to $25 billion of loans to financial institutions secured by certain government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments and help address liquidity pressures that may arise. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

At this time, we hold the majority of our cash on deposit at SVB (which has been assumed by First Citizens) and we have not experienced any adverse impact to our current and projected business operations, financial condition or results of operations as a result of the closure of SVB or any other banks. We have diversified our cash deposit holdings between multiple financial institutions. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened.

Although we have assessed our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations. In addition, one or more of our critical vendors, third party manufacturers, or other business partners could be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any business partner bankruptcy or insolvency, or any breach or default by a business partner, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for shares of Legacy Q32 capital stock. An active trading market for our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing securityholders of Homology and Legacy Q32 sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. As of December 31, 2025, we had 12,858,047 shares of common stock outstanding. Stockholders are not restricted from selling shares of our common stock held by them, other than by applicable securities laws. In addition, shares of common stock that are subject to outstanding options or warrants of Legacy Q32 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

The administrator of the 2024 Plan is authorized to exercise its discretion, and has exercised such discretion, to affect the repricing of stock options and there may be adverse consequences to our business due to the exercise of discretion by the administrator of the 2024 Plan.

Pursuant to our 2024 Plan, we are authorized to grant equity awards, including stock options, to our employees, directors and consultants. Our board of directors is the administrator of the 2024 Plan and is authorized to exercise its discretion to reduce the exercise price of stock options or effect the repricing of such awards. To provide added incentives to retain and motivate key contributors, our board of directors approved the Option Repricing in February 2025. As a result of such repricing or any potential future repricing, certain proxy advisory firms or institutional investors may be unsupportive of such actions and publicly criticize our compensation practices, and proxy advisory firms may recommend an "against" or "withhold" vote for members of our compensation committee. In addition, as we hold an advisory vote on named executive officer compensation (known as the "say-on-pay" vote) at the time of, or subsequent to, any such repricing, it is likely that proxy advisory firms would issue an "against" recommendation on our say-on-pay vote and institutional investors may not be supportive of our say-on-pay vote. If proxy advisory firms or institutional investors are successful in aligning their views with our broader stockholder base and we are required to make changes to the composition of our board and its committees, or if we need to make material changes to our compensation and corporate governance practices, our business might be disrupted and our stock price might be negatively impacted. Even if we are able to successfully rationalize the exercise of such discretionary power, defending against any "against" or "withhold" recommendation for members of our compensation committee, any "against" recommendation on our say on pay vote or public criticism could be distracting to management, and responding to such positions from such firms or investors, even if remedied, can be costly and time-consuming.

In addition, we have incurred costs, including accounting and administrative costs and attorneys' fees, and have recognized incremental compensation expense as a result of the option repricing conducted in February 2025, and may further incur significant costs or be required to recognize incremental compensation expense as a result of any potential future repricing, even absent negative reactions from proxy advisory firms and institutional investors. These actions could cause our stock price to decrease and experience periods of increased volatility, which could result in material adverse consequences to our business.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of December 31, 2025, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 56.4% of our outstanding shares of common stock. As a result, if these stockholders were to 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 stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability, as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Annual Report:

- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts.
- We face competition from entities that have developed or may develop programs for the diseases we plan to address with bempikibart or other product candidates.
- Bempikibart and the rest of our pipeline are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on the success of our most advanced product candidate, bempikibart, and our clinical trials of our lead candidate may not be successful.
- Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.
- If we are unable to attract and retain qualified key management and scientists, staff, consultants and advisors, our ability to implement our business plan may be adversely affected.

Due to the various factors mentioned herein, and others, the results of any of our prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

Our financial results may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. Our stock price may also decline as a result of unexpected clinical trial results in one or more of our ongoing or future clinical trials.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of these resources may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources.

Unfavorable global economic conditions could adversely affect our business, financial condition, results of operations or cash flows.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our certificate of incorporation and bylaws and the provisions under Delaware law could make an acquisition of our company more difficult and may prevent attempts by our stockholders to replace or remove out management.

Provisions in our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their 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 will be 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:

- establish a classified board of directors such that all members of the board are not elected at one time;
- do not provide for cumulative voting in the election of directors;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- provide that only the board of directors may fill vacancies on the board of directors created by the expansion of the board of directors or the resignation, death or removal of a director;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue 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 stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding voting stock from merging or combining with us. Although Homology and Legacy Q32 believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees of the company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which for purposes of this risk factor refers to herein as the "Delaware Forum Provision." The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act and the Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which for purposes of this risk factor is referred to herein as the "Federal Forum Provision." In addition, our certificate of incorporation and bylaws that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that

stockholders cannot and will not be deemed to have waived its compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

On May 19, 2025, we received written notice (the "Notice") from the listing qualifications staff of the Nasdaq Stock Market LLC (the "Staff") notifying us that, based on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, which reported our stockholders' equity (deficit) of approximately ($4.0 million), we were no longer in compliance with the minimum stockholders' equity requirement of $2.5 million for continued listing on the Nasdaq Capital Market per Listing Rule 5550(b)(1). Additionally, the Notice also stated that as of May 19, 2025, we did not meet the alternatives of market value of listed securities of $35.0 million per Listing Rule 5550(b)(2) or net income from continuing operations of $0.5 million in our most recently completed fiscal year or in two of our three most recently completed fiscal years per Listing Rule 5550(b)(3), and as such, we did not comply with the Listing Rule 5550 for continued listing on the Nasdaq Capital Market.

Our equity (deficit) was negatively impacted by the accounting treatment associated with the re-acquisition of bempikibart from Amgen in the fourth quarter of 2023. In 2022, Legacy Q32 and Horizon entered into the Horizon Collaboration Agreement to develop bempikibart in autoimmune diseases, pursuant to which Legacy Q32 received $55.0 million from Horizon, and Horizon had an option to acquire the bempikibart program at a prespecified price, subject to certain adjustments. In October 2023, Amgen completed its acquisition of Horizon plc. Following the closing of Amgen's acquisition of Horizon plc, Legacy Q32 and Horizon entered into the Horizon Termination Agreement, pursuant to which Horizon's option to acquire bempikibart was terminated. As a result, the Company retained all initial consideration and development funding received and agreed to pay Horizon regulatory and sales milestone payments of up to an aggregate amount of $75.1 million upon the first achievement of certain regulatory and sales milestones with respect to bempikibart. As a result of the Horizon Termination Agreement, we recorded a $55.0 million refund liability associated with the cash received by Horizon in 2022.

On November 7, 2025, we and Amgen entered into an amendment to the Horizon Termination Agreement (the "Amgen Amendment") pursuant to which we issued Horizon a one-time equity grant of 553,695 shares of the Company's common stock as full consideration of the milestone payments outlined in the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, we have no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. Therefore, we derecognized the refund liability previously recorded for the $55.0 million of cash received under the Horizon Collaboration Agreement. The completion of the transactions increases our stockholders' equity by $55.0 million, which brings us back into compliance with the minimum stockholders' equity listing requirement for continued listing on the Nasdaq Capital Market per Listing Rule 5550(b)(1).

On November 18, 2025, we received Notice from the Staff indicating that based on the disclosure in our Quarterly Report on Form 10-Q for the period ended September 30, 2025, we are in compliance with the stockholders' equity requirement for continued listing on the Nasdaq Capital Market per Listing Rule 5550(b)(1).

Should we fail to satisfy other continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum share price requirement, or fail to regain compliance with Listing Rule 550(b)(1), Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum share price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from Nasdaq for any reason, and are quoted on the over-the-counter bulletin board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We designed and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF").

Our cybersecurity risk management program is integrated into our overall risk management program, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas.

We leverage the support of third-party information technology and security providers, including for periodic security testing, as part of our risk management process, designed to identify, assess, and manage cybersecurity risks. We maintain an incident response and notification plan designed to assist us in identifying, responding to, and recovering from cybersecurity incidents, and we have a process to assess the security practices of certain third-party vendors. We have also engaged a third-party with specialized expertise in cybersecurity to conduct an audit, which resulted in no notable findings, and reported the results to the Audit Committee.

We, like other companies in our industry, face a number of cybersecurity risks in connection with our business. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we and/or our vendors have, from time to time, experienced threats to, or security incidents, related to our data and systems or that had the potential to otherwise impact our business.

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (the "Committee") oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program.

The Committee receives periodic reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any significant cybersecurity incidents.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also periodically receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from our management team as part of the Board's continuing education on topics that impact public companies.

Our management team, with the assistance of the Company's third-party information technology providers, is responsible for assessing and managing our material risks from cybersecurity threats. Internal personnel, including our Senior Vice President, Finance, have primary responsibility for our overall cybersecurity risk management program and supervise both our internal cybersecurity personnel and our retained external cybersecurity consultants. Members of our senior management do not have direct cybersecurity expertise obtained through certifications, but their experience managing the Company, which includes consulting and coordinating as necessary with third-party information technology and cybersecurity experts, enables them to assess and manage material risks from cybersecurity threats.

Our management team stays informed about and monitors efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include: briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources; and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties.

Our principal office is located at 830 Winter Street, Waltham, Massachusetts 02451, where we lease approximately 15,771 square feet of office space. The lease term began in January 2022 and will end in December 2031. We believe that this facility will be adequate to meet our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on commercially reasonable terms to accommodate any such expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. 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 is currently listed on the Nasdaq Capital Market under the symbol "QTTB." Prior to the consummation of the Merger, the common stock was listed on the Nasdaq Global Select Market under the symbol "FIXX."

Holders

As of March 1, 2026, we had approximately 14,629,463 shares of common stock issued and outstanding held of record by approximately 23 registered holders. The number of holders of record does not include a substantially greater number of "street name" holders or beneficial holders whose shares of Company common stock are held of record by banks, brokers and other financial institutions.

Dividends

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

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.

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 year ended December 31, 2025.

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 together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report on Form 10-K.

Unless otherwise indicated or the context otherwise requires, references to "Legacy Q32" refers to the business and operations of Q32 Bio Operations Inc. (previously Q32 Bio Inc.) and its consolidated subsidiaries prior to the Merger, and references to "the Company," "we," "us," "our" and other similar terms refer to the business and operations of Q32 Bio Inc. (previously Homology Medicines, Inc., or Homology) and its consolidated subsidiary following the Merger.

Overview

We are a clinical stage biotechnology company focused on developing novel biologics to effectively and safely restore healthy immune balance in patients with alopecia areata ("AA") and other autoimmune and inflammatory diseases driven by pathological immune dysfunction.

Bempikibart (ADX-914)

Bempikibart (ADX-914), our most advanced product candidate, is a fully human anti–interleukin-7 receptor alpha ("IL-7Rα"), antagonist monoclonal antibody designed to re-regulate adaptive immune function by potently blocking signaling mediated by interleukin-7 ("IL-7"), and thymic stromal lymphopoietin ("TSLP"). We have completed two Phase 2a clinical trials evaluating bempikibart, SIGNAL-AA Part A, for the treatment of AA, and SIGNAL-AD, for the treatment of atopic dermatitis ("AD").

In December 2024, we announced topline results from both of these trials, as well as our intention to advance bempikibart for the treatment of AA. In April 2025, we announced dosing of the first patients in both the Part A open-label extension and Part B of the SIGNAL-AA Phase 2a clinical trial and in October 2025, we announced completion of enrollment in SIGNAL-AA Part B. Bempikibart is being evaluated for the treatment of AA in the ongoing Part B of the SIGNAL-AA Phase 2a clinical trial. Enrollment has been completed in the Part B portion of the clinical trial, with 33 patients enrolled and dosing remains ongoing. We expect to report 36-week topline data from the SIGNAL-AA Part B trial in mid-2026.

Patients in the SIGNAL Phase 2a clinical trials were dosed with 200mg subcutaneous ("SC") bempikibart every two weeks. In SIGNAL-AA Part A, 44 patients with severe and very severe AA were enrolled. Patients were dosed for 24 weeks and followed for an additional 12 weeks following the end of treatment. At the 24-week endpoint, we observed more hair regrowth compared to placebo and evidence of durable responses in patients. The average hair regrowth across patients in the trial continued to improve from week 24 to week 36 despite patients being off therapy during the 12-week follow-up period. In AD, bempikibart was evaluated in two parts, Part A (15 patients) and Part B (106 patients). While encouraging results were seen in Part A, the primary endpoint was not met in Part B.

Across the trials, at the 200mg Phase 2a dose, we achieved our desired receptor occupancy ("RO") and observed favorable pharmacokinetics ("PK") / pharmacodynamic ("PD") properties, consistent with those from the Phase 1 clinical trial. Minimal anti-drug antibodies ("ADAs") were observed in the trials.

In addition, across the two trials, we observed changes in biomarkers consistent with the IL-7Rα mechanism and activity mediated by both the TSLP and IL-7 receptors. In the SIGNAL-AD trial, we observed meaningful decreases in key Th2 biomarkers of TARC, IgE, and eosinophils, each of which were statistically significant at multiple timepoints suggestive of potent TSLP inhibition. In the SIGNAL-AA trial, we observed a CD3+ T cell decrease, which was also statistically significant at multiple timepoints, suggestive of potent IL-7 inhibition. These findings were consistent with expected target engagement and IL-7Rα blockade. Across all clinical trials, bempikibart has been dosed in over 150 participants to-date and has demonstrated a favorable safety and tolerability profile, with no Grade 3 or higher related adverse events.

The Part B portion of SIGNAL-AA is an open-label clinical trial dosing severe or very severe AA patients with a maximum duration of current episode of four years. Patients will be treated with bempikibart for 36 weeks, with follow-up out to 52 weeks. Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, followed by a maintenance dose of 200mg every-other-week over a 32-week period for a total dosing period of 36 weeks. Efficacy will be

evaluated on the basis of mean percentage change from baseline in Severity of Alopecia Tool ("SALT") scores as well as the proportion of subjects achieving various relative and absolute SALT score improvements at week 36, with follow-up through week 52. The trial is intended to support advancement into pivotal trials upon completion, pending review of the results. We expect to report 36-week topline data from the SIGNAL-AA Part B trial in mid-2026.

In April 2025, we announced that the FDA has granted Fast Track designation ("FTD") to bempikibart for the treatment of AA. FTD is a process designed to facilitate the development and expedite the review of new drugs to treat serious diseases and fill an unmet medical need with the purpose of getting important new drugs to patients earlier. A drug that receives FTD may be eligible for more frequent meetings and communications with the FDA to discuss development plans and ensure the collection of appropriate data needed to support approval and for a rolling review of an application for marketing approval.

ADX-097

In addition to bempikibart, our strategy has been focused on the advancement of our proprietary tissue-targeted complement inhibitor platform. ADX-097, a Phase 2 asset from this platform, is a humanized anti-C3d monoclonal antibody ("mAb") fusion protein that completed Phase 1 clinical trials. However, in February 2025, we announced a corporate restructuring to focus on the advancement of bempikibart for the treatment of patients with AA. On November 28, 2025, we entered into an Asset Purchase Agreement with Akebia Therapeutics, Inc. ("Akebia") pursuant to which we sold to Akebia substantially all of our assets related to the research, development, manufacture and commercialization of ADX-097 (the "ADX-097 Asset Sale"). Following the ADX-097 Asset Sale, Akebia is now responsible for any future development and commercialization of ADX-097. As consideration for the ADX-097 Asset Sale, we received an upfront payment of $7.0 million and will receive a payment of $3.0 million on the six-month anniversary of the transaction. We will also receive a near-term milestone payment of $2.0 million upon the earlier of achievement of the first milestone under the Asset Purchase Agreement or December 31, 2026. In addition to these payments, we are eligible to receive up to $580 million upon the achievement of specified milestones, including up to $92.5 million related to development and regulatory milestones and up to $487.5 million related to commercial milestones. We are also eligible to receive tiered royalties on potential future sales of ADX-097 ranging from low single-digit to mid-teen percentages of annual net sales. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

ADX-096/Complement Inhibitor Platform

In addition to ADX-097, we developed a proprietary tissue-targeted complement platform, which is designed to inhibit complement activation in the tissue while minimizing systemic complement blockade, a key differentiator versus current complement therapeutics. Other assets developed from our proprietary platform include ADX-096, a C3d mAb – $CR_{11\text{-}10}$ fusion protein with preclinical data supportive of its use in ophthalmologic indications as well as potential utility in a broad range of other indications, and C3d mAb fusions and nanobodies designed for tissue-targeted complement inhibition. We retain the rights to our wholly owned tissue-targeted complement inhibitor platform, including ADX-096 and other remaining early-stage assets, and are continuing to evaluate strategic options for these programs.

Rights to Bempikibart

From August 2022 until November 2023, Legacy Q32 was a party to the Collaboration and Option Agreement (the "Horizon Collaboration Agreement") and the Asset Purchase Agreement (the "Purchase Agreement", and together with the Horizon Collaboration Agreement, the "Horizon Agreements"), each between Legacy Q32 and Horizon Therapeutics Ireland DAC ("Horizon"), pursuant to which Legacy Q32 received $55.0 million in initial consideration and staged development funding to complete two ongoing Phase 2 trials for bempikibart, and granted Horizon an option to acquire the bempikibart program at a prespecified price, subject to certain adjustments.

In October 2023, Amgen Inc. ("Amgen") completed the acquisition of Horizon Therapeutics public limited company ("Horizon plc"). Following the acquisition, Legacy Q32 agreed with Amgen to mutually terminate the Horizon Agreements. In November 2023, Legacy Q32 entered into a termination agreement with Horizon (the "Horizon Termination Agreement"), pursuant to which Horizon's option to acquire the bempikibart program was terminated. As a result, Legacy Q32 retained the initial consideration and development funding received under the Horizon Collaboration Agreement and regained full development and commercial rights to bempikibart. In consideration for the Horizon Termination Agreement, Legacy Q32 agreed to pay Horizon regulatory and sales milestone payments of up to an aggregate amount of $75.1 million upon the first achievement of certain regulatory and sales milestones with respect to bempikibart.

These potential payments to Horizon are not in exchange for a distinct good or service and therefore, we accounted for consideration payable to Horizon as a reduction of the transaction price under the Financial Accounting Standards Board

("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). We concluded that the $55.0 million of arrangement consideration previously recognized should be fully constrained as a result of the contingent consideration payable to Horizon, and accordingly, the amounts previously recognized were reversed in the fourth quarter of 2023 and a refund liability was established for the $55.0 million cash received during the term of the Horizon Collaboration Agreement.

On November 7, 2025, we entered into an amendment to the Horizon Termination Agreement (the "Amgen Amendment") with Amgen pursuant to which we issued Horizon a one-time equity grant of 553,695 shares of our common stock as full consideration of the milestone payments under the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, we have no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. Therefore, we derecognized the refund liability previously recorded for the $55.0 million of cash received under the Horizon Collaboration Agreement and recognized collaboration arrangement revenue for the difference between the equity issuance, and the refund liability as the consideration was no longer constrained.

Merger with Homology and Pre-Closing Financing

On November 16, 2023, Legacy Q32 entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Homology and Kenobi Merger Sub, Inc., a wholly-owned subsidiary of Homology ("Merger Sub"). The Merger was completed on March 25, 2024. Pursuant to the Merger Agreement, Merger Sub merged with and into Legacy Q32, with Legacy Q32 continuing as the surviving company and as a wholly-owned subsidiary of Homology (the "Merger"). Homology changed its name to Q32 Bio Inc. ("Q32"), and Legacy Q32, which remains as a wholly-owned subsidiary of Q32, changed its name to Q32 Bio Operations Inc. On March 26, 2024, the combined company's common stock began trading on the Nasdaq Global Market under the ticker symbol "QTTB." The business of Legacy Q32 continues as the business of the combined company. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended. In connection with the Merger Agreement, certain parties entered into a subscription agreement with us to purchase shares of our common stock for an aggregate purchase price of $42.0 million (the "Pre-Closing Financing").

On March 25, 2024 (the "Closing Date"), following approval by our stockholders and by Homology's stockholders, the Pre-Closing Financing closed immediately prior to the consummation of the Merger. Shares of Legacy Q32's common stock issued pursuant to the Pre-Closing Financing were converted into the right to receive 1,682,045 shares of Homology common stock after taking into account the Reverse Stock Split. On March 25, 2024, in connection with, and prior to the completion of the Merger, Homology effected a one-for-eighteen reverse stock split (the "Reverse Stock Split") of its then outstanding common stock. Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, which was March 25, 2024, all issued and outstanding shares of the Legacy Q32's common stock (including common stock issued upon the conversion of all Legacy Q32's Series A, Series A-1 and Series B preferred stock, conversion of Legacy Q32 convertible notes, but excluding the common stock issued in Pre-Closing Financing) converted into the right to receive 7,017,842 shares of Homology's common stock based on the final exchange ratio of 0.0480 (the "Exchange Ratio"). Lastly, each option to purchase Legacy Q32's shares that was outstanding and unexercised immediately prior to the effective time of the Merger was converted into an option to purchase shares of Homology common stock based on the final Exchange Ratio. Immediately following the Merger, Legacy Q32 stockholders owned approximately 74.4% of the outstanding common stock of the combined company.

The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America ("GAAP"). For accounting purposes, Legacy Q32 is considered the accounting acquirer and Homology is the acquired company based on the terms of the Merger Agreement and other factors, such as relative voting rights and the composition of the combined company's board of directors and senior management. Accordingly, the Merger was treated as the equivalent of Legacy Q32's issuing stock to acquire the net assets of Homology. As a result of the Merger, the net assets of Homology were recorded at their acquisition-date fair value in the financial statements of the combined company and the reported operating results prior to the Merger are those of Legacy Q32. Legacy Q32's historical financial statements became the historical consolidated financial statements of the combined company. All issued and outstanding Legacy Q32 common stock, convertible preferred stock and options prior to the effective date of the Merger have been retroactively adjusted to reflect the Exchange Ratio, which reflects the impact of the reverse stock split, for all periods presented.

At the effective time of the Merger, each person who as of immediately prior to the effective time of the Merger was a stockholder of record of Homology or had the right to receive Homology's common stock received a contractual contingent value right ("CVR"), issued by Homology subject to and in accordance with the terms and conditions of a Contingent Value Rights Agreement between Homology and the rights agent (the "CVR Agreement"), representing the contractual right to receive

cash payments from the combined company upon the receipt of certain proceeds from a disposition of Homology's pre-merger assets, calculated in accordance with the CVR Agreement.

Financial Overview

As of December 31, 2025, we had cash and cash equivalents of $48.3 million. We expect that our cash and cash equivalents, combined with gross proceeds from our registered direct offering completed in February 2026 and guaranteed near-term milestone payments from the ADX-097 Asset Sale, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2027. This estimate is based on assumptions that may prove to be wrong, and we could use our capital resources sooner than currently anticipated.

We do not expect our existing cash and cash equivalents will be sufficient for us to advance any of our programs through regulatory approval, and we will need to raise additional capital to complete the development and potential commercialization of any of our programs. We may also use a portion of our cash and cash equivalents to acquire, in-license or invest in products, technologies or businesses that are complementary to our business. The amounts and timing of actual expenditures will depend on numerous factors, including the progress of development efforts, operating costs and other factors described under "Risk Factors" in this Annual Report on Form 10-K.

The expected use of proceeds represents current intentions based upon present plans and business conditions. As of the date of this Annual Report on Form 10-K, we cannot predict with complete certainty all of the particular uses for our current cash and cash equivalents or the actual amounts that we will spend on the uses set forth above.

Components of Results of Operations

Revenue

Since its inception, Legacy Q32 has not generated any revenue from product sales, and our management does not expect the combined company to generate any revenue from the sale of products in the foreseeable future.

Legacy Q32 entered into the Horizon Agreements on August 12, 2022. Per the terms of the Horizon Collaboration Agreement, Legacy Q32 received a total of $55.0 million upon initiation of certain development activities associated with the planned clinical trials and related activities. Prior to its termination, the Purchase Agreement also provided Horizon the option to purchase bempikibart, which would have triggered a prespecified payment to Legacy Q32, if exercised. Legacy Q32 was also entitled to receive from Horizon additional payments based on the achievement of future development and regulatory milestones as well as royalty payments on annual net sales.

Prior to the Horizon Termination Agreement, Legacy Q32 concluded that the arrangement was within the scope of ASC 606. Specifically, Legacy Q32 concluded that the research services required to be performed as part of the Horizon Collaboration Agreement represented an output of Legacy Q32's ordinary activities, and this represented a contract with a customer. At the commencement of the collaboration arrangement with Horizon, Legacy Q32 identified two performance obligations related to the development activities of bempikibart, one of each of the specified clinical trials in AD and AA, with each composing the services related to the clinical trial and other related development activity. Legacy Q32 also identified a material right related to the option for Horizon to purchase bempikibart. The material right was considered a separate performance obligation pursuant to the provisions of ASC 606. Legacy Q32 determined the transaction price to be $55.0 million which it allocated to the three performance obligations based on the estimated stand-alone selling price of each performance obligation. Legacy Q32 concluded that the consideration allocated to the research service performance obligations should be recognized over time as Horizon received the benefit of the research activities as the activities were performed. Legacy Q32 determined that this method was most appropriate as progress towards completion of research is largely driven by time and effort spent and costs incurred to perform this research. As of December 31, 2023, Legacy Q32 had received the full $55.0 million, which the combined company retains. The Horizon Termination Agreement was accounted for as a modification because it did not result in the addition of distinct goods or services. Since the two performance obligations and the material right are terminated with no further performance obligations aside from the contingent payments to Horizon of up to $75.1 million, Legacy Q32 recognized the remaining deferred revenue in the fourth quarter of 2023.

Upon the execution of the Horizon Termination Agreement, Legacy Q32 became obligated to pay Horizon up to $75.1 million contingent on regulatory and sales-based milestones, consisting of a $5.0 million payment upon the first regulatory approval in the U.S. or in any of five specified major western European markets, and up to $70.1 million ranging from mid-single digit to low-double digit millions of dollars upon the achievement of specified annual sales thresholds, which range from

exceeding $250 million to exceeding $1.5 billion. If bempikibart does not achieve the milestones set forth in the Horizon Termination Agreement, the Company will not be obligated to make any payments nor repay any amounts to Horizon.

These potential payments to the customer were not in exchange for a distinct good or service; therefore, we accounted for the consideration payable to a customer as a reduction of the transaction price under ASC 606. Legacy Q32 concluded that the $55.0 million of arrangement consideration previously recognized should be fully constrained as a result of the contingent consideration payable to the customer, and accordingly, all amounts previously recognized as revenue were reversed in the fourth quarter of 2023 and a refund liability was established for the $55.0 million cash received during the term of the collaboration agreement.

On November 7, 2025, we entered into the Amgen Amendment pursuant to which we issued Horizon a one-time equity grant of 553,695 shares of our common stock as full consideration of the milestone payments outlined in the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, we have no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. Therefore, we derecognized the refund liability previously recorded for the $55.0 million of cash received under the Horizon Collaboration Agreement and recognized collaboration arrangement revenue for the difference between the equity issuance, and the refund liability as the consideration was no longer constrained.

Operating Expenses

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 account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates. External expenses include:

- expenses incurred in connection with our research and development activities, including costs related to agreements with third parties such as consultants, contractors and clinical research organizations (“CROs”);
- costs related to contract development and manufacturing organizations (“CDMOs”), that are primarily engaged to provide drug substance and product for our preclinical studies, clinical trials and research and development programs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- costs related to compliance with quality and regulatory requirements;
- employee-related expenses, including salaries, benefits, and stock-based compensation expense, for personnel engaged in research and development functions;
- facilities-related expenses, depreciation, supplies, travel expenses and other allocated expenses; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Costs are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and may be reflected in our consolidated financial statements as prepaid or accrued expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed or when it is no longer expected that the goods will be delivered or the services rendered.

We do not allocate direct external research and development costs to specific programs or product candidates until there is an internally designated development candidate. We typically use our employee and infrastructure resources across our product candidates and development programs. We do not allocate personnel costs or other internal costs to research and development programs and product candidates.

We expect that future changes to our research and development expenses will depend significantly on the success of our clinical data. We expect that research and development expenses will increase substantially as we continue to advance our

programs into and through clinical development. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any product candidates. A change in the outcome of any number of variables with respect to product candidates we may develop could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidates we may develop. The successful development of any product candidate is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the ability to raise additional funds necessary to complete clinical development of and commercialize our product candidates;
- the successful initiation, enrollment and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates;
- the availability of raw materials for use in production of our product candidates;
- establishing agreements with third-party manufacturers for supply of product candidate components for our clinical trials;
- our ability to maintain our current research and development programs and to establish new programs;
- significant and changing government regulations;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our other rights in our intellectual property portfolio;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- obtaining and maintaining third-party insurance coverage and adequate reimbursement for any approved products.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, bonuses, related benefits, and stock-based compensation expense for personnel in executive, finance, and administrative functions; professional fees for corporate legal and patent matters, consulting, accounting, and audit services; and travel expenses, insurance, technology costs and other allocated expenses. General and administrative expenses also include corporate facility costs, including rent, utilities, depreciation, and maintenance, not otherwise included in research and development expense. We recognize general and administrative expenses in the periods in which they are incurred. General and administrative expenses are expected to increase as we continue to operate as a public company.

Change in Fair Value of Convertible Notes

Legacy Q32 recognized a liability as a result of the issuance of convertible promissory notes (the "Convertible Notes"). We account for all convertible notes issued under the fair value option election of FASB ASC Topic 825, *Financial Instruments* ("ASC 825"). The financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized within other income (expense), net in the accompanying consolidated statements of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss, if any.

Upon closing of the Merger, Legacy Q32 converted the outstanding Convertible Notes plus accrued interest into shares of common stock at 90% of the purchase price of the mandatory conversion event. As the Convertible Notes are recorded at fair value, a noncash gain of $15.9 million on the change in fair value prior to the conversion of convertible notes is reflected in the consolidated statement of operation for the year ended December 31, 2024.

Gain on Sale of Asset

On November 28, 2025, we completed the ADX-097 Asset Sale. As consideration for the ADX-097 Asset Sale, we received an upfront payment of $7.0 million and will receive a payment of $3.0 million on the six-month anniversary of the transaction. We will also receive a near-term milestone payment of $2.0 million upon the earlier of achievement of the first milestone under the Asset Purchase Agreement or December 31, 2026. In addition to these payments, we are eligible to receive up to $580 million upon the achievement of specified milestones and tiered royalties on potential future sales of ADX-097. We accounted for the transaction as an asset sale and recognized $11.7 million, comprised of $12.0 million in guaranteed upfront and near-term milestones less certain contractual offsets, as a gain on sale of asset included in other income (expense) in the consolidated statements of operations in the fourth quarter of 2025. Any future milestones and royalties will be recognized when achieved.

Other Income (Expense), Net

Other income (expense), net consists of interest income primarily earned on money market fund accounts and interest expense related to our debt obligations. We use the cost method to account for an investment in an entity in which we do not have the ability to exercise significant influence over operating and financial policies. Investments recorded using the cost method are assessed for any decrease in value that has occurred that is other than temporary and the other than temporary decrease in value is recognized in other income (expense), net. We recognize the change in fair value of the CVR liability in other income (expense), net.

Income Taxes

Since inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for earned research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2025, we had federal and state net operating loss carryforwards of $217.4 million and $205.9 million, respectively. The federal NOLs are not subject to expiration and the state NOLs expire at various dates beginning in 2040. As of December 31, 2025, we also had federal and state research and development tax credit carryforwards of $6.3 million and $2.4 million, respectively, that expire at various dates beginning in 2038.

Loss from Equity Method Investment

We use the equity method of accounting to account for an investment in an entity that we do not control, but in which we have the ability to exercise significant influence over operating and financial policies. Our proportionate share of the net income or loss of the entity is recorded as loss from equity method investment. Prior to May 22, 2024, we accounted for our investment in Oxford Biomedica (US) LLC (“OXB (US) LLC”) using the equity method of accounting and recorded our share of gains or losses from OXB (US) LLC on a quarterly basis.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Collaboration arrangement revenue	$ 53,737	$ —	$ 53,737
Operating expenses:			
Research and development	19,156	48,143	(28,987)
General and administrative	17,679	17,959	(280)
Total operating expenses	36,835	66,102	(29,267)
Income (loss) from operations	16,902	(66,102)	83,004
Change in fair value of convertible notes	—	15,890	(15,890)
Gain on sale of asset	11,737	—	11,737
Other income (expense), net	1,182	4,125	(2,943)
Total other income (expense), net	12,919	20,015	(7,096)
Income (loss) before provision for income taxes and loss from equity method investment	29,821	(46,087)	75,908
Provision for income taxes	—	(21)	21
Loss from equity method investment	—	(1,625)	1,625
Net income (loss)	$ 29,821	$ (47,733)	$ 77,554

Collaboration Arrangement Revenue

Collaboration arrangement revenue for the year ended December 31, 2025, is comprised of the recognition of $53.7 million of non-cash revenue related to the Amgen Amendment, which effectively terminated all obligations to and from Amgen, and is therefore not expected to continue in future years. See further discussion under “Revenue” above. There was no revenue recognized for the year ended December 31, 2024.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Direct research and development expense by program:			
Bempikibart	$ 6,713	$ 28,726	$ (22,013)
ADX-097	1,920	5,253	(3,333)
Discovery and other	155	856	(701)
Unallocated expenses:			
Personnel-related and consulting (including stock-based compensation)	7,778	10,435	(2,657)
Indirect research and development expense	2,590	2,873	(283)
Total research and development expenses	$ 19,156	$ 48,143	$ (28,987)

Research and development expenses were $19.2 million for the year ended December 31, 2025, compared to $48.1 million for the year ended December 31, 2024. The decrease of $29.0 million was primarily due to decreased bempikibart program expenses of $22.0 million due to lower clinical costs and lower costs related to manufacturing clinical trial materials, as well as higher costs in the prior year since we were advancing clinical trials for both AA and AD. ADX-097 program expenses decreased by $3.3 million primarily due to the discontinuation of the Phase 2 renal basket clinical trial of ADX-097 in the first quarter of 2025 and the ADX-097 Asset Sale in November 2025.

The decrease in personnel-related and consultant costs was primarily related to lower headcount as compared to the same period in the prior year. Personnel-related and consultant costs for the year ended December 31, 2025 and 2024 included stock-based compensation expense of $0.9 million and $1.1 million, respectively.

General and Administrative Expenses

General and administrative expenses were $17.7 million for the year ended December 31, 2025, compared to $18.0 million for the year ended December 31, 2024. The decrease of $0.3 million was primarily due to decreased personnel-related costs as a result of reduced headcount in the year ended December 31, 2025 associated with the restructuring in February 2025, as well as decreased consulting costs as compared to the prior year, partially offset by higher legal and insurance expense. General and administrative expenses include stock-based compensation expense of $4.3 million and $3.3 million for the years ended December 31, 2025 and 2024, respectively.

Change in Fair Value of Convertible Notes

Upon closing of the Merger in March 2024, Legacy Q32 converted its outstanding Convertible Notes plus accrued interest into shares of common stock at 90% of the purchase price of the mandatory conversion event. As the Convertible Notes are recorded at fair value, a gain of $15.9 million on the change in fair value prior to the conversion of the Convertible Notes is reflected in the consolidated statement of operation for the year ended December 31, 2024.

Gain on Sale of Asset

We recognized an $11.7 million gain related to the ADX-097 Asset Sale to Akebia for the year ended December 31, 2025, as compared to none for the year ended December 31, 2024. See further discussion under “Gain on Sale of Asset” above.

Other Income (Expense), Net

Other income (expense), net was $1.1 million for the year ended December 31, 2025, compared to $4.1 million for the year ended December 31, 2024. Other income (expense), net for the year ended December 31, 2025 includes interest income of $2.2 million as well as a gain recorded for the change in fair value of the CVR liability of $0.4 million. These amounts are partially offset by interest expense of $1.1 million on our venture debt. Other income (expense), net for the year ended December 31, 2024 includes interest income of $3.9 million, as well as a gain recorded for the change in fair value of the CVR liability of $2.2 million. These amounts are partially offset by interest expense of $1.1 million on our venture debt and an other-than-temporary impairment charge of approximately $0.7 million we recorded because it was determined that the fair value of our equity investment in OXB (US) LLC was less than its carrying value. The decrease in other income (expense), net is primarily due to a smaller gain recorded in the current year for the change in fair value of the CVR liability as compared to the prior year, as well as lower interest income as a result of a lower average cash balance at December 31, 2025.

Provision for Income Taxes

Provision for income taxes was less than $0.1 million for the year ended December 31, 2024. There was no provision for income taxes recorded for the year ended December 31, 2025.

Since inception, we have not recorded any U.S. federal or state income tax benefits for net losses incurred in each year or for earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2025, we have had no gross unrecognized tax benefits.

Loss from Equity Method Investment

Prior to May 22, 2024, we accounted for our investment in OXB (US) LLC using the equity method of accounting and recorded our share of gains or losses from OXB (US) LLC on a quarterly basis. For the year ended December 31, 2024, we recorded a loss from equity method investment of $1.6 million, representing our share of OXB (US) LLC’s net loss. See Notes 2 and 7 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information regarding the equity method of accounting.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have funded our operations primarily through proceeds from the sales of our convertible preferred stock and convertible notes, as well as proceeds from our venture debt, the ADX-097 Asset Sale, the Horizon Collaboration Agreement, the Merger with Homology and accompanying Pre-Closing Financing. From inception through December 31, 2025, we have raised $136.0 million in aggregate cash proceeds, net of issuance costs, from the sale of our convertible preferred stock and convertible notes. In addition, we received $55.0 million in payments under the Horizon Collaboration Agreement, $12.5 million in proceeds from our venture debt, $61.3 million, net of issuance costs, in connection with the Merger with Homology, $42.0 million pursuant to the Pre-Closing Financing and $7.0 million pursuant to the ADX-097 Asset Sale. As of December 31, 2025, we had cash and cash equivalents of $48.3 million.

Going Concern

We have incurred significant operating losses since inception and, as of December 31, 2025, had an accumulated deficit of $205.0 million. We expect negative cash flows from operations and net losses for the foreseeable future as we continue to invest significantly in research and development of our product candidates and platform. We have not yet commercialized any product and do not expect to generate revenue from sales of any products for several years, if at all.

As of December 31, 2025, we had cash and cash equivalents of $48.3 million. We expect that our cash and cash equivalents as of December 31, 2025, combined with gross proceeds from our registered direct offering completed in February 2026 and guaranteed near-term milestone payments from the ADX-097 Asset Sale, will be sufficient to fund our operations into the fourth quarter of 2027. Management based its projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than management expects. We expect to seek to raise additional capital through private or public equity or debt financings, loans or other capital sources, which could include collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants, and may be required to seek additional capital sooner than planned. However, there can be no assurances that we will be able to raise additional capital from these sources on favorable terms, or at all.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Years Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (33,543)	$ (67,715)
Net cash provided by investing activities	7,000	19,925
Net cash provided by (used in) financing activities	(3,125)	95,138
Increase/(decrease) in cash, cash equivalents and restricted cash	$ (29,668)	$ 47,348

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in developing clinical programs, drug discovery efforts and related infrastructure.

For the year ended December 31, 2025, net cash used in operating activities was $33.5 million, which was primarily utilized for the funding of our operating expenses of $36.8 million as we incurred expenses associated with research and development activities including clinical trial activities associated with our bempikibart program. Non-cash gains include non-cash revenue from the settlement of our customer refund liability of $53.7 million as a result of the execution of the Amgen Amendment (see further discussion under “Collaboration and Arrangement Revenue” above), as well as a gain of $11.7 million recognized on the sale of ADX-097 to Akebia. These gains are partially offset by stock-based compensation expense of $5.3 million, non-cash lease expenses of $0.6 million and depreciation expense of $0.4 million. The change in net operating assets

and liabilities was primarily attributable to a decrease in accrued expenses and other current liabilities of $3.3 million, a decrease in accounts payable of $2.1 million, and a decrease in our operating lease liability of $0.6 million, partially offset by a decrease in other noncurrent assets of $1.9 million and a decrease in prepaid expenses and other current assets of $0.1 million.

For the year ended December 31, 2024, net cash used in operating activities was $67.7 million, which was primarily utilized for the funding of our operating expenses of $66.1 million as we incurred expenses associated with research and development activities including clinical trial activities associated with our bempikibart and ADX-097 programs, adjusted for non-cash expenses of $10.3 million. Non-cash expenses include a gain of $15.9 million recognized on the change in fair value prior to the conversion of the Convertible Notes pursuant to the Merger with Homology on March 25, 2024, a gain of $2.2 million recognized on the change in fair value of the CVR liability and amortization of premium on short-term investments of $0.2 million, partially offset by stock-based compensation expense of $4.4 million, losses related to our investment in OXB (US) LLC of $2.3 million, non-cash lease expenses of $0.6 million, depreciation expense of $0.5 million and amortization of debt discount and issuance costs of $0.2 million. The change in net operating assets and liabilities was primarily attributable to a decrease in accrued expenses and other current liabilities of $7.7 million, a decrease in accounts payable of $1.0 million, and a decrease in our operating lease liability of $1.5 million, partially offset by a decrease in other noncurrent assets of $0.4 million and a decrease in prepaid expenses and other current assets of $0.3 million.

Investing Activities

For the year ended December 31, 2025, net cash provided by investing activities consisted of proceeds from the sale of ADX-097 to Akebia.

For the year ended December 31, 2024, net cash provided by investing activities consisted of maturities of short-term investments during the period since the Merger, partially offset by purchases of property and equipment.

Financing Activities

For the year ended December 31, 2025, net cash used in financing activities consisted of principal payments made pursuant to our venture debt.

For the year ended December 31, 2024, net cash provided by financing activities consisted of $53.2 million of cash acquired as part of the Merger, $42.0 million of proceeds from the issuance of common stock in the pre-closing financing, $7.0 million of proceeds from the borrowings under a new loan and security agreement and $1.7 million of proceeds from the exercise of stock options, slightly offset by payments of $8.7 million of transaction costs related to the Merger.

Pre-Closing Financing

In connection with the Merger Agreement, certain third parties entered into the Pre-Closing Financing as described above under "Merger with Homology and the Pre-Closing Financing." On the Closing Date, following approval by the stockholders of Legacy Q32 and Homology, the Pre-Closing Financing closed immediately prior to the consummation of the Merger. Shares of Legacy Q32's common stock issued pursuant to the Pre-Closing Financing were converted into the right to receive 1,682,045 shares of Homology common stock, after taking into account the Reverse Stock Split.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing bempikibart and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of our product candidates;

- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies, if any.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

We believe that, based on our current operating plan, our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2027. Management based its projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

To complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that management believes will be necessary to commercialize our product candidates, if approved, we will require substantial additional capital. Accordingly, until such time that we can generate sufficient revenue from product sales or other sources, if ever, management expects to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be or could 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 equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our own common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from recent bank failures. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Management cannot provide assurance that we will ever generate positive cash flow from operating activities.

Contractual Obligations and Commitments

Lease Obligations

We lease space under an operating lease for administrative offices and lab space in Waltham, Massachusetts, which expires in December 2031.

The following table summarizes our contractual obligations and commitments as of December 31, 2025 (in thousands):

	Payments Due by Period			
	Total	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligation	$ 7,061	$ 3,374	$ 2,421	$ 1,266

We have agreements with certain vendors for various services, including services related to preclinical and clinical operations and support, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Our most significant contracts relate to agreements with CROs for clinical trials and preclinical studies and CDMOs, which we enter into in the normal course of business. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors to reimburse them for their unrecoverable outlays incurred prior to cancellation. The exact amounts of such obligations are dependent on the timing of termination and the exact terms of the relevant agreement and cannot be reasonably estimated. We do not include these payments in the table above as they are not fixed and estimable.

In addition, we enter into standard indemnification agreements and/or indemnification sections in other agreements in the ordinary course of business. Pursuant to these agreements, we agree to indemnify, hold harmless and reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally our business partners. The term of these indemnification agreements is generally perpetual upon execution of the agreement. The maximum potential amount of future payments we could be required to make under these indemnification agreements cannot be reasonably estimated and therefore is not included in the table above.

Collaboration and License Agreements

Bempikibart—License Agreement – Bristol-Myers Squibb Company

In September 2019, Legacy Q32 entered into a license agreement, as amended in August 2021 and July 2022 (the "BMS License Agreement") with Bristol-Myers Squibb Company ("BMS"), pursuant to which we obtained sublicensable licenses from BMS to research, develop and commercialize licensed products, including bempikibart, for any and all uses worldwide. The licenses granted to us are exclusive with respect to BMS's patent rights and know-how relating to certain antibody fragments (including certain fragments of bempikibart) and non-exclusive with respect to BMS's patent rights and know-how relating to the composition of matter and use of a specific region of bempikibart. BMS retained the right for it and its affiliates to use the exclusively licensed patents and know-how for internal, preclinical research purposes. Under the BMS License Agreement, we are prohibited from engaging in certain clinical development or commercialization of any antibody other than a licensed compound with the same mechanism of action until the earlier of the expiration of our obligation to pay BMS royalties or September 2029.

In consideration for the license, we made an upfront payment to BMS of $8 million, issued 318,278 Series A preferred shares to BMS and agreed to use commercially reasonable efforts to develop and commercialize at least one licensed product in key geographic markets. In addition, we agreed to pay BMS (i) development and regulatory milestone payments in aggregate amounts ranging from $32 million to $49 million per indication for the first three indications and commercial milestone payments in an aggregate amount of up to $215 million on net sales of licensed products, (ii) tiered royalties ranging from rates in the mid-single digit percentages to up to 10% of net sales, with increasing rates depending on the cumulative net sales, (iii) up to 60% of sublicense income, which percentage decreases based on the development stage of bempikibart at the time of the sublicensing event, and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents.

Our obligation to pay BMS royalties under subsection (ii) above commences, on a licensed product-by-licensed product and country-by-country basis, on the first commercial sale of a licensed product in a country and expires on the later of (x) 12 years from the first commercial sale of such licensed product in such country, (y) the last to expire licensed patent right covering bempikibart or such licensed product in such country, and (z) the expiration or regulatory or marketing exclusivity for such licensed product in such country (the "Royalty Term"). If we undergo a change of control prior to certain specified phase of development, the development and milestone payments are subject to increase by a low double digit percentage and the royalty rates are subject to increase by a low sub-single digit percentage.

Unless terminated earlier by either party pursuant to its terms, the BMS License Agreement will expire on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last to expire Royalty Term with respect to such licensed product in such country. Either party may terminate the BMS License Agreement for the other party's material breach, subject to a specified notice and cure period. BMS may terminate the BMS License Agreement if we fail to meet our

diligence obligations under the BMS License Agreement, for our insolvency, or if we or our affiliates challenges the validity, scope, enforceability, or patentability of any of the licensed patents. We may terminate the BMS License Agreement for any reason upon prior written notice to BMS, with a longer notice period if a licensed product has received regulatory approval. If the BMS Agreement is terminated for our material breach, BMS will regain rights to bempikibart and we must grant BMS an exclusive license under our patent rights covering bempikibart, subject to a low single digit percentage royalty on net sales of bempikibart payable to us by BMS. We have the right to terminate the agreement for any reason upon written notice, and therefore, this agreement has not been included in the discussion above. In July 2024, we made a $4.0 million development milestone payment to BMS.

Bempikibart – Collaboration and Option Agreement, Asset Purchase Agreement and Termination Agreement – Horizon Therapeutics Ireland DAC

From August 2022 until November 2023, Legacy Q32 was a party to the Horizon Agreements, pursuant to which Legacy Q32 received $55.0 million in initial consideration and staged development funding to complete two ongoing Phase 2 trials for bempikibart, and granted Horizon an option to acquire the bempikibart program at a prespecified price, subject to certain adjustments.

In October 2023, Amgen completed the acquisition of Horizon plc. Following its acquisition of Horizon plc, Legacy Q32 agreed with Amgen to mutually terminate the Horizon Agreements and in November 2023, Legacy Q32 and Horizon entered into the Horizon Termination Agreement, pursuant to which Horizon's option to acquire the bempikibart program was terminated. As a result, Legacy Q32 retained all initial consideration and development funding received under the Horizon Collaboration Agreement and regained full development and commercial rights to bempikibart. In consideration for the Horizon Termination Agreement, Legacy Q32 agreed to pay Horizon regulatory and sales milestones payments of up to an aggregate amount of $75.1 million upon the first achievement of certain regulatory and sales milestones with respect to bempikibart.

On November 7, 2025, we entered into the Amgen Amendment pursuant to which we issued Horizon a one-time equity grant of 553,695 shares of our common stock as full consideration of the milestone payments outlined in the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, we have no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. Therefore, we derecognized the refund liability previously recorded for the $55.0 million of cash received under the Horizon Collaboration Agreement and recognized collaboration arrangement revenue for the difference between the equity issuance, and the refund liability as the consideration was no longer constrained.

ADX-097—License Agreement – The Regents of the University of Colorado

In August 2017, Legacy Q32 entered into an exclusive license agreement, as amended in February 2018, September 2018, and April 2019 (the "Colorado License Agreement") with The Regents of the University of Colorado ("Colorado"), pursuant to which we obtained worldwide, royalty-bearing, sublicensable licenses under certain patents and know-how owned by Colorado and Medical University of South Carolina ("MUSC"), relating to the research, development and commercialization of ADX-097. The licenses granted to us are exclusive with respect to certain patent families and know-how and non-exclusive with certain other patent families and know-how. The licenses granted to us are also subject to certain customary retained rights of Colorado and MUSC and rights of the United States government owing to federal funding giving rise to inventions covered by the licensed patents. We agreed to use commercially reasonable efforts to develop, manufacture and commercialize ADX-097, including by using commercially reasonable efforts to achieve specified development and regulatory milestones by specified dates.

In addition, we agreed to pay Colorado (i) development and sales milestone payments in an aggregate amount of up to $2.2 million per licensed product for the first three products, (ii) tiered royalty rates on cumulative net sales of licensed products in the low single digit percentages, (iii) 15% of sublicense income and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents. Our obligation to pay royalties to Colorado commences, on a licensed product-by-licensed product and country-by-country basis, from the first commercial sale of a licensed product in any country and expires on the later of (i) the last to expire valid claim within the licensed patents covering such licensed product in such country, and (ii) 20 years following the effective date of the Colorado License Agreement, or April 2037, or the Royalty Term.

On November 28, 2025, in connection with the ADX-097 Asset Sale, the Colorado License Agreement was amended and restated and all of our rights and obligations thereunder were transferred to Akebia.

Critical Accounting Policies and Significant Judgments and 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 GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. We consider many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. We must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and we must select an amount that falls within that range of reasonable estimates. Actual results could materially differ from those estimates.

While our critical accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, management believes that the following accounting policy is the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses and Related Accrued and Prepaid Expenses

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, costs for clinical research organizations, manufacturing expenses and costs of other outside vendors and other outsourced activities; laboratory supplies; technology licenses, software and other information technology support; facilities and depreciation.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development expenses in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

As part of the process of preparing our consolidated financial statements, management is required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel 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. Management makes estimates of its prepaid and accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to us at that time. Management periodically confirms the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include fees paid to:

- CROs and investigative sites in connection with performing research services, preclinical studies and clinical trials;
- vendors, including research laboratories, in connection with preclinical and clinical development activities; and
- vendors, including CDMOs, related to product manufacturing, development and distribution of preclinical studies and clinical trial materials.

Management bases the expense recorded related to contract research and manufacturing on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CDMOs and CROs that supply materials and conduct services. The financial terms of these agreements are 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. In accruing service fees, management estimates 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 the estimate, management adjusts the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and certain recently adopted accounting pronouncements that have or may potentially impact our financial position and results of operations is included in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We have determined that the effects of any such pronouncements will not have a material impact on our consolidated financial position and results of operations.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K beginning on page F-1. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, 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.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), as appropriate, to allow timely decisions regarding required disclosure. 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.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025 and, based on this evaluation, concluded that our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a)

None.

(b)

Rule 10b5-1 Trading Arrangements

No Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements, as defined in Item 408(c) of Regulation S-K, were adopted, modified, or terminated by officers or directors of the Company, nor were there any material changes to the procedures by which security holders may recommend nominees to the Company's board of directors, during the three months ended December 31, 2025.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

We have adopted a Code of Conduct applicable to all officers, directors and other employees, including our principal executive officer, principal financial officer, principal accounting officer and controller, and persons performing similar functions. A copy of our Code of Conduct is available at the Investors & Media section of our website, located at www.q32bio.com, under "Investors & Media–Corporate Governance–Documents and Charters." We intend to disclose on our website any amendments to, or waivers from, our Code of Conduct that are required to be disclosed pursuant to the rules of the SEC, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers. Information that is contained in and can be accessed through our website is not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial Statement Schedules.

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

(3) Exhibits.

Exhibit Number	Description
2.1+	Agreement and Plan of Merger, dated as of November 16, 2023, by and among Homology Medicines, Inc., Kenobi Merger Sub, Inc. and Q32 Bio Inc (incorporated by reference to Exhibit 2.1 of the Registrant's Registration Statement on form S-4 filed December 18, 2023 (File No. 333-276093)).
3.1	Restated Certificate of Incorporation, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed April 3, 2018 (File No. 001-38433)).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company-reverse stock split and authorized share increase, dated March 25, 2024 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company-name change, dated March 25, 2024 (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company-officer exculpation, dated June 16, 2025 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed June 17, 2025 (File No. 001-38433)).
3.5	Amended and Restated Bylaws, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed December 18, 2020 (File No. 001-38433)).
4.1*	Description of Registrant's Securities.
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed February 17, 2026 (File No. 001-38433)).
10.1+	Subscription Agreement, dated November 16, 2023, by and among Q32 Bio Operations Inc. (formerly Q32 Bio Inc.) and certain parties thereto (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.2+	Registration Rights Agreement, dated March 25, 2024, by and among Q32 Bio Operations Inc. (formerly Q32 Bio Inc.) and certain parties thereto (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.3	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed February 17, 2026 (File No. 001-38433)).
10.4	Contingent Value Rights Agreement dated March 23, 2024, by and between Homology Medicines Inc. and Equiniti Trust Company, LLC (incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.5#	Form of Indemnification Agreement for Officers of Q32 Bio Inc. (incorporated by reference to Exhibit 10.6 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.6#	Form of Indemnification Agreement for Directors of Q32 Bio Inc. (incorporated by reference to Exhibit 10.7 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.7#	Q32 Bio Inc. 2017 Stock Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.8 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.8#	Q32 Bio Inc. 2024 Stock Option and Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.9 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.9#	Q32 Bio Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).

10.10#	Q32 Bio Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.11 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.11#	Q32 Bio Inc. Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.12 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.12	Q32 Bio Inc. Warrant to Purchase Common Stock dated December 11, 2020 (incorporated by reference to Exhibit 10.13 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.13	Q32 Bio Inc. Warrant to Purchase Common Stock dated July 12, 2023 (incorporated by reference to Exhibit 10.14 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.14#	Employment Agreement between Q32 Bio Inc. and Jodie Morrison, dated March 25, 2024 (incorporated by reference to Exhibit 10.15 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.15#	Employment Agreement between Q32 Bio Inc. and Lee Kalowski, dated March 25, 2024 (incorporated by reference to Exhibit 10.16 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.16#	Employment Agreement between Q32 Bio Inc. and Shelia Violette, dated March 25, 2024 (incorporated by reference to Exhibit 10.18 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.17+†	Asset Purchase Agreement, dated August 12, 2022, by and between Q32 Bio Inc. and Horizon Therapeutics Ireland DAC (incorporated by reference to Exhibit 10.36 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.18+†	License Agreement, dated as of September 14, 2019, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.43 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.19†	First Amendment to License Agreement, dated as of August 13, 2021, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.44 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.20	Second Amendment to License Agreement, dated as of July 26, 2022, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.45 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.21†	Third Amendment to License Agreement, dated as of July 26, 2022, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.46 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.22+	Lease Agreement, dated March 20, 2021, by and between Q32 Bio Inc. and PPF OFF 828-830 WINTER STREET LLC (incorporated by reference to Exhibit 10.47 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.23+	Loan and Security Agreement, dated as of December 11, 2020, by and between Q32 Bio Inc. and Silicon Valley Bank, as amended (incorporated by reference to Exhibit 10.50 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.24	First Amendment to Loan and Security Agreement, dated December 30, 2021, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.51 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.25	Second Amendment to Loan and Security Agreement, dated June 30, 2022, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.52 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.26+	Third Amendment to Loan and Security Agreement, dated August 10, 2022, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.53 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.27+	Fourth Amendment to Loan and Security Agreement, dated December 21, 2022, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.54 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.28+	Fifth Amendment to Loan and Security Agreement, dated April 26, 2023, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.55 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.29+	Sixth Amendment to Loan and Security Agreement, dated July 12, 2023, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.56 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.30	Seventh Amendment to Loan and Security Agreement, dated November 2, 2023, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.57 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).

10.31+	Consent and Eighth Amendment to Loan and Security Agreement, by and between Q32 Bio Inc. and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, dated March 22, 2024 (incorporated by reference to Exhibit 10.5 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.32*†+	Asset Purchase Agreement, dated November 28, 2025, by and among Q32 Bio Inc., Q32 Bio Operations Inc. and Akebia Therapeutics, Inc.
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 of the Registrant's Form 10-K filed March 11, 2025 (File No. 001-38433)).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Form 10-K/A filed April 12, 2024 (File No. 001-38433)).
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm of the Registrant.
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.
97.1	Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 of the Registrant's Form 10-K/A filed April 12, 2024 (File No. 001-38433)).
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith. This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

† Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) is the type of information that the registrant treats as private or confidential.

+ Annexes, schedules and exhibits have been omitted pursuant to Item 601(b)(2) or 601(a)(5), as applicable, of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.

# Indicates a management contract or any compensatory plan, contract or arrangement.

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, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Q32 BIO INC.

Date: March 10, 2026 /s/ Jodie Morrison

Name: Jodie Morrison
Title: Chief Executive Officer and Director

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.

Signature	Title	Date
/s/ Jodie Morrison Jodie Morrison	Chief Executive Officer and Director *Principal Executive Officer*	March 10, 2026
/s/ Lee Kalowski Lee Kalowski	Chief Financial Officer and President *Principal Financial Officer and Principal Accounting Officer*	March 10, 2026
/s/ David Grayzel David Grayzel	Director	March 10, 2026
/s/ Diyong Xu Diyong Xu	Director	March 10, 2026
/s/ Isaac Manke Isaac Manke	Director	March 10, 2026
/s/ Arthur Tzianabos Arthur Tzianabos	Director	March 10, 2026
/s/ Kathleen LaPorte Kathleen LaPorte	Director	March 10, 2026
/s/ Mary Thistle Mary Thistle	Director	March 10, 2026
/s/ Mark Iwicki Mark Iwicki	Director	March 10, 2026
/s/ Bill Lundberg Bill Lundberg	Director	March 10, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Q32 Bio Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Q32 Bio Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosure to which it relates.

Accrued and Prepaid Research and Development Expenses

Description of the Matter

The Company's accrued external research and development expenses totaled $0.5 million at December 31, 2025. In addition, the Company's prepaid external research and development expenses totaled $0.5 million at December 31, 2025. As discussed in Note 2 to the consolidated financial statements, the Company is required to estimate external research and development expenses. This process involves analyzing the progress of the research activities, including the phase or completion of events, invoices received and contracted costs, reviewing open contracts and purchase orders, communicating with internal personnel to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows.

Auditing the Company's accrued and prepaid external research and development expenses was complex, as the amounts are based on various estimates from third-party vendors, as well as other inputs estimated by members of management, such as, actual costs incurred but not yet billed, estimated project timelines, and the costs associated with these services. Furthermore, due to the duration of the Company's external research and development activities and the timing of invoices received from third parties, the actual amounts incurred are not typically known by the date the financial statements are issued.

How We Addressed the Matter in Our Audit

To evaluate the accrued and prepaid research and development expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the judgments and estimates made by management to determine the recorded accruals and prepayments. To test the judgments and estimates, we corroborated the progress of research and development activities through discussion with the Company's research and development personnel that oversee the research and development projects and inspected the Company's contracts with vendors and pending change orders to assess the impact on amounts recorded. We obtained direct confirmations from certain vendors confirming costs incurred as of the reporting date to verify that prepaids and accruals are complete and accurate. We also analyzed fluctuations in prepaids and accruals by vendor and by clinical trial throughout the period subject to audit and tested subsequent invoices received from vendors.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Boston, Massachusetts

March 10, 2026

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Q32 BIO INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 48,297	$ 77,965
Prepaid expenses and other current assets	6,753	3,912
Total current assets	55,050	81,877
Equity investment	—	2,600
Property and equipment, net	979	1,370
Right-of-use asset, operating leases	5,100	5,722
Restricted cash and restricted cash equivalents	647	647
Other noncurrent assets	—	116
Total assets	$ 61,776	$ 92,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 879	$ 2,989
Accrued expenses and other current liabilities	4,232	7,479
CVR liability	—	2,900
Venture debt, current portion	6,235	3,097
Total current liabilities	11,346	16,465
Lease liability, net of current portion	4,943	5,636
Venture debt, net of current portion	3,473	9,556
Other noncurrent liabilities	—	55,000
Total liabilities	19,762	86,657
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 400,000,000 shares authorized, 12,858,047 and 12,197,615 shares issued and outstanding at December 31, 2025 2024, respectively	2	2
Additional paid-in capital	247,005	240,487
Accumulated deficit	(204,993)	(234,814)
Total stockholders' equity	42,014	5,675
Total liabilities and stockholders' equity	$ 61,776	$ 92,332

The accompanying notes are an integral part of these consolidated financial statements.

Q32 BIO INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	Years Ended December 31,	
	2025	2024
Collaboration arrangement revenue	$ 53,737	$ —
Operating expenses:		
Research and development	19,156	48,143
General and administrative	17,679	17,959
Total operating expenses	36,835	66,102
Income (loss) from operations	16,902	(66,102)
Change in fair value of convertible notes	—	15,890
Gain on sale of asset	11,737	—
Other income (expense), net	1,182	4,125
Total other income (expense), net	12,919	20,015
Income (loss) before provision for income taxes and loss from equity method investment	29,821	(46,087)
Provision for income taxes	—	(21)
Loss from equity method investment	—	(1,625)
Net income (loss)	$ 29,821	$ (47,733)
Net income (loss) per share—basic	$ 2.42	$ (5.12)
Net income (loss) per share—diluted	$ 2.42	$ (6.58)
Weighted-average common shares—basic	12,300,568	9,320,884
Weighted-average common shares—diluted	12,314,796	9,657,696

The accompanying notes are an integral part of these consolidated financial statements.

Q32 BIO INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(amounts in thousands, except share and per share data)

	Years Ended December 31,	
	2025	2024
Net income (loss)	$ 29,821	$ (47,733)
Other comprehensive income (loss):		
Change in unrealized gain (loss) on available for sale securities, net	—	—
Total other comprehensive gain (loss)	—	—
Comprehensive income (loss)	$ 29,821	$ (47,733)

The accompanying notes are an integral part of these consolidated financial statements.

Q32 BIO INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(amounts in thousands, except share data)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2023	2,286,873	$ 47,458	312,094	$ 4,132	2,625,896	$ 59,855	359,569	$ 1	$ 4,159	$ (187,081)	$ (182,921)
Conversion of convertible preferred stock to common stock in connection with the Merger	(2,286,873)	(47,458)	(312,094)	(4,132)	(2,625,896)	(59,855)	5,224,863	1	111,444	—	111,445
Issuance of common stock in the pre-closing financing	—	—	—	—	—	—	1,682,045	—	42,000	—	42,000
Issuance of common stock for conversion of convertible notes	—	—	—	—	—	—	1,433,410	—	22,705	—	22,705
Issuance of common stock to Homology shareholders in reverse recapitalization	—	—	—	—	—	—	3,229,633	—	64,292	—	64,292
Issuance of common stock from option exercises	—	—	—	—	—	—	255,486	—	1,694	—	1,694
Issuance of common stock from RSU vesting	—	—	—	—	—	—	12,609	—	—	—	—
Reverse recapitalization transaction costs	—	—	—	—	—	—	—	—	(10,013)	—	(10,013)
Issuance of CVR at fair value	—	—	—	—	—	—	—	—	(180)	—	(180)
Stock-based compensation expense	—	—	—	—	—	—	—	—	4,386	—	4,386
Other comprehensive gain (loss)	—	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(47,733)	(47,733)
Balance as of December 31, 2024	—	$ —	—	$ —	—	$ —	12,197,615	$ 2	$ 240,487	$ (234,814)	$ 5,675
Issuance of common stock from RSU vesting	—	—	—	—	—	—	106,737	—	—	—	—
Issuance of common stock to Amgen	—	—	—	—	—	—	553,695	—	1,263	—	1,263
Stock-based compensation expense	—	—	—	—	—	—	—	—	5,255	—	5,255
Net income	—	—	—	—	—	—	—	—	—	29,821	29,821
Balance as of December 31, 2025	—	$ —	—	$ —	—	$ —	12,858,047	$ 2	$ 247,005	$ (204,993)	$ 42,014

The accompanying notes are an integral part of these consolidated financial statements.

Q32 BIO INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Years Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net income (loss)	$ 29,821	$ (47,733)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash revenue from settlement of customer refund liability	(53,737)	—
Amortization of debt discount and issuance costs	180	194
Amortization of premium on short-term investments	—	(221)
Depreciation expense	391	487
Stock-based compensation expense	5,255	4,386
Non-cash lease expense	622	579
Loss from equity method investment	—	1,625
Loss on impairment of equity investment	74	675
Change in fair value of CVR liability	(374)	(2,180)
Change in fair value of convertible notes	—	(15,890)
Gain on sale of asset	(11,737)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,896	276
Other noncurrent assets	116	386
Accounts payable	(2,110)	(1,043)
Operating lease liability	(612)	(1,542)
Accrued expenses and other current liabilities	(3,328)	(7,714)
Net cash used in operating activities	(33,543)	(67,715)
Cash flows from investing activities:		
Purchases of property and equipment	—	(75)
Proceeds from sale of asset	7,000	—
Maturities of short-term investments	—	20,000
Net cash provided by investing activities	7,000	19,925
Cash flows from financing activities:		
Proceeds from borrowings under loan and security agreement	—	7,000
Proceeds from issuance of common stock in pre-closing financing	—	42,000
Cash acquired in connection with reverse recapitalization	—	53,158
Payment of reverse recapitalization transaction costs	—	(8,714)
Principal payments on venture debt	(3,125)	—
Proceeds from exercise of common stock options	—	1,694
Net cash provided by (used in) financing activities	(3,125)	95,138
Net increase (decrease) in cash, cash equivalents, restricted cash and restricted cash equivalents	(29,668)	47,348
Cash, cash equivalents, restricted cash and restricted cash equivalents at beginning of period	78,612	31,264
Cash, cash equivalents, restricted cash and restricted cash equivalents at end of period	$ 48,944	$ 78,612
Supplemental disclosure of non-cash operating, investing and financing activities:		
Interest payments on venture debt	$ 961	$ 856
Issuance of common stock to Amgen at fair value	$ 1,263	$ —
Short-term investments acquired in connection with reverse recapitalization	$ —	$ 19,905
Issuance of CVR at fair value	$ —	$ 180

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business

Q32 Bio Inc. ("Q32" or the "Company") is a clinical stage biotechnology company focused on developing novel biologics to effectively and safely restore healthy immune balance in patients with autoimmune and inflammatory diseases driven by pathological immune dysfunction. Q32 has multiple product candidates across a variety of autoimmune and inflammatory diseases. The Company was formed in 2017 as Admirx, Inc. under the laws of the state of Delaware and is headquartered in Waltham, Massachusetts. On March 20, 2020, the Company changed its name to Q32 Bio Inc.

Sale of ADX-097

On November 28, 2025, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Q32 Bio Operations Inc., a wholly-owned subsidiary of the Company ("Q32 Bio Operations" and, together with the Company, the "Seller"), and Akebia Therapeutics, Inc. ("Akebia") pursuant to which the Seller sold to Akebia substantially all of the Seller's assets related to the research, development, manufacture and commercialization of ADX-097 (the "ADX-097 Asset Sale"). Following the ADX-097 Asset Sale, Akebia will be responsible for any future development and commercialization of ADX-097 (see Note 4 for more details surrounding the accounting for the ADX-097 Asset Sale).

Merger with Homology

On March 25, 2024, Kenobi Merger Sub, Inc. ("Merger Sub"), a wholly-owned subsidiary of Homology Medicines, Inc. ("Homology"), completed its merger with and into Q32 Bio Operations Inc. (previously named Q32 Bio Inc. and also referred to herein as "Legacy Q32"), with Legacy Q32 continuing as the surviving entity as a wholly-owned subsidiary of Homology. This transaction is referred to as the "Merger." Homology changed its name to Q32 Bio Inc., and Legacy Q32, which remains as a wholly-owned subsidiary of the Company, changed its name to Q32 Bio Operations, Inc. The Merger was effected pursuant to an Agreement and Plan of Merger (the "Merger Agreement"), dated as of November 16, 2023, by and among Homology, Legacy Q32, and Merger Sub. In connection with the Merger Agreement, certain parties entered into a subscription agreement with the Company to purchase shares of Legacy Q32's common stock for an aggregate purchase price of $42.0 million (the "Pre-Closing Financing").

On March 25, 2024 (the "Closing Date"), the Pre-Closing Financing closed immediately prior to the consummation of the Merger. Shares of Legacy Q32's common stock issued pursuant to the Pre-Closing Financing were converted into the right to receive 1,682,045 shares of Homology common stock after taking into account the Reverse Stock Split. On March 25, 2024, Homology effected a one-for-eighteen reverse stock split of its then outstanding common stock (the "Reverse Stock Split") where all issued and outstanding shares of Legacy Q32's common stock (including common stock issued upon the conversion of all Legacy Q32's Series A, Series A-1 and Series B preferred stock, conversion of Legacy Q32 convertible notes, but excluding the common stock issued in Pre-Closing Financing) converted into the right to receive an aggregate of 7,017,842 shares of Homology's common stock based on the final exchange ratio of 0.0480 (the "Exchange Ratio"). Lastly, each option to purchase the Legacy Q32's shares that was outstanding and unexercised immediately prior to the Merger was converted into an option to purchase shares of Homology based on the Exchange Ratio. Immediately following the Merger, Legacy Q32 stockholders owned approximately 74.4% of the outstanding common stock of the combined company.

The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America ("GAAP"). For accounting purposes, Legacy Q32 is considered the accounting acquirer and Homology is the acquired company based on the terms of the Merger Agreement and other factors, such as relative voting rights and the composition of the combined company's board of directors and senior management. Accordingly, the Merger was treated as the equivalent of Legacy Q32's issuing stock to acquire the net assets of Homology. As a result of the Merger, the net assets of Homology were recorded at their acquisition-date fair value in the financial statements of the combined company and the reported operating results prior to the Merger are those of Legacy Q32. Legacy Q32's historical financial statements became the historical consolidated financial statements of the combined company. All issued and outstanding Legacy Q32 common stock, convertible preferred stock and options prior to the effective date of the Merger have been retroactively adjusted to reflect the Exchange Ratio, which reflects the impact of the reverse stock split, for all periods presented.

At the effective time of the Merger, each person who as of immediately prior to the effective time of the Merger was a stockholder of record of Homology or had the right to receive Homology's common stock received a contractual contingent value right ("CVR") issued by Homology representing the contractual right to receive cash payments from the combined company upon

the receipt of certain proceeds from a disposition of Homology's pre-merger assets (see Note 3 for more details surrounding the accounting for the Merger and the CVRs).

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, obtaining regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Programs currently under development will require significant additional research and development efforts, including preclinical and clinical testing, and will need to obtain regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales. Since its inception, the Company's operations have been focused on organizing and staffing, business planning, raising capital, establishing the Company's intellectual property portfolio and performing research and development of its product candidates, programs and platform. The Company has primarily funded its operations with proceeds from the sale of convertible preferred stock, convertible notes, venture debt, the Merger with Homology and accompanying Pre-Closing Financing and its collaboration arrangement with Horizon.

Liquidity and Going Concern

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

As of December 31, 2025, the Company had an accumulated deficit of $205.0 million and cash and cash equivalents of $48.3 million. The Company expects that its cash and cash equivalents, combined with gross proceeds from our registered direct offering completed in February 2026 (see Note 21) and guaranteed near-term milestone payments from the ADX-097 Asset Sale, will be sufficient to fund its operating expenditures and capital expenditure requirements necessary to advance its research efforts and clinical trials for at least one year from the date of issuance of these consolidated financial statements.

The Company has incurred recurring operating losses since its inception. During the year ended December 31, 2025, the Company had net income of $29.8 million, primarily due to the collaboration revenue recognized upon the execution of the Amgen Amendment (as defined in Note 15 below). The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with 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.

Principles of Consolidation

The accompanying consolidated financial statements include those of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in the consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management

must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the common stock and convertible notes prior to the effective date of the Merger, the fair value of CVR liability, and the prepaid and accrued research and development expenses. The Company utilizes certain estimates to record expenses relating to research and development contracts. These contract estimates, which are primarily related to the length of service of each contract and the amount of service provided as of each measurement date, are determined by the Company based on input from internal project management, as well as from service providers. Estimates are periodically reviewed considering changes in circumstances, facts and historical experience. Actual results may differ from the Company's estimates.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in determining how to allocate resources and in assessing performance. The Company has one reporting segment (see Note 20). The segment consists of the development of clinical and preclinical product candidates for the development of the Company's novel biologics. The Company's chief operating decision maker is the chief executive officer ("CEO").

The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the segment based on net loss, which is reported on the income statement. The measure of segment assets is reported on the balance sheet as total consolidated assets.

The CODM uses cash forecast models in deciding how to invest into the segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budget versus actual results is used in assessing the performance of the segment and in establishing management's compensation, along with cash forecast model.

Foreign Currency Translations

The Company's functional currency is the United States dollar. Foreign currency transaction gains and losses are recorded in the consolidated statement of operations.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially expose the Company to credit risk primarily consist of cash, cash equivalents, restricted cash and restricted cash equivalents. The Company maintains its cash, cash equivalents, restricted cash and restricted cash equivalents balances with accredited financial institutions and, consequently, the Company does not believe it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company's cash management limits investment to investment-grade securities with the objective to preserve capital and to maintain liquidity until the funds can be used in business operations. The Company maintains its cash in bank deposit accounts that are Federal Deposit Insurance Corporation ("FDIC") insured up to $250,000. At times, the Company's bank accounts may exceed the federal insurance limit.

The Company is dependent on contract development and manufacturing organizations ("CDMOs") to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients, other raw materials and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients, other raw materials and formulated drugs. The Company is also dependent on contract research organizations ("CROs") which provide services related to the research and development activities in its programs.

Off Balance Sheet Risk

As of December 31, 2025 and 2024, the Company had no off balance sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders.

Cash, Cash Equivalents, Restricted Cash and Restricted Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash with maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents are comprised of money market accounts invested in U.S. Treasury securities.

Restricted cash and restricted cash equivalents are comprised of deposits held by financial institutions as collateral for the company's venture debt and used to collateralize letters of credit related to the Company's lease arrangements.

The Company includes the restricted cash and restricted cash equivalents balance together with its cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the consolidated statements of cash flows.

Cash, cash equivalents, restricted cash and restricted cash equivalents consisted of the following (in thousands):

	December 31,	
	2025	2024
Cash and cash equivalents	$ 48,297	$ 77,965
Restricted cash and cash equivalents	647	647
Total cash, cash equivalents, restricted cash and restricted cash equivalents	$ 48,944	$ 78,612

Deferred Transaction Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred transaction costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the transaction, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the transaction. Should the in-process equity financing be abandoned, the deferred transaction costs would be expensed immediately as a charge to operating expenses in the consolidated statements of operations.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. 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 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.

Investments in Equity Securities

The Company uses the equity method of accounting to account for an investment in an entity that it does not control, but in which it has the ability to exercise significant influence over operating and financial policies. The Company's proportionate share of the net income or loss of the entity is included in consolidated net income (loss). Judgments regarding the level of influence

over the equity method investment include consideration of key factors such as the Company's ownership interest, representation on the board of directors or other management body and participation in policy-making decisions.

Under the equity method of accounting, the Company's investment is initially recorded at fair value on the consolidated balance sheets. Upon initial investment, the Company evaluates whether there are basis differences between the carrying value and fair value of the Company's proportionate share of the investee's underlying net assets. Typically, the Company amortizes basis differences identified on a straight-line basis over the underlying assets' estimated useful lives when calculating the attributable earnings or losses, excluding the basis differences attributable to in-process research and development that has no alternative future use. If the Company is unable to attribute all of the basis differences to specific assets or liabilities of the investee, the residual excess of the cost of the investment over the proportional fair value of the investee's assets and liabilities is considered to be equity method goodwill and is recognized within the equity investment balance, which is tracked separately within the Company's memo accounts. The Company subsequently records in the statements of operations its share of income or loss of the other entity within other income/expense, which results in an increase or decrease to the carrying value of the investment. If the share of losses exceeds the carrying value of the Company's investment, the Company will suspend recognizing additional losses and will continue to do so unless it commits to providing additional funding; however, if there are intra-entity profits this can cause the investment balance to go negative.

The Company evaluates its equity method investments for impairment whenever events or changes in circumstances indicate that a decline in value has occurred that is other than temporary. Evidence considered in this evaluation includes, but would not necessarily be limited to, the financial condition and near-term prospects of the investee, recent operating trends and forecasted performance of the investee, market conditions in the geographic area or industry in which the investee operates and the Company's strategic plans for holding the investment in relation to the period of time expected for an anticipated recovery of its carrying value. If the investment is determined to have a decline in value deemed to be other than temporary it is written down to estimated fair value.

The Company uses the cost method to account for an investment in an entity in which it does not have the ability to exercise significant influence over operating and financial policies. Investments recorded using the cost method will be assessed for any decrease in value that has occurred that is other than temporary and the other than temporary decrease in value shall be recognized.

As and when circumstances and facts change, the Company will evaluate the Company's ability to significantly influence operational and financial policy to establish a basis for converting the investment accounted for using the cost method to the equity method of accounting and vice versa.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets. Major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operations as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

	Estimated Useful Life (Years)
Lab equipment	5
Furniture and fixtures	3
Computer equipment	3
Leasehold improvements	Shorter of useful life or term of associated lease

Leases

The Company evaluates whether an arrangement is or contains a lease at contract inception. If a contract is or contains a lease, lease classification is determined at lease commencement, which represents the date at which the underlying asset is made available for use by the Company. The Company's lease terms are generally measured at the respective lease's noncancelable term and exclude any optional extension terms as the Company is not reasonably certain to exercise such options. The Company

elected the short-term lease exemption and therefore does not recognize lease liabilities and right of use assets for lease arrangements with original lease terms of twelve months or less.

Lease liabilities represent the Company's obligation to make lease payments under a lease arrangement. Lease liabilities are measured as the present value of fixed lease payments, discounted using an incremental borrowing rate, as interest rates implicit in the Company's lease arrangements are generally not readily determinable. The Company elected the practical expedient to not separate lease and non-lease components for its real estate leases and therefore both are considered when determining the lease payments in a lease arrangement. Variable lease costs are expensed as incurred.

The incremental borrowing rate represents the interest rate at which the Company could borrow a fully collateralized amount equal to the lease payments, over a similar term, in a similar economic environment. The Company determines the incremental borrowing rate at lease commencement, generally using a synthetic credit rating based on the Company's financial position and negative cash flows, factoring in adjustments for additional risks based on the Company's economic condition, a survey of comparable companies with similar credit and financial profiles, as well as additional market risks, as may be applicable.

Right-of-use assets represent the Company's right to use an underlying asset over its lease term. Right-of-use assets are initially measured as the associated lease liability, adjusted for prepaid rent and tenant incentives. The Company remeasures right-of-use assets and lease liabilities when a lease is modified, and the modification is not accounted for as a separate contract. A modification is accounted for as a separate contract if the modification grants the Company an additional right of use not included in the original lease agreement and the increase in lease payments is commensurate with the additional right of use. The Company assesses its right-of-use assets for impairment consistent with its policy for impairment of long-lived assets held and used in operations.

Impairment of Long-Lived Assets

The Company continually monitors events and changes in circumstances that could indicate carrying amounts of long-lived assets may be impaired, and assesses their recoverability based upon estimated future undiscounted future cash flows expected to be generated by the long-lived assets. If the estimated aggregate undiscounted cash flows are less than the carrying amount of the long-lived assets, an impairment charge, calculated as the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets, is recorded. The estimated fair value of the long-lived assets is determined based on the estimated discounted cash flows expected to be generated from the long-lived assets.

Debt and Warrant Issuance Costs

The carrying value of the Company's venture debt was recorded net of issuance costs and discount relating to the issuance of warrants. The amounts are amortized over the term of the debt using the effective interest method and recognized as interest expense.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and Development expenses are comprised of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, costs for clinical research organizations and other outsourced activities; laboratory supplies; technology licenses, software and other information technology support; facilities and depreciation. Upfront payments and milestone payments made for the licensing of technology are expensed as research and development expenses in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

The Company has entered into various research and development related contracts with external parties. The payments under these agreements are recorded as research and development expenses as the underlying services are performed or the goods are received. The Company records accrued liabilities for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued and prepaid balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications, including direct application fees, and the legal and consulting expenses related to making such applications, and such costs are included in general and administrative expenses within the Company's statement of operations.

Revenue Recognition

Under FASB Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* (ASC 606), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations.

Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying good or service relative to the option exercise price. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the license terms, the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is determined and allocated to the identified performance obligations in proportion to their stand-alone selling prices (SSP) on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The amount of variable consideration included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty related to the variable consideration is resolved. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in

the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property 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 royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

Stock-Based Compensation

The Company accounts for stock-based awards in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation* (ASC 718). ASC 718 requires all stock-based awards issued to employees and members of the Company's board of directors for their services to be recognized as expense in the statements of operations based on their grant date fair values. For stock options and time-based restricted stock awards, the Company expenses the fair value of the awards on a straight-line basis over each award's service period, which is generally the period in which the related services are received. For performance-based stock awards, the Company uses the accelerated attribution method to expense the awards over the implicit service period based on the probability of achieving the performance conditions. The Company accounts for stock-based awards to non-employees consistently with the accounting for awards to employees and measures stock-based awards granted to non-employees based on their grant date fair value and recognizes the resulting value as stock-based compensation expense during the period the related services are rendered. The Company has not issued any stock-based awards with market-based vesting conditions.

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 accounts for forfeitures as they occur.

The Company's equity incentive plan allows for the issuance of restricted stock awards to employees and non-employee consultants that may be subject to vesting. The unvested shares of any restricted stock awards are held in escrow as the stock award vests or until award holder termination, whichever occurs first. In the event of a sale of the Company, the Company has the obligation to repurchase at cost, the portion of unvested stock awards from the award holder. For all unvested stock awards, a liability is established related to the Company's obligation for unvested awards at cost.

Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, *Income Taxes* (ASC 740), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. Should the actual amounts differ from these estimates, the amount of the Company's valuation allowance could be materially impacted. Changes in these estimates may result in significant increases or decreases to the tax provision in a period in which such estimates are changed, which in turn would affect net income or loss.

Income taxes are accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is

recognized in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Subsequent Event Considerations

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. The Company has evaluated events occurring after the date of its consolidated balance sheet through the date these consolidated financial statements were issued (see Note 21).

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The amendments in this update improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses. All disclosure requirements of the update are required for entities with a single reportable segment. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and should be applied on a retrospective basis to all periods presented. The Company adopted this standard as of January 1, 2024. The Company determined that adopting the amendments in ASU 2023-07 had no impact on the Company's reportable segment identified and additional required disclosures have been included.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 provides more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and incomes taxes paid information. For public companies, the amendments are effective for annual periods beginning after December 15, 2024, and should be applied prospectively. The Company adopted this standard as of January 1, 2025. The Company determined that the effects of adopting the amendments in ASU 2023-09 had no impact on its consolidated financial position and the results of its operations and additional required disclosures have been included.

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation Disclosures (Subtopic 220-40)—Disaggregation of Income Statement Expenses* ("ASU 2024-03") which is intended to improve disclosures about a public business entity's expenses, primarily through additional disaggregation of income statement expenses. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The amendments in ASU 2024-03 should be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating ASU 2024-03 to determine the impact on the Company's disclosures.

3. Accounting for the Merger

As described in Note 1, Merger Sub merged with and into Legacy Q32, with Legacy Q32 surviving as a wholly-owned subsidiary of the Company on March 25, 2024. The Merger was accounted for as a reverse recapitalization in accordance with GAAP with Legacy Q32 as the accounting acquirer of Homology. Legacy Q32 was determined to be the accounting acquirer based on the terms of the Merger Agreement and other factors, including: (i) Legacy Q32's shareholders own a majority of the

voting rights in the combined company; (ii) Legacy Q32 designated a majority (seven of nine) of the initial members of the board of directors of the combined company; (iii) Legacy Q32's executive management team became the management team of the combined company; (iv) the pre-combination assets of Homology were primarily cash and cash equivalents, short-term investments, and other non-operating assets; and (v) the combined company was named Q32 Bio Inc. and is headquartered in Legacy Q32's office in Waltham, Massachusetts.

At the effective time of the Merger, substantially all of the assets of Homology consisted of cash and cash equivalents, short-term investments, as well as other non-operating assets. Under such reverse recapitalization accounting, the assets and liabilities of Homology were recorded at their fair value in the Company's financial statements at the effective time of the Merger, which approximated book value due to the short-term nature, except for the equity method investment as described below. Homology's development programs had ceased prior to the Merger and were deemed to be de minimis in value at the transaction date. No goodwill or intangible assets were recognized.

Consequently, the consolidated financial statements of the Company reflect the operations of Legacy Q32 for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders Homology, the legal acquirer, and a recapitalization of the equity of Legacy Q32, the accounting acquirer.

As part of the recapitalization, the Company obtained the assets and liabilities listed below (in thousands):

Cash and cash equivalents	$	53,158
Short-term investments		19,905
Prepaid expenses		964
Equity method investment		4,900
Accounts payable and accrued liabilities		(7,903)
CVR liability		(5,080)
Net assets acquired	$	65,944

In addition, the Company recognized $2.1 million in personnel cost related to severance payments and retention bonuses to Homology employees and this amount was recorded in general and administrative expense in the accompanying consolidated statement of operations for the year ended December 31, 2024. The Company also incurred transaction costs of $10.0 million and this amount is recorded in additional paid-in capital in the accompanying consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2024.

With respect to the CVRs issued in connection with the Merger, each CVR represents the contractual right to receive payments from the Company upon the actual receipt by the Company or its subsidiaries of certain contingent proceeds derived from any cash consideration that is paid to the Company or its subsidiaries as a result of the sale, transfer, license, assignment or other divestiture, disposition or commercialization of any of the Company's assets, rights and interests relating to the following pre-merger assets of Homology: HMI-103, HMI-204, capsids and human hematopoietic stem cell-derived adeno-associated virus vector ("AAVHSC") platform, including any equity interests held directly or indirectly by the Company in OXB (US) LLC.

The Company believes that the achievement of the milestones outlined in the CVR agreement related to Homology's HMI-103, HMI-204, capsids and AAVHSC platform are highly susceptible to factors outside the Company's influence that are not expected to be resolved for a long period of time, if at all. In particular, these amounts are primarily influenced by the actions and judgments of third parties and the licensors of such assets and are based on the licensors of such assets progressing the in-process research and development assets, and in the case of one of the draft agreements, to certain milestones. As of March 25, 2024, the date of the Merger, the Company recorded a CVR liability of $0.2 million on the balance sheet relating to such contingent payments.

For the portion of the CVR agreement that is related to Homology's equity interest in OXB (US) LLC, the Company recorded a CVR liability of $4.9 million representing its estimated fair value as of the date of the Merger. Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB (US) LLC, at any time following the three-year anniversary of the closing of the transaction between OXB (US) LLC, Oxford Biomedica (US), Inc. and the Company (formerly known as Homology Medicines, Inc.) on March 10, 2022, (i) Oxford Biomedica (US), Inc. had an option to cause the Company to sell and transfer to Oxford Biomedica (US), Inc., and (ii) the Company had an option to cause Oxford Biomedica (US), Inc. to purchase from the Company, in each case, all of the Company's equity ownership interest in OXB (US) LLC based on the Company's pro rata share of OXB (US) LLC (10%) times a predetermined multiple of revenue for the immediately preceding 12-month period increased by OXB (US) LLC's cash balance and decreased by OXB (US) LLC's debt balance as of the exercise date (together, the "Options"), subject to a maximum amount of $74.1 million. The Company utilized a monte carlo simulation model,

also known as a probability simulation, to estimate the fair value of the CVR liability. For each simulated path of future revenue, a market approach using the predetermined revenue multiple was employed to determine the future value of the equity interest, which was then discounted to present value using OXB (US) LLC's estimated cost of debt.

Pursuant to a change in control provision in the Amended and Restated Limited Liability Company Agreement of OXB (US) LLC, on March 1, 2025, Oxford Biomedica (US), Inc. exercised its option to cause the Company to sell and transfer to Oxford Biomedica (US), Inc., all of the Company's equity ownership interest in OXB (US) LLC. The sale price was based on a formula using the Company's pro rata share of OXB (US) LLC (10%), times a predetermined multiple of revenue for the immediately preceding 12-month period increased by OXB (US) LLC's cash balance and decreased by OXB (US) LLC's debt balance as of the exercise date. The Company and Oxford Biomedica (US), Inc. finalized the transaction and paid the CVR holders during the second quarter of 2025. See Notes 6 and 7 for more details surrounding this transaction.

4. Sale of Asset

On November 28, 2025, the Company completed the ADX-097 Asset Sale. As consideration for the ADX-097 Asset Sale, the Company (i) received an upfront payment of $7.0 million on November 28, 2025, and (ii) will receive a payment of $3.0 million on the six-month anniversary of the closing, or May 28, 2026. The Company will also receive a near-term milestone payment of $2.0 million upon the earlier of achievement of the first milestone under the Asset Purchase Agreement or December 31, 2026. In addition to these payments, the Company is eligible to receive up to $580.0 million upon the achievement of additional specified milestones, including up to $92.5 million related to development and regulatory milestones and up to $487.5 million related to commercial milestones. The Company is also eligible to receive tiered royalties on potential future sales of ADX-097 ranging from low single-digit to mid-teen percentages of annual net sales. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

On November 28, 2025, in connection with the ADX-097 Asset Sale, the Colorado License Agreement (defined in Note 10) was amended and restated and all of the Company’s rights and obligations thereunder were transferred to Akebia.

The Company accounted for the transaction as an asset sale and recognized $11.7 million, comprised of $12.0 million in guaranteed upfront and near-term milestones less certain contractual offsets, as a gain on sale of asset included in other income (expense) in the consolidated statements of operations for the year ended December 31, 2025. Any future milestones and royalties will be recognized when achieved.

5. Fair Value Measurements

The carrying values of the Company’s prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair value due to their short-term nature. The carrying value of the Company’s term loan as of December 31, 2025 (see Note 11) approximated fair value based on interest rates currently available to the Company.

The tables below present information about the Company’s assets and liabilities that are regularly measured and carried at fair value on a recurring basis at December 31, 2025 and December 31, 2024 and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, which is described further within Note 2, *Summary of Significant Accounting Policies*.

Financial assets measured at fair value on a recurring basis as of December 31, 2025 are summarized as follows (in thousands):

Description	Balance as of December 31, 2025	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets				
Cash equivalents:				
Money market funds	$ 46,941	$ 46,941	$ —	$ —
Total cash equivalents	$ 46,941	$ 46,941	$ —	$ —
Total financial assets	$ 46,941	$ 46,941	$ —	$ —

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2024 are summarized as follows (in thousands):

Description	Balance as of December 31, 2024	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets				
Cash equivalents:				
Money market funds	$ 76,089	$ 76,089	$ —	$ —
Total cash equivalents	$ 76,089	$ 76,089	$ —	$ —
Total financial assets	$ 76,089	$ 76,089	$ —	$ —
Liabilities				
CVR liability	$ 2,900	$ —	$ —	$ 2,900
Total financial liabilities	$ 2,900	$ —	$ —	$ 2,900

Money market funds

Money market funds were valued by the Company using quoted prices in active markets for identical securities, which represent a Level 1 measurement within the fair value hierarchy.

CVR liability

As discussed in Notes 1 and 3, at the effective time of the Merger, each person who as of immediately prior to the effective time of the Merger was a stockholder of record of Homology or had the right to receive Homology's common stock received a CVR, issued by Homology subject to and in accordance with the terms and conditions of a CVR Agreement, representing the contractual right to receive cash payments from the combined company upon the receipt of certain proceeds from a disposition of Homology's pre-merger assets, calculated in accordance with the CVR Agreement. The Company concluded that the CVR liability was a derivative liability accounted for at fair value. The fair value of the CVR liability was based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. For the portion of the CVR liability that was related to Homology's equity interest in OXB (US) LLC, the Company utilized a monte carlo simulation model, also known as a probability simulation, to estimate the fair value of the CVR liability at December 31, 2024. This model requires the use of estimates and assumptions including estimated future revenues and discount rates. Upon Oxford Biomedica (US), Inc.'s exercise of its option to cause the Company to sell and transfer to Oxford Biomedica (US), Inc. all of the Company's equity ownership interest in OXB (US) LLC in June 2025, the Company received proceeds from Oxford Biomedica (US), Inc. and then remitted those proceeds to the CVR holders, and subsequently removed the associated CVR liability and recorded $0.4 million for the change in estimated fair value during the twelve months ended December 31, 2025 in other income (expense), net.

For the portion of the CVR liability related to Homology's HMI-103, HMI-204, capsids and AAVHSC platform, the Company's fair value assessment includes judgments around the probability of progressing the in-process research and development assets. As of December 31, 2025, the Company's assessment resulted in a CVR liability of zero.

Convertible Notes

Legacy Q32 issued convertible notes (the "Convertible Notes") totaling $30.0 million during the year ended December 31, 2022. Legacy Q32 concluded that the Convertible Notes and its related features are within the scope of FASB ASC Topic 825, *Financial Instruments* ("ASC 825"), as a combined financial instrument, and Legacy Q32 elected the fair value option where changes in fair value of the Convertible Notes are measured through the accompanying consolidated statement of operations until settlement. The Convertible Notes liability represents a Level 3 measurement within the fair value hierarchy as it has been valued using certain unobservable inputs.

Upon closing of the Merger, Legacy Q32 converted the outstanding Convertible Notes plus accrued interest into shares of common stock at 90% of the purchase price of the mandatory conversion event. As the Convertible Notes are recorded at fair value, a gain of $15.9 million on the change in the fair value prior to the conversion of convertible notes is reflected in the consolidated statement of operations for the year ended December 31, 2024 (see Note 11).

During the years ended December 31, 2025 and 2024, there were no transfers between Level 1, Level 2 and Level 3 measurements. There have been no impairments of the Company's assets measured and carried at fair value during the years ended December 31, 2025 and 2024.

6. Investment in Equity Securities

As part of the Merger, the Company obtained Homology's 20% equity interest in OXB (US) LLC, an AAV vector process development and manufacturing services company. At that time, the Company had significant influence over, but did not control, OXB (US) LLC through its noncontrolling representation on OXB (US) LLC's board of directors and the Company's equity interest in OXB (US) LLC. Accordingly, the Company did not consolidate the financial statements of OXB (US) LLC and accounted for its investment using the equity method of accounting.

The Company recorded its equity method investment in OXB (US) LLC at fair value upon the effective date of the Merger. The fair value of the equity method investment was determined based on the market approach. This approach estimated the fair value of OXB (US) LLC based on the implied value for the entity, including the Options (as defined in Note 3 above), for a controlling interest in OXB (US) LLC at the entity's formation. As part of its fair value analysis, the Company determined that the Options were embedded in the Company's ownership units of OXB (US) LLC because the Options were not legally detachable or separately exercisable. Accordingly, the equity method investment and the Options represented one unit of account and the fair value recorded reflected the value of the equity interest and the Options (refer to Note 3 for more information for how the fair value was determined).

As a result of transactions by OXB (US) LLC, the Company's investment was diluted to a 10% equity interest in OXB (US) LLC on May 22, 2024, and the Company no longer had the ability to exert significant influence over the operating and financial policies of OXB (US) LLC. The Company discontinued the equity method of accounting for the investment in OXB (US) LLC on May 22, 2024 and determined the remaining investment to be an equity security accounted for in accordance with FASB ASC Topic 321, *Investments—Equity Securities* ("ASC 321") at the date the investment no longer qualified for the equity method of accounting. The Company recorded the equity instrument at fair value and applied the measurement alternative under ASC 321 such that the Company would not change the amount recorded for the equity instrument unless the Company identified observable price changes in orderly transactions for the identical or similar investment of the same issuer or the equity instrument was otherwise deemed to be impaired.

At each reporting period, the Company was required to make a qualitative assessment considering impairment indicators to evaluate whether the investment was impaired. If deemed impaired, the Company was required to estimate the fair value of the investment and recognize an impairment loss equal to the difference between the fair value of the investment and its carry amount.

On March 1, 2025, Oxford Biomedica (US), Inc. exercised its option to cause the Company to sell and transfer to Oxford Biomedica (US), Inc. all of the Company's equity ownership interest in OXB (US) LLC. In June 2025, the Company finalized the sale of its 10% equity interest in OXB (US) LLC to Oxford Biomedica (US), Inc. and received $2.5 million from Oxford Biomedica (US), Inc., calculated using the Company's pro rata share of OXB (US) LLC (10%), times a predetermined multiple of revenue for the immediately preceding 12-month period increased by OXB (US) LLC's cash balance and decreased by OXB (US) LLC's debt balance as of the exercise date, and reduced the associated equity investment on its condensed consolidated balance sheet to zero.

7. Property and Equipment, Net

Property and equipment, net consisted of the following as of (in thousands):

	December 31,	
	2025	2024
Lab equipment	$ 1,382	$ 1,382
Furniture and fixtures	351	351
Computer equipment	89	89
Leasehold improvements	1,001	1,001
Total property and equipment	2,823	2,823
Less accumulated depreciation	(1,844)	(1,453)
Property and equipment, net	$ 979	$ 1,370

Depreciation expense for the years ended December 31, 2025 and 2024 was approximately $0.4 million and $0.5 million, respectively. No impairment losses occurred in 2025 and 2024. The Company had no losses on disposal of fixed assets in 2025 and 2024.

8. Prepaid Expenses, Other Current Assets and Other Noncurrent Assets

Prepaid expenses and other current assets consisted of the following as of (in thousands):

	December 31,	
	2025	2024
Amounts due under Asset Purchase Agreement	$ 4,837	$ —
Prepaid external research and development	528	2,076
Payroll tax credit	555	555
Prepaid expenses	813	885
Other	20	396
Total prepaid expenses and other current assets	$ 6,753	$ 3,912

Included in prepaid external research and development is a deposit of $0.2 million that has been transferred to a payment processor to pay out investigator site fees related to our SIGNAL-AA Part B and OLE trials.

Other noncurrent assets consisted of the following as of (in thousands):

	December 31,	
	2025	2024
Prepaid external research and development - long term	$ —	$ 116
Total other noncurrent assets	$ —	$ 116

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of (in thousands):

	December 31,	
	2025	2024
Accrued compensation and related expenses	$ 2,486	$ 2,782
Accrued external research and development	462	2,611
Accrued professional services and other	591	1,474
Operating lease liability, current	693	612
Total accrued expenses and other current liabilities	$ 4,232	$ 7,479

10. Commitments and Contingencies

As of December 31, 2025, the Company had ongoing clinical studies in various clinical trial stages. Its most significant contracts relate to agreements with CROs for clinical trials and preclinical studies and CDMOs for manufacturing which the Company enters into in the normal course of business. The contracts with CROs and CDMOs are generally cancellable, with notice, at the Company's option.

Operating lease

In 2021 the Company entered into a long-term operating lease agreement for its current corporate headquarters in Waltham, Massachusetts ("headquarters lease"). The headquarters lease provides approximately 15,000 square feet for general office use and research lab facilities. The headquarters lease commencement date was January 1, 2022 and the Company did not take control or have the right to use the leased property until this time. The lease term ends in December 2031. The Company has an option to extend the lease term for an additional five years. The initial rent for the office space is approximately $1.0 million per year, increasing every year by 3% for total aggregate payment of $11.1 million. Upon the commencement date, the Company established a right-of-use asset and lease liability on the consolidated balance sheet. As part of the agreement, the Company arranged for a letter of credit for $0.6 million as a security for the headquarters lease, which is considered restricted cash and included as restricted cash and restricted cash equivalents in the consolidated balance sheet. The Company received $0.4 million in a tenant improvement allowance that was applied against the right-of-use asset.

As of December 31, 2025, the Company's headquarters lease had a weighted-average remaining lease term of 6.0 years and weighted average incremental borrowing rate of 7.5%.

Amounts reported in the consolidated balance sheet for leases where the Company is the lessee as of December 31, 2025 and December 31, 2024 were as follows (in thousands):

	December 31, 2025	December 31, 2024
Assets:		
Operating lease right-of-use assets	$ 5,100	$ 5,722
Total operating lease right-of-use assets	$ 5,100	$ 5,722
Liabilities:		
Current:		
Operating lease liabilities	$ 693	$ 612
Noncurrent:		
Operating lease liabilities, net of current portion	4,943	5,636
Total operating lease liabilities	$ 5,636	$ 6,248

The following table summarizes operating lease costs for the years ended December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Fixed lease costs	$ 1,060	$ 1,029
Variable lease costs	702	436
Total lease costs	$ 1,762	$ 1,465

Variable lease costs were primarily related to operating expenses, taxes and insurance associated with the operating lease, which were assessed based on the Company's proportionate share of such costs for the leased premises. As these costs are generally variable in nature, they were not included in the measurement of the operating lease right-of-use asset and related lease liability. Total lease costs are included as operating expenses in the Company's consolidated statements of operations. Future minimum lease payments under non-cancelable lease agreement as of December 31, 2025 and a reconciliation to the carrying amount of the lease liabilities presented in the consolidated balance sheet are as follows (in thousands):

	Minimum Rental Payments
2026	$ 1,092
2027	1,124
2028	1,158
2029	1,193
2030	1,229
Thereafter	1,265
Total minimum lease payments	7,061
Less imputed interest	(1,425)
Total lease liability	$ 5,636
Lease liability, current portion	693
Lease liability, net of current portion	4,943
Total	$ 5,636

Prior to the Merger, Homology was subleasing office and research and development laboratory space in Bedford, Massachusetts, under a sublease agreement with OXB (US) LLC that expired in December 2024. At the effective time of the Merger, the Company recorded a liability of approximately $1.0 million representing the present value of the future minimum

lease payments due under this sublease. As of December 31, 2025, all amounts under the sublease agreement have been paid and there are no accrued expenses or liabilities on the Company's consolidated balance sheet related to the sublease.

License Agreements

License Agreement with the University of Colorado

In August 2017, the Company entered into an exclusive license agreement, as amended in February 2018, September 2018, and April 2019 (the "Colorado License Agreement"), with The Regents of the University of Colorado ("Colorado"), pursuant to which the Company obtained worldwide, royalty-bearing, sublicensable licenses under certain patents and know-how owned by Colorado and Medical University of South Carolina ("MUSC") relating to the research, development and commercialization of ADX-097. The licenses granted to the Company are exclusive with respect to certain patent families and know-how and non-exclusive with certain other patent families and know-how. The licenses granted to the Company are also subject to certain customary retained rights of Colorado and MUSC and rights of the United States government owing to federal funding giving rise to inventions covered by the licensed patents. The Company agreed to use commercially reasonable efforts to develop, manufacture and commercialize ADX-097, including by using commercially reasonable efforts to achieve specified development and regulatory milestones by specified dates.

In addition, the Company agreed to pay Colorado (i) development and sales milestone payments in an aggregate amount of up to $2.2 million per licensed product for the first three products, (ii) tiered royalty rates on cumulative net sales of licensed products in the low single digit percentages, (iii) 15% of sublicense income and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents. The Company's obligation to pay royalties to Colorado commences, on a licensed product-by-licensed product and country-by-country basis, from the first commercial sale of a licensed product in any country and expires on the later of (a) the last to expire valid claim within the licensed patents covering such licensed product in such country, and (b) 20 years following the effective date of the Colorado License Agreement, or April 2037 (the "Royalty Term").

On November 28, 2025, in connection with the ADX-097 Asset Sale, the Colorado License Agreement was amended and restated and all of the Company's rights and obligations thereunder were transferred to Akebia.

During the years ended December 31, 2025 and 2024, the Company had zero research and development expense for any milestone related to the Colorado License Agreement. The financial statements as of December 31, 2025 and 2024 do not include liabilities with respect to royalty fees on the license agreement as the Company has not yet generated revenue and the achievement of certain milestones is not yet probable.

License Agreement with Bristol-Myers Squibb Company

In September 2019, the Company entered into a license agreement, as amended in August 2021 and July 2022 (the "BMS License Agreement"), with Bristol-Myers Squibb Company ("BMS"), pursuant to which the Company obtained sublicensable licenses from BMS to research, develop and commercialize licensed products, including bempikibart, for any and all uses worldwide. The licenses granted to the Company are exclusive with respect to BMS's patent rights and know-how relating to certain antibody fragments (including certain fragments of bempikibart) and non-exclusive with respect to BMS's patent rights and know-how relating to the composition of matter and use of a specific region of bempikibart. BMS retained the right for it and its affiliates to use the exclusively licensed patents and know-how for internal, preclinical research purposes. Under the BMS License Agreement, the Company is prohibited from engaging in certain clinical development or commercialization of any antibody other than a licensed compound with the same mechanism of action until the earlier of the expiration of Q32's obligation to pay BMS royalties or September 2029.

In consideration for the license, the Company made an upfront payment to BMS of $8 million, issued 318,278 Series A preferred shares to BMS and agreed to use commercially reasonable efforts to develop and commercialize at least one licensed product in key geographic markets. In addition, the Company agreed to pay BMS (i) development and regulatory milestone payments in aggregate amounts ranging from $32 million to $49 million per indication for the first three indications and commercial milestone payments in an aggregate amount of up to $215 million on net sales of licensed products, (ii) tiered royalties ranging from rates in the mid-single digit percentages to up to 10% of net sales, with increasing rates depending on the cumulative net sales, (iii) up to 60% of sublicense income, which percentage decreases based on the development stage of bempikibart at the time of the sublicensing event, and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents.

The Company's obligation to pay BMS royalties under subsection (ii) above commences, on a licensed product-by-licensed product and country-by-country basis on the first commercial sale of a licensed product in a country and expires on the later of (x)

12 years from the first commercial sale of such Licensed Product in such country, (y) the last to expire licensed patent right covering bempikibart or such licensed product in such country, and (z) the expiration or regulatory or marketing exclusivity for such licensed product in such country (Royalty Term). If the Company undergoes a change of control prior to certain specified phase of development, the development and milestone payments are subject to increase by a low double digit percentage and the royalty rates are subject to increase by a low sub single digit percentage.

Unless terminated earlier by either party pursuant to its terms, the BMS License Agreement will expire on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last to expire Royalty Term with respect to such licensed product in such country. Either party may terminate the BMS License Agreement for the other party's material breach, subject to a specified notice and cure period. BMS may terminate the BMS License Agreement if the Company fails to meet its diligence obligations under the BMS License Agreement, for the Company's insolvency, or if the Company or its affiliates challenges the validity, scope, enforceability, or patentability of any of the licensed patents. The Company may terminate the BMS License Agreement for any reason upon prior written notice to BMS, with a longer notice period if a licensed product has received regulatory approval. If the BMS Agreement is terminated for the Company's material breach, BMS will regain rights to bempikibart and the Company must grant BMS an exclusive license under the Company's patent rights covering bempikibart, subject to a low single digit percentage royalty on net sales of bempikibart payable to the Company by BMS.

In July 2024, the Company made a $4.0 million development milestone payment to BMS and recorded it as research and development expenses. As of December 31, 2025, no further events have occurred that would require payment of milestones, royalties or sublicense fees.

Legal Proceedings

The Company is not currently party to any material legal proceedings. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and reasonably estimable. Legal costs associated with these matters are expensed when incurred.

Indemnification Arrangements

As permitted under Delaware law, the Company has agreements whereby it indemnifies certain of its investors, stockholders, employees, officers, and directors (collectively, the "Indemnified Parties") for certain events or occurrences while the Indemnified Parties are, or were serving, at its request in such capacity. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has an Executive Liability insurance policy that limits its exposure and enables it to recover a portion of any future amounts paid up to $5.0 million. The Company believes the estimated fair value of these indemnification agreements is minimal. The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the Indemnified Parties for losses suffered or incurred by the Indemnified Parties, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

11. Debt

Venture Debt

In December 2020, the Company entered into a Loan and Security Agreement, as amended in June 2022, August 2022, December 2022, April 2023, July 2023, November 2023, March 2024 and July 2024, with Silicon Valley Bank, a California corporation (the "Loan Agreement") for a lending facility of up to $25.0 million. The Company received $5.0 million upon execution of the Loan Agreement which it repaid in July 2023, a $5.5 million term loan advance in July 2023 and a $7.0 million term loan advance in March 2024. The Company no longer has the ability to draw down any additional loan advances. The term loan bears interest at an annual rate equal to the greater of the prime rate minus 0.25% or 8.00%. The Loan Agreement provided for interest-only payments until July 1, 2025, followed by 24 equal monthly payments of principal plus interest. The loan matures on July 1, 2027. In addition, the Company paid a fee of $0.1 million upon closing and is required to pay a fee of 3.5% of the aggregate amount of advances under the Loan Agreement at maturity. At its option, the Company may elect to prepay all or a portion of the outstanding advances by paying the principal balance, and all accrued and unpaid interest, and a prepayment premium. In connection with the Loan Agreement, the Company granted the lender a security interest in all of its personal property now owned or hereafter acquired, excluding intellectual property (but including the rights to payment and proceeds from the sale, licensing or disposition of intellectual property), and a negative pledge on intellectual property. The Loan Agreement

also contains certain events of default, representations, warranties and non-financial covenants of the Company. If the Company fails to make payments when due or breaches any operational covenant or has any event of default, this could have a material adverse effect on its business and financial condition. The Company was in compliance with all covenants at December 31, 2025.

In conjunction with the Loan Agreement, in December 2020, the Company issued warrants to purchase 7,988 shares of common stock to the lender at a per share price of $6.87 with a maximum contractual term of 10 years and in July 2023, warrants to purchase 10,156 shares of common stock to the lender at a per share price of $7.50 with a maximum contractual term of 10 years. The warrants had a *de minimis* total relative fair value at the time of issuance. Pursuant to FASB ASC Topic 480, *Distinguishing Liabilities from Equity* and FASB ASC Topic 815, *Derivatives and Hedging*, the warrants were classified as equity and were initially measured at fair value. Subsequent changes to fair value will not be recognized so long as the instrument continues to be equity classified.

Interest expense for the years ended December 31, 2025 and 2024 was $1.1 million in each period. The effective rate on the Loan Agreement, including the amortization of the debt discount and issuance costs was 9.45% and 9.55%, respectively, at each of December 31, 2025 and 2024. The components of the long-term debt balance are as follows (in thousands):

	December 31,	
	2025	2024
Principal amount of term loans	$ 9,375	$ 12,500
Unamortized debt discount and issuance costs	333	153
Carrying amount	9,708	12,653
Less current portion	(6,235)	(3,097)
Long-term debt, net	$ 3,473	$ 9,556

Convertible Notes

In May 2022, the Company entered into an agreement with the existing investors of the Company to issue, and for the existing investors to purchase, the Convertible Notes for up to an aggregate of $30.0 million. The Convertible Notes bore interest at 5.0% per annum. Interest expense was $0.3 million for the year ended December 31, 2024. The Convertible Notes converted into share of common stock in March 2024 per the Merger (see discussion below and in Note 1).

The Convertible Notes contained mandatory conversion features whereby the total outstanding amount of principal and accrued and unpaid interest of the Convertible Notes automatically converted into shares of common stock upon certain qualified financings. The total outstanding amount of principal and accrued and unpaid interest of the Convertible Notes convert into shares of common stock at 90% of the purchase price of the mandatory conversion events.

The Company elected to account for the Convertible Notes at fair value where changes in fair value of the notes are measured through the consolidated statements of operations until settlement. Subsequent to December 31, 2023 and per the Merger further discussed in Note 1, the Convertibles Notes converted into 1,433,410 shares of common stock. The Company recorded a gain on the change in fair value prior to the conversion of the Convertible Notes of $15.9 million in other income (expense), net during the year ended December 31, 2024.

12. Convertible Preferred Stock

On March 25, 2024, immediately prior to completing the Merger, all classes of convertible preferred stock of Legacy Q32 were converted to Legacy Q32 common stock, and then exchanged in the Merger for shares of the Company's common stock using the Exchange Ratio. The Series A convertible preferred stock converted into an aggregate of 2,286,873 shares of Legacy Q32 common stock, the Series A-1 convertible preferred stock converted into an aggregate of 312,094 shares of Legacy Q32 common stock and the Series B convertible preferred stock converted into an aggregate of 2,625,896 shares of Legacy Q32 common stock. The conversion of the Legacy Q32 preferred stock into shares of Legacy Q32 common stock resulted in an increase of less than $0.1 million to common stock and an increase of $111.4 million to additional paid-in-capital immediately prior to completing the Merger.

13. Common Stock

As of December 31, 2025, the Company's Certificate of Incorporation, as amended, authorized the Company to issue 400,000,000 shares of common stock, $0.0001 par value per share.

The Company has reserved the following shares of common stock for future issuance:

	December 31,	
	2025	2024
Shares reserved for future issuance under the 2024 Stock Incentive Plan	1,997,963	1,760,657
Shares reserved for future issuance under the 2024 Employee Stock Purchase Plan	242,813	120,836
Shares reserved for stock option exercises	2,186,531	1,942,920
Shares reserved for vesting of restricted stock units	317,213	—
Shares reserved for warrants	18,144	18,144
	4,762,664	3,842,557

14. Stock-Based Compensation

2017 Stock Option and Grant Plan

Legacy Q32 adopted the 2017 Stock Option and Grant Plan and subsequent amendments (the "2017 Plan") with 1,246,290 shares of common stock reserved for issuance to employees, directors, and consultants. The 2017 Plan allowed for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock awards. As of December 31, 2025, there were no additional shares available for future grant under the 2017 Plan.

2024 Stock Option and Incentive Plan

On March 15, 2024, Homology's board of directors adopted and subsequently, Homology's stockholders approved the Q32 Inc. 2024 Stock Option and Incentive Plan (the "2024 Plan"), which became effective upon the closing of the Merger. The 2024 Plan replaced the 2017 Plan, as well as the Homology 2015 Stock Incentive Plan (the "Homology 2015 Plan"), and the Homology 2018 Plan (together with the Homology 2015 Plan, the "Homology Incentive Plans"). Upon effectiveness of the 2024 Plan, the Company ceased granting new awards under the 2017 Plan and the Homology Incentive Plans.

The 2024 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 officers, employees, directors and consultants of the Company. The number of shares of common stock initially available for issuance under the 2024 Plan was 2,839,888 shares of common stock. The 2024 Plan provides that the number of shares reserved and available for issuance under the 2024 Plan will automatically increase each January 1, beginning on January 1, 2025, by 5% of the outstanding number of shares on the immediately preceding December 31, or such lesser amount as determined by the plan administrator. As of December 31, 2025, there were 1,997,964 shares available for future grant under the 2024 Plan.

2024 Employee Stock Purchase Plan

On March 15, 2024, Homology's board of directors adopted and subsequently, Homology's stockholders approved the Q32 Inc. 2024 Employee Stock Purchase Plan (the "2024 ESPP"). The 2024 ESPP allows employees to buy Company stock through after-tax payroll deductions at a discount from market value. The 2024 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 2024 ESPP was 120,836 shares of common stock. The 2024 ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2025, by the lesser of 241,677 shares, a number of shares equal 1% of the outstanding number of shares on the immediately preceding December 31, or such lesser amount as determined by the plan administrator. As of December 31, 2025, there were 242,813 shares available for future grant under the 2024 ESPP.

Under the 2024 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 2024 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 2024 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).

There were no shares issued under the 2024 ESPP during the years ended December 31, 2025 and 2024.

Stock Options

Stock options granted by the Company typically vest over a four-year period and have a ten-year contractual term. The following table summarizes the Company's stock option activity during the year ended December 31, 2025:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	1,942,920	$ 12.93	8.33	$ 12
Granted	505,911	$ 2.73		
Exercised	—	$ —		
Cancelled	(262,300)	$ 10.77		
Outstanding at December 31, 2025	2,186,531	$ 2.82	7.81	$ 1,567
Vested and expected to vest at December 31, 2025	2,186,531	$ 2.82	7.81	$ 1,567
Exercisable at December 31, 2025	1,132,223	$ 3.00	6.90	$ 841

The per share weighted-average grant date fair value of options granted in the year ended December 31, 2025 was $2.14 prior to the Option Repricing (as defined below) in February 2025 and $2.06 after. The total fair value of options vested during the year ended December 31, 2025 was $1.5 million. As of December 31, 2025, total unrecognized compensation costs to the unvested stock options were approximately $8.0 million, which is expected to be recognized over a weighted-average period of 1.3 years.

Stock Option Modifications

On February 23, 2025, the Company's board of directors approved a stock option repricing (the "Option Repricing"), which was effective on February 24, 2025 (the "Repricing Date"). The Option Repricing applied to outstanding options to purchase shares of common stock of the Company granted under the Company's 2017 Plan and 2024 Plan (collectively, "the Plans"), which, as of the Repricing Date, were held by current employees and non-employee directors of the Company and had an exercise price in excess of the current trading price of the common stock (so-called "underwater options") with grant dates prior to February 23, 2025 (the "Eligible Options"). As of the Repricing Date, the Eligible Options were repriced such that the exercise price per share for such Eligible Options was reduced to the closing price of the common stock on the Nasdaq Global Market on the Repricing Date (the "Repriced Exercise Price"). The total number of shares of common stock underlying all Eligible Options was 1,871,416.

The Eligible Options will revert to the original exercise price (the "Original Price") if (i) such Eligible Options are exercised prior to the one-year anniversary of the Repricing Date (the "Retention Date"), (ii) an Eligible Option holder's employment is terminated by the Company for Cause (as defined in the 2024 Plan) prior to the Retention Date, or (iii) an Eligible Option holder resigns for any reason prior to the Retention Date. If an Eligible Option holder is terminated by the Company other than for Cause prior to the Retention Date (a "Terminated Employee"), any Eligible Options vested as of the date of such termination shall be exercisable at the Repriced Exercise Price (the "Terminated Employee Vested Options"), even prior to the Retention Date; provided that any unvested Eligible Options as of the date of such termination shall revert to the Original Price as of the date of termination. The deadline to exercise any Terminated Employee Vested Options, and any other Eligible Options held by a Terminated Employee that may become vested, shall be extended (but not truncated) to the later of (a) the one-year anniversary of the Terminated Employee's termination date and (b) to align with the Eligible Option holder's severance period (whether now or later implemented); provided that no extension shall exceed the Terminated Employee Vested Option's expiration date, if earlier. In the event of a change-in-control prior to the Retention Date, each Eligible Option shall retain the Repriced Exercise Price to the extent it has not otherwise reverted to the Original Price. For the avoidance of doubt, the Eligible Options as modified by the Option Repricing are subject to the severance or change-in-control provisions in the current or future employment agreements, programs, policies or plans the Company has entered into or implemented or will enter into or implement with its directors, executive officers and other employees. There were no changes to the number of shares, the vesting schedule, or the expiration date of the Repriced Options except as outlined above.

The repricing of the Eligible Options was accounted for as a modification under FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). Accordingly, the Company calculated incremental compensation cost on the modification date in an amount equal to the difference between the fair value of the awards before and after modification, determined using a lattice

model based on the Hull-White framework, and recognized $0.3 million in its statement of operations for the year ended December 31, 2025. An additional $0.1 million is being recognized over the remaining vesting terms of the modified awards.

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 two or three equal installments. The following table summarizes the Company's RSU activity during the year ended December 31, 2025:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2025	—	$ —
Granted	467,150	$ 2.54
Vested	(106,737)	$ 2.54
Forfeited	(43,200)	$ 2.54
Outstanding at December 31, 2025	317,213	$ 2.54

As of December 31, 2025, total unrecognized compensation costs to the unvested RSUs were approximately $0.6 million, which is expected to be recognized over a weighted-average period of 2.2 years. The total fair value of RSUs vested during the year ended December 31, 2025 was $0.3 million.

Stock-Based Compensation Expense

The underlying assumptions used to value stock options granted using the Black-Scholes option-pricing model prior to the Option Repricing during the years ended December 31, 2025 and 2024 were as follows:

	Years Ended December 31,	
	2025	2024
Risk-free interest rate range	3.66% — 4.46%	3.48% — 4.34%
Expected dividend rate	—	—
Expected term (years) range	5.23 — 6.11	5.17 — 6.11
Expected stock price volatility range	93.7% — 95.8%	92.0% — 94.1%

Risk-Free Interest Rate – The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock options.

Expected Dividend – The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

Expected Term – The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term, which calculates the expected term as the average time-to-vesting and the contractual life of the options for stock options issued to employees. The expected term for options granted to non-employees is based on the contractual life of the options.

Expected Volatility – Due to the Company's limited operating history and lack of sufficient company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price.

Fair Value of Common Stock – Prior to the Merger, as there had been no public market for the Company's common stock, the estimated fair value of its common stock was determined by the Company using estimates and assumptions on the respective grant dates of the awards. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred securities and the superior likelihood of achieving a liquidity event, such as an IPO or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

As discussed above, incremental stock-based compensation expense for the Option Repricing on February 24, 2025 was calculated using a lattice model based on the Hull-White framework. This approach incorporated key assumptions, including suboptimal exercise multiples for both staff and executives, derived from empirical data. The model also accounted for additional factors such as vesting periods, employee turnover based on the accounting of forfeitures, volatility, contractual expiry, and risk-free rates.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development	$ 933	$ 1,105
General and administrative	4,322	3,281
Total stock-based compensation expense	$ 5,255	$ 4,386

15. Agreements with Horizon

From August 2022 until November 2023, Legacy Q32 was a party to the Collaboration and Option Agreement (the "Horizon Collaboration Agreement") and the Asset Purchase Agreement (the "Purchase Agreement," and together with the Horizon Collaboration Agreement, the "Horizon Agreements"), each between Legacy Q32 and Horizon Therapeutics Ireland DAC ("Horizon"), pursuant to which Legacy Q32 received $55.0 million in initial consideration and staged development funding for the completion of the two ongoing Phase 2 trials for bempikibart, and Horizon had an option to acquire the bempikibart program at a prespecified price, subject to certain adjustments.

The Company has received $55.0 million of the $55.0 million transaction price from Horizon. In October 2023, Amgen Inc. ("Amgen") completed its acquisition of Horizon Therapeutics public limited company ("Horizon plc"). Following the closing of Amgen's acquisition of Horizon plc, the Company agreed with Amgen to mutually terminate the Horizon Agreements and in November 2023, the Company and Horizon entered into a termination agreement (the "Horizon Termination Agreement"), pursuant to which Horizon's option to acquire the bempikibart program was terminated. As a result, the Company retained all initial consideration and development funding received under the Horizon Collaboration Agreement (as defined below) and regained full development and commercial rights to bempikibart. In consideration for the Horizon Termination Agreement, the Company agreed to pay Horizon regulatory and sales milestones payments of up to an aggregate amount of $75.1 million upon the first achievement of certain regulatory and sales milestones with respect to bempikibart.

The Company concluded that the consideration allocated to the research service performance obligations should be recognized over time as Horizon received the benefit of the research activities as the activities were performed. The Company has determined that this method was most appropriate as progress towards completion of research is largely driven by time and effort spent and costs incurred to perform this research. The Horizon Termination Agreement is accounted for as a modification because it does not result in the addition of distinct goods or services. Since the two performance obligations and the material right are terminated with no further performance obligations aside from the contingent payments to Horizon of up to $75.1 million, the Company recognized the remaining deferred revenue in the fourth quarter of 2023.

Upon the execution of the Horizon Termination Agreement, the Company became obligated to pay Horizon up to $75.1 million contingent on regulatory and sales-based milestones, consisting of a $5.0 million payment upon the first regulatory approval in the U.S. or in any of five specified major western European markets, and up to $70.1 million ranging from mid-single digit to low-double digit millions of dollars upon the achievement of specified annual sales thresholds, which range from exceeding $250 million to exceeding $1.5 billion. If bempikibart does not achieve the milestones set forth in the Horizon Termination Agreement, the Company will not be obligated to make any payments nor repay any amounts to Horizon.

These potential payments to Horizon are not in exchange for a distinct good or service; therefore, the Company accounts for consideration payable to Horizon as a reduction of the transaction price under FASB ASC 606, *Revenue from Contracts with*

Customers. The Company concluded that the $55.0 million of arrangement consideration previously recognized should be fully constrained as a result of the contingent consideration payable to Horizon, and accordingly, all amounts previously recognized as revenue were reversed in the fourth quarter of 2023 and a refund liability was established for the $55.0 million cash received during the term of the Horizon Collaboration Agreement. No amounts have been recognized related to the remaining potential payment to Horizon (up to $20.1 million) as it is not probable that the respective milestones will be achieved at this time.

On November 7, 2025, the Company and Amgen entered into an amendment to the Horizon Termination Agreement (the "Amgen Amendment") pursuant to which the Company issued Horizon a one-time equity grant of 553,695 shares of the Company's common stock as full consideration of the milestone payments under the Horizon Termination Agreement. Following the transactions contemplated by the Amgen Amendment, the Company has no remaining obligations to Amgen, including with respect to the $75.1 million in regulatory and sales-based milestone payments set forth in the Horizon Collaboration Agreement. Therefore, the Company derecognized the $55.0 million refund liability previously recorded for the $55.0 million of cash received under the Horizon Collaboration Agreement and recognized collaboration arrangement revenue for the difference between the equity issuance, and the refund liability as the consideration was no longer constrained.

16. Related Party Transactions

The Company has consulting and advisory agreements with certain investors and board members which are considered to be related party transactions. The Company did not incur expense for the years ended December 31, 2025 and 2024 related to services provided by these investors and board members.

No amounts were due to related parties at December 31, 2025 or December 31, 2024.

17. Defined Contribution Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants the option to elect to defer a portion of their annual compensation on a pretax basis, as well as Roth post tax deferrals. As currently designed, the Company is not required to make and has not made any contributions to the 401(k) Plan.

18. Income Taxes

The Company adopted ASU 2023-09 effective January 1, 2025, on a prospective basis. The disclosures required by the standard are included below for the year ended December 31, 2025. Comparative prior period disclosures have not been revised.

The components of the Company's income (loss) before provision for income taxes are as follows (in thousands):

	Year Ended December 31, 2025
Domestic	$ 29,843
Foreign	—
Total income (loss) before income taxes	$ 29,843

The Company has had immaterial tax expense due to operating losses incurred since inception and no deferred tax provision in the current period.

Total state income taxes paid (net of refunds) for the year ended December 31, 2025 were related to Massachusetts. During the years ended December 31, 2025 and 2024, the Company made cash payments for income taxes of less than $0.1 million in each period.

The following table reconciles the U.S. federal statutory income tax rate to the Company's effective income tax rate for the year ended December 31, 2025:

	Year Ended December 31, 2025	
	Amount (in thousands)	Percentage
Federal statutory income tax rate	$ 6,267	21.0 %
State and local income taxes, net of federal income tax effect	(2)	— %
Foreign tax effects:		
Other foreign jurisdictions	—	— %
Tax credits:		
Research and development tax credits	(103)	(0.3)%
Changes in valuation allowances	(6,712)	(22.5)%
Nontaxable or nondeductible items		
Excess tax benefits on share-based payments	361	1.2 %
Other	189	0.6 %
Effective income tax rate	—	— %

As previously disclosed for the year ended December 31, 2024, prior to the adoption of ASU 2023-09, the effective income tax rate differed from the federal statutory income tax rate as follows:

	Year Ended December 31, 2024
Federal income tax expense at statutory rate	21.0 %
State income taxes, net of federal benefit	9.1
Permanent differences	(0.8)
Stock-based compensation expense	1.3
Gain/loss on convertible note conversion	7.1
CVR liability revaluation	0.7
Research and development tax credits	3.8
Change in valuation allowance	(42.2)
Effective income tax rate	— %

The Company's effective income tax rates for the years ended December 31, 2025 and 2024 were primarily due to state income tax resulting from interest income.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of the Company's net deferred income taxes were as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 58,663	$ 32,554
Capitalized R&D expenditures	27,599	46,552
Tax credit carryforwards	8,136	7,978
Capitalized intangible assets	3,282	3,591
Operating lease liability	1,529	1,682
Stock compensation and other	1,387	733
Contingent liability	—	14,801
Accruals and reserves	673	743
Total deferred tax assets	101,269	108,634
Valuation allowance	(98,471)	(106,876)
Total deferred tax assets, net of valuation allowance	2,798	1,758
Deferred tax liabilities:		
Operating right-of-use asset	(1,384)	(1,540)
Fixed assets	(129)	(218)
Installment sale	(1,285)	—
Total deferred tax liabilities	(2,798)	(1,758)
Net deferred tax assets	$ —	$ —

The Company's income tax provision for the year ended December 31, 2025 related to state and foreign income taxes. The Company has evaluated the positive and negative evidence bearing upon the reliability of its deferred tax assets. Based on this evaluation, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. During the year ended December 31, 2025, the valuation allowance decreased by $8.4 million primarily due to the recognition of deferred tax benefits associated with the expensing of previously capitalized research and development costs under IRC Section 174.

As of December 31, 2025, the Company has $217.4 million and $205.9 million of federal and state net operating loss carryforwards, respectively. The federal NOLs are not subject to expiration and the state NOLs begin to expire in 2040. These loss carryforwards are available to reduce future federal taxable income, if any. As of December 31, 2025, the Company also had federal and state research and development tax credit carryforwards of $6.3 million and $2.4 million respectively, to offset future income taxes, which will begin to expire in December 2038. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

Utilization of the Company's NOL carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 as well as similar state provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings could result in a change of control as defined by Section 382. The Company has not yet conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2025, would limit or otherwise restrict its ability to utilize its NOL and research and development credit carryforwards. In addition, future changes in ownership occurring after December 31, 2025 could affect the limitation in future years, and any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization.

The Company generated research and development tax 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 tax credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development tax credit carryforwards and, if an

adjustment is required, this adjustment would result in an adjustment to the deferred tax asset established for the research and development tax credit carryforwards and the valuation allowance.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. Among other provisions, this act includes permanently extended and modified certain expiring provisions of the 2017 Tax Cuts and Jobs Act and restored the immediate expensing of domestic research and development expenses. The Company has evaluated the impacts of these provisions and has concluded the OBBBA does not have a material impact on its consolidated financial statements other than reclassifications of the deferred tax assets.

The Company follows the provisions of ASC 740 which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements, requires certain disclosures of uncertain tax matters, specifies how reserves for uncertain tax positions should be classified on the consolidated balance sheets, and provides transition and interim period guidance, among other provisions. As of December 31, 2025 and 2024, the Company has not recorded any amounts for uncertain tax positions. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, the Company had no reserves for uncertain tax positions. For the years ended December 31, 2025 and 2024, no estimated interest or penalties were recognized on uncertain tax positions.

The Company files federal income tax returns in the United States and Australia and state income tax returns in Massachusetts and various other state jurisdictions. The Company's U.S. tax returns for the years ended December 31, 2022 to December 31, 2025 remain open and subject to examination by the Internal Revenue Service and state taxing authorities. The statute of limitations for assessment by the Australian Taxation Office is four years from the date of return filing. The Company is not currently under examination by the Australian Taxation Office for any tax years.

The Company's current intention is to permanently reinvest the total amount of its unremitted earnings in the local international jurisdiction. As such, the Company has not provided for taxes on the unremitted earnings of its international subsidiary. As of December 31, 2025, the Company's foreign subsidiary does not have any unremitted earnings.

19. Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the applicable period. In computing diluted net income (loss) per share, only potential shares of common stock that are dilutive are included. The Company considered each issue or series of issues of potential shares of common stock separately when determining whether potential shares of common stock are dilutive or antidilutive. The Company made such determination in sequence from the most dilutive to the least dilutive and concluded that its Convertible Notes are dilutive to net income per share for the year ended December 31, 2024. Pursuant to FASB ASC Topic 260, *Earnings Per Share*, the Company applied the if-converted method to determine the effect of its Convertible Notes on the diluted earnings per share calculations. Pursuant to such method, the Company adjusted the numerator for the gains or losses recognized during the period in net income from the Convertible Notes and the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the Convertible Notes were converted as of the beginning of the period.

	Years Ended December 31,	
(in thousands, except per share amounts)	**2025**	**2024**
Numerator:		
Net income (loss)-basic	$ 29,821	$ (47,733)
Net income (loss)-diluted	$ 29,821	$ (63,533)
Denominator:		
Weighted-average common shares outstanding-basic	12,300,568	9,320,884
Dilutive securities	14,228	336,812
Weighted-average common shares outstanding-diluted	12,314,796	9,657,696
Net income (loss) per share-basic	$ 2.42	$ (5.12)
Net income (loss) per share-diluted	$ 2.42	$ (6.58)

As of December 31, 2025, the Company's potentially dilutive securities, which include stock options, restricted stock units and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss

per share. As of December 31, 2024, the Company's potentially dilutive securities, which include stock options and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Years Ended December 31,	
	2025	2024
Options to purchase common stock	2,186,531	1,942,920
Restricted stock units	302,985	—
Warrants to purchase common stock	18,144	18,144

In addition, during the year ended December 31, 2022, Legacy Q32 issued the Convertible Notes with a principal balance of $30.0 million. As described in Note 11, the Convertible Notes contained conversion features whereby the Convertible Notes and any accrued interest may have converted into either a variable number of shares of common stock or into shares of Series B preferred stock based on a fixed exchange ratio. Any shares of Series B preferred stock issued to settle the Convertible Notes would then be convertible into shares of common stock. The Convertible Notes were excluded from the computation of diluted net loss per share attributable to common stockholders for the year ended December 31, 2024, because including them would have had an anti-dilutive effect. Per the Merger further discussed in Note 1, the Convertible Notes converted into 1,433,410 shares of common stock at the effective date of the Merger.

20. Segment Reporting

The Company operates as one operating segment, focused on research, development, and discovering, developing and delivering therapies for its novel biologics. The Company's CEO, as the chief operating decision maker ("CODM"), manages and allocates resources to the operations of the Company on a consolidated basis. Managing and allocating resources on a total-company basis enables the CODM to assess the overall level of resources available and how to best deploy those resources across research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, the CODM uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. When evaluating the Company's overall performance, the CODM is focused on the timing and progress of its preclinical and clinical development activities. The CODM regularly reviews total expenses, as well as direct research and development expenses by program and makes decisions using this information on a company-wide basis.

The accounting policies of the reportable segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance and decides how to allocate resources based on consolidated net loss. This measure is used to monitor budget versus actual results to assess performance of the segment. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

The following table presents reportable segment net (income) loss, including significant expenses regularly provided to the CODM, attributable to the Company's reportable segment for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	2024
	(in thousands)	
Direct research and development expense by program:		
Bempikibart	$ 6,713	$ 28,726
ADX-097	1,920	5,253
Discovery and other	155	856
Personnel-related costs (excluding stock-based compensation)	12,575	16,122
Other G&A expenses	9,709	9,586
Interest (income) expense, net	(1,055)	(2,832)
Other segment items (1)	(59,838)	(9,978)
Total segment net (income) loss	$ (29,821)	$ 47,733

(1) Other segment items are included in order to reconcile to total segment net (income) loss. Other segment items include non-cash items such as depreciation and amortization expense, stock-based compensation expense and the change in fair value of

contingent value rights. In 2025, other segment items also include the recognition of collaboration arrangement revenue related to the Amendment with Amgen (see Note 16) and the gain recognized related to the ADX-097 Sale (see Note 4). In 2024, other segment items also include gains and losses on the change in fair value of convertible notes and a loss from equity method investment.

21. Subsequent Events

Registered Direct Offering

On February 17, 2026, the Company entered into a definitive agreement for the issuance and sale of 1,666,679 shares of common stock and pre-funded warrants to purchase up to 1,025,654 shares of common stock at an offering price of $3.90 per share of common stock, which was the closing price per share of the Company's common stock on Nasdaq on February 13, 2026, and $3.8999 per pre-funded warrant, which represents the price per share for the common stock less the $0.0001 per share exercise price for each pre-funded warrant. The pre-funded warrants will be immediately exercisable after the date of issuance and may be exercised at any time until the pre-funded warrants are exercised in full. The issuance of the shares was completed on February 19, 2026.

The securities referenced above were offered pursuant to a shelf registration statement on Form S-3 (333-286491) that was filed with the SEC on April 11, 2025, and was declared effective by the SEC on April 21, 2025.

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES

The following description summarizes some of the terms of our restated certificate of incorporation, as amended, and amended and restated bylaws and of the Delaware General Corporation Law. This description is summarized from, and qualified in its entirety by reference to, our restated certificate of incorporation, as amended, and amended and restated bylaws, each of which has been publicly filed with the SEC.

Our authorized capital stock consists of:

- 400,000,000 shares of common stock, par value $0.0001 per share; and
- 10,000,000 shares of preferred stock, par value $0.0001 per share

Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol "QTTB."

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation, as amended, and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation, as amended. See below under *"—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions*."

Rights Upon Liquidation. In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Transfer Agent

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Dividend

Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock. We have never declared or paid any cash dividends on our common stock. We do not intend to declare or pay cash dividends for the foreseeable future. We currently expect to retain all future earnings, if any, for use in the development, operation and expansion of our business. Any determination to pay cash dividends in the future will depend upon, among other things, our results of operations, plans for expansion, tax considerations, available net profits and reserves, limitations under law, financial condition, capital requirements and other factors that our board of directors considers to be relevant.

Preferred Stock

Under the terms of our restated certificate of incorporation, as amended, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors have the

discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing the board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

Registration Rights

In connection with an Agreement and Plan of Merger, or the Merger Agreement, Q32 Bio Operations Inc. (previously named Q32 Bio Inc. and referred to herein as Legacy Q32) entered into a subscription agreement in November 2023, or the Subscription Agreement, with certain investors to consummate their purchase of shares of Legacy Q32's common stock for an aggregate purchase price of $42.0 million, or the Pre-Closing Financing. On March 25, 2024, Kenobi Merger Sub, Inc., a wholly-owned subsidiary of Homology Medicines, Inc., or Homology, completed its merger, or the Merger, with and into Legacy Q32, with Legacy Q32 continuing as the surviving entity as a wholly-owned subsidiary of Homology. Pursuant to the Subscription Agreement, on March 25, 2024, we entered into a registration rights agreement, or the Registration Rights Agreement, with the investors in the Pre-Closing Financing. Under the Registration Rights Agreement, among other things, we agreed to register for resale certain shares of our common stock held by such investors from time to time, including shares of our common stock issued in the Merger in exchange for the shares of Legacy Q32 common stock issued in the Pre-Closing Financing.

Pursuant to the Registration Rights Agreement, we are obligated to prepare and file a shelf registration statement covering the resale of covered shares of our common stock within forty-five (45) calendar days following the closing of the Merger, subject to certain exceptions, pursuant to Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. We also agreed to use our reasonable best efforts to keep such registration statement continuously effective under the Securities Act until the earlier of the date that all registrable securities covered by such registration statement (a) have been sold, thereunder or pursuant to Rule 144 of the Securities Act, or Rule 144, or (b) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for us to be in compliance with the current public information requirement under Rule 144. The registration rights agreement also provides that we will pay certain expenses of the securityholders and indemnify the applicable securityholders against certain liabilities.

Pre-Funded Warrants

As of March 1, 2026, we had 1,025,654 shares of common stock issuable upon the exercise of pre-funded warrants and each of such pre-funded warrants has an initial exercise price per share equal to $0.0001. The pre-funded warrants are immediately exercisable upon issuance and may be exercised at any time until they are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassification, reorganizations or similar events affecting our common stock and the exercise price.

A holder of the pre-funded warrants will not have the right to exercise any portion of the pre-funded warrants if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of our shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder may increase or decrease such percentage, but in no event may such percentage be increased to more than 9.99%, provided that any increase will not be effective until the 61st day after such election.

The pre-funded warrants will be exercisable, at the option of the holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of shares of common stock underlying the pre-funded warrants under the securities act is effective and available for the issuance of such shares, or an exemption from registration under the securities act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. The pre-funded warrants may also be exercised, in whole or in part, at such time by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant.

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of our common stock, the holder of a pre-funded warrant will not have the rights or privileges of a holder of our common stock, including any voting rights or rights to receive dividends, until the holder exercises the pre-funded warrant.

There is no established trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the pre-funded warrants on any national securities exchange or other trading market.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of the Delaware law, our restated certificate of incorporation, as amended, and amended and restated bylaws could make the following transactions more difficult: an acquisition by means of a tender offer; an acquisition by means of a proxy contest or otherwise; or the removal incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of it. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation, as amended, eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of our company, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our restated certificate of incorporation, as amended, and amended and restated bylaws provide that, subject to the rights of holders of any series of preferred stock, no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote in the election of directors. Subject to the rights of holders of any series of preferred stock, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority

of directors then in office, unless our board of directors determines by resolution that any such vacancy or newly created directorship shall be filled by our stockholders.

Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation, as amended, does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our restated certificate of incorporation, as amended, provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against it arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation, as amended, or amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. Our restated certificate of incorporation, as amended, also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation, as amended, is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

In addition, our amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act and any person or entity purchasing or otherwise acquiring or holding any interest in our shares of capital stock shall be deemed to have notice of and consented to this choice of forum provision.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation, as amended, and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Exhibit 10.32

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

ASSET PURCHASE AGREEMENT

between

Q32 Bio Inc.

and

Q32 Bio Operations Inc.

and

Akebia Therapeutics, Inc.

Dated as of November 28, 2025

TABLE OF CONTENTS

ASSET PURCHASE AGREEMENT

This **ASSET PURCHASE AGREEMENT**, dated as of November 28, 2025 (this "**Agreement**"), is made by and between Akebia Therapeutics, Inc., a Delaware corporation ("**Buyer**"), on the one hand, and Q32 Bio Inc., a Delaware corporation, and Q32 Bio Operations Inc., a Delaware corporation (together, the "**Seller**"), on the other hand. Buyer and Seller are each referred to as a "**Party**," and, together, the "**Parties**." Capitalized terms used herein shall have the meanings assigned to such terms in the text of this Agreement or in Section 7.1 (*Certain Terms*).

R E C I T A L S:

WHEREAS, Seller, directly and indirectly through certain of its Affiliates, owns, licenses or otherwise holds certain rights to research, develop, manufacture, and commercialize Products (as defined below) in the Territory in the Field and to the Acquired Program (such business in the Territory, the "**Business**"); and

WHEREAS, Seller desires to sell (or cause to be sold), and Buyer desires to purchase or cause certain of its Affiliates to purchase, certain of its assets related to the Business and Buyer is willing to assume or cause certain of its Affiliates to assume certain liabilities related to the Business, in each case, upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1

SALE AND PURCHASE OF ASSETS, ASSUMPTION OF LIABILITIES

Section 1.1Sale and Purchase.

(a) Purchase and Sale of Transferred Assets. Subject to the terms and conditions hereof, at the Closing, Seller will, and will cause the Selling Affiliates to, sell, convey, assign, and transfer to Buyer, and Buyer will purchase, acquire, and accept from Seller all rights, title, and interests in and to the Transferred Assets, in each case free and clear of all Liens other than Permitted Liens. Notwithstanding the foregoing or anything to the contrary in this Agreement, but subject to the obligations set forth in Section 4.2 (*Confidentiality*), Buyer acknowledges and agrees that Seller may retain such copies of all or any part of the documentation that is included in the Transferred Assets, as may be reasonably necessary for archival purposes and for purposes of complying with applicable Law and Seller's document retention policy.

(b) Excluded Assets. Notwithstanding any provision to the contrary set forth in this Agreement, Buyer will not acquire, pursuant to this Agreement or any of the transactions contemplated hereby, any rights, title or interests in any Excluded Asset.

(c) Assumed Liabilities. Subject to the terms and conditions hereof, at the Closing, Buyer shall assume or cause certain of its Affiliates to assume the Assumed Liabilities and shall satisfy and discharge the Assumed Liabilities as and when they become due. After the Closing, Buyer shall pay or cause certain of its Affiliates to pay all Assumed Liabilities as and when such Assumed Liabilities become due.

(d) Excluded Liabilities. Neither Buyer nor any of its Affiliates shall assume or be obligated to pay, perform or otherwise discharge any Excluded Liability. Seller and/or the Selling Affiliates, as the case may be, will remain liable to pay, perform and discharge all Excluded Liabilities as and when such Excluded Liabilities become due.

(e) Business Transfer Documents. To the extent required under applicable Law or as reasonably deemed necessary by either of the Parties hereto, to effect the transactions contemplated hereunder, the Parties shall execute and deliver, or cause their respective Affiliates to execute and deliver, such asset and/or business transfer agreements, bills of sale, deeds, assignments, assumptions and other documents and instruments of sale, conveyance, assignment, novation, transfer and assumption (the "**Business Transfer Documents**") as are necessary to effect any transfer of the Transferred Assets at the Closing or such other time for transfer as contemplated by Section 1.1(g) (*Transferred Assets Subject to Third-Party Consent*), Section 4.4 (*Shared Contracts*), or Section 4.17 (*Transferred Materials*) or any assumption of the Assumed Liabilities at the Closing. The Business Transfer Documents shall be in form and substance reasonably agreed to by the Parties and as is usual and customary in the applicable jurisdiction; provided that the Parties agree and acknowledge that the Business Transfer Documents are intended solely to formalize the terms and conditions of this Agreement in order to comply with any applicable Law and shall be, in all respects, consistent with the terms and conditions set forth in this Agreement. In the event of any inconsistency between this Agreement and a Business Transfer Document, this Agreement shall control. For the avoidance of doubt, Business Transfer Documents shall include confirmatory assignments, declarations, and related paperwork necessary to perfect Buyer's title in the Transferred IP (including all inventions claimed or disclosed in any Transferred Patent Right).

(f) Designation of Affiliates; Performance of Obligations by Affiliates. To the extent that any of the Transferred Assets are under the control of any of the Selling Affiliates, Seller shall cause such Selling Affiliates to promptly take such legal action as may be necessary to consummate the transfer to Buyer of such Transferred Assets under terms and conditions which are consistent with and subject to the terms of this Agreement. Any obligation of Seller under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Seller's sole and exclusive option, either by Seller directly, or by any Selling Affiliate that Seller causes to satisfy, meet or fulfill such obligation, in whole or in part. Notwithstanding the foregoing, this Section 1.1(f) (*Designation of Affiliates; Performance of Obligations by Affiliates*) shall not be construed to relieve Seller from any of its obligations under this Agreement.

(g) Transferred Assets Subject to Third-Party Consent.

(i) To the extent that the sale, conveyance, assignment or transfer or attempted sale, conveyance, assignment or transfer to Buyer of any Transferred Asset or Assumed Liability would require any governmental or Third Party consent, authorization,

approval or waiver (each, a "**Transfer Approval**" and such Transferred Asset or Assumed Liability subject to such Transfer Approval, the "**Unassigned Right**") and such Transfer Approval shall not have been obtained prior to the Closing, this Agreement shall not constitute a sale, conveyance, assignment or transfer thereof. With respect to any such Transferred Contract, during the period commencing on the Closing Date and continuing until the earlier of (A) the [**] of the later of (1) the Closing Date or (2) the Contract Expiration Date, the Parties shall use commercially reasonable efforts and cooperate with each other to obtain promptly such Transfer Approvals with respect to such Unassigned Right; provided that neither Seller nor the Selling Affiliates shall be required to pay any consideration, or to commence, defend, or participate in any Litigation or offer or grant any financial or other accommodation to any Third Party in connection with the foregoing; provided that providing administrative assistance to effectuate a Transfer Approval (*e.g.*, administrative actions of either Party to enter into a new agreement to account for Buyer's purchase of the Unassigned Rights in the applicable Transferred Contract) will not be deemed an accommodation to any Third Party. Notwithstanding the foregoing, and for the avoidance of doubt, if any such Transfer Approval is obtained following the Closing Date with respect to any Transferred Asset, Seller or the Selling Affiliates, as applicable, shall promptly assign, convey and transfer any such Transferred Asset to Buyer at no additional cost.

(ii) Unless otherwise provided in any Ancillary Agreement, from the Closing Date until the earlier of (x) the Contract Expiration Date, if applicable, or (y) the date a Transfer Approval with respect to an Unassigned Right is obtained, Seller shall, and shall cause the Selling Affiliates to, use commercially reasonable efforts to (A) maintain the effectiveness of, and to the extent required by the terms of the applicable Transferred Asset, operate or act in respect of such Transferred Asset in all material respects in the ordinary course of business consistent with past practice and taking into account the transactions contemplated by this Agreement and (B) enforce, at Buyer's written request, or allow Buyer and its Affiliates to enforce, in each case at Buyer's cost, any rights of the Seller or Selling Affiliates under or in respect of any such Transferred Asset against the other Party or parties thereto. In addition, Seller and Buyer shall, and shall cause their respective Affiliates to, cooperate in an arrangement, reasonable and lawful as to Seller and Buyer, designed to provide Buyer and its Affiliates the benefits arising under or resulting from such Transferred Asset, which arrangement shall include Seller consulting with Buyer as to the operation of or actions to be taken in respect of such Transferred Asset, except as prohibited by Law. Seller shall, and shall cause the Selling Affiliates to, without further consideration therefor, pay and remit to Buyer promptly all monies, rights and other consideration in respect of such performance as promptly as practicable after receipt thereof. Buyer shall pay, perform and discharge fully, promptly when due, all of the obligations of Seller or the Selling Affiliates in respect of such performance (other than obligations arising out of a breach by Seller or the Selling Affiliate that did not occur due to any action directed by Buyer or any of its Affiliates to be taken or not to be taken), and Buyer shall be responsible for all Assumed Liabilities related thereto.

(iii)Under no circumstances shall the Upfront Consideration be reduced or Seller or the Selling Affiliates be subject to any liability or indemnification under this Agreement solely as a result of the failure to obtain any Transfer Approval so long as Seller

has fulfilled its obligations under this Agreement with respect thereto, including its obligations under this Section 1.1(g). Buyer further agrees that no representation, warranty, or covenant of Seller contained in this Agreement shall be breached or deemed breached solely as a result of the failure to obtain any Transfer Approval with respect to an Unassigned Right. Notwithstanding anything herein to the contrary, Section 4.4 (and not this Section 1.1(g)) shall govern the transfer of any Shared Contracts.

(iv)To the extent any Transferred Contract that provides Seller or the Selling Affiliate, as the case may be, the ability to extend such Transferred Contract, Buyer may request, by written notice no later than [**] prior to the date such extension must be triggered, such Seller or Selling Affiliate to exercise such extension (subject to the terms and conditions of the relevant Transferred Contract), in which case the Contract Expiration Date shall be extended in accordance with such extension; provided that no more than one such extension (whether formally requested from the applicable Third Party by Seller or the applicable Selling Affiliate or by way of an automatic or evergreen extension provision contained in such Transferred Contract) may be requested by Buyer with respect to any particular Transferred Contract; provided, further, that, Seller shall provide written notice to Buyer no later than [**] prior to the date such extension must be triggered.

(h) Buyer's Recording and Similar Responsibilities. Notwithstanding the foregoing provisions of this Section 1.1 (*Sale and Purchase*), it shall be Buyer's responsibility (i) to prepare the applicable Patent Right assignments, which shall be in the form attached to this Agreement as Exhibit C, and to record such assignments following execution thereof by Seller or a Selling Affiliate at the Closing and (ii) to bear the fees and other costs in accordance with Section 1.12 (*Withholding*) and any Taxes arising from such activities.

Section 1.2Closing. The closing of the sale and purchase of the Transferred Assets and the assumption of the Assumed Liabilities (the "**Closing**") shall take place remotely on the date hereof ("**Closing Date**") through the exchange of electronic copies of duly executed documents, of the documents and agreements contemplated herein. At the Closing:

(a) Seller shall deliver or cause to be delivered to Buyer (unless previously delivered), the following:

(i) duly executed counterparts of:

(A) the Assignment and Assumption Agreement;

(B) the Bill of Sale;

(C) the Patent Assignment;

(D) the License Agreement Novation Agreement;

(E) and any other Ancillary Agreements to which Seller or the Selling Affiliates is a party; and

(ii) the Security Interest Release;

(iii)evidence that requests for consents to assign of each Transferred Contract set forth on Section 2.3(b)(1) of the Seller Disclosure Letter have been sent to the applicable Third Party thereto;

(iv)evidence reasonably satisfactory to Buyer that a written notice of assignment for each Transferred Contract set forth on Section 2.3(b)(3) of the Seller Disclosure Letter was delivered to the applicable Third Party thereto prior to or on the Closing Date;

(v) an IRS Form W-9 properly executed and completed by each Selling Affiliate that owns any Transferred Asset; and

(vi)a certificate, dated as of the Closing Date and signed by the secretary or equivalent officer of the Seller (in such officer's capacity as such an officer and not in his or her individual capacity), certifying to Buyer that attached to such certificate are copies of the resolutions duly adopted by directors of Seller authorizing the execution, delivery and performance of this Agreement and each of the Ancillary Agreements and the consummation of the transactions contemplated hereby and thereby.

(b) Buyer shall deliver or cause to be delivered to Seller, or as designated by Seller, one or more of the Selling Affiliates (unless previously delivered), the following:

(i) the Upfront Closing Consideration;

(ii) duly executed counterparts of:

(A) the Assignment and Assumption Agreement;

(B) the Bill of Sale;

(C) the Patent Assignment;

(D) the License Agreement Novation Agreement; and

(E) and any other Ancillary Agreements to which Buyer or any of its Affiliates is a party;

(iii)a duly executed copy of the A&R License Agreement; and

(iv)a certificate, dated as of the Closing Date and signed by the secretary or equivalent officer of the Buyer (in such officer's capacity as such an officer and not in his or her individual capacity), certifying to Seller that attached to such certificate are copies of the resolutions duly adopted by directors of Buyer authorizing the execution, delivery and performance of this Agreement and each of the Ancillary Agreements and the consummation of the transactions contemplated hereby and thereby.

Section 1.3Purchase Price.

(a) Purchase Price. In consideration of the sale and transfer of the Transferred Assets from Seller to Buyer at Closing, Buyer agrees to (y) assume, satisfy, and discharge the Assumed Liabilities and (z) pay the following consideration to Seller:

(i) on the Closing Date, Buyer shall pay or cause to be paid to Seller, by wire transfer of immediately available funds to the account designated in writing by Seller on or prior to the Closing Date, an amount equal to $7,000,000 (the "**Upfront Closing Consideration**");

(ii) on the sixth-month anniversary of the Closing Date (or, if such date falls on a day that is not a Business Day, then the first Business Day following such anniversary), Buyer shall pay or cause to be paid to Seller, by wire transfer of immediately available funds to the account designated in writing by Seller prior to such anniversary, an amount equal to $3,000,000 by wire transfer of immediately available funds (the "**Upfront Second Consideration**" and, together with the Upfront Closing Consideration, the "**Upfront Consideration**");

(iii)when due and payable, Buyer shall pay or cause to be paid to Seller, each of the Development and Regulatory Milestone Payments, the Commercial Milestone Payments, and the Royalties, as applicable, in accordance with this Agreement.

(b) Upfront Consideration. The Upfront Consideration shall be noncreditable, nonrefundable and not subject to set-off.

Section 1.4Contingent Consideration.

(a) Development and Regulatory Milestone Payments.

(i) Following the Closing, subject to the remainder of this Section 1.4(a) (*Development and Regulatory Milestone Payments*), upon the first achievement by a Buyer Party of each milestone event set forth in the table below (each, a "**Development and Regulatory Milestone Event**"), Buyer shall pay, or cause to be paid, by wire transfer of immediately available funds to the Seller an amount equal to the corresponding one- time payment set forth in the table below (each, a "**Development and Regulatory Milestone Payment**") in accordance with Section 1.4(a)(v) and Section 1.4(a)(vi).

Development and Regulatory Milestone Event	**Development and Regulatory Milestone Payment**
1) Initiation of a Phase 2 Clinical Trial for a Product	$2,000,000
2) [**]	$[**]
3) [**]	$[**]
4) [**]	$[**]
5) [**]	$[**]

6)	[**]	$[**]
7)	[**]	$[**]
8)	[**]	$[**]
9)	[**]	$[**]
Total		**$94,500,000**

(ii) Notwithstanding the definition of Phase 2 Clinical Trial, the Development and Regulatory Milestone Payment for the Development and Regulatory Milestone Event 1 (*i.e.*, "Initiation of a Phase 2 Clinical Trial") is payable upon Initiation of the first Clinical Trial (or portion thereof) by a Buyer Party following the Closing where a Product is administered to patients. To the extent Development and Regulatory Milestone Event 1 has not been achieved by a Buyer Party by December 31, 2026, the associated Development and Regulatory Milestone Payment shall become due and payable as of such date. In such case, Seller will issue an invoice equal to the associated Development and Regulatory Milestone Payment and Buyer will, within [**] following receipt thereof, pay the amount set forth in such invoice by wire transfer of immediately available funds.

(iii)For clarity, each Development and Regulatory Milestone Payment shall become due and payable only once upon the first achievement of the corresponding Development and Regulatory Milestone Event by a Buyer Party regardless of the number of times it is achieved by the same or different Products. Each Development and Regulatory Milestone Payment shall be noncreditable, nonrefundable, and not subject to set-off, other than as set forth in [**].

(iv)Solely with respect to each of Development and Regulatory Milestone Events [**], the corresponding Development and Regulatory Milestone Payment shall only be payable upon the achievement of the applicable Development and Regulatory Milestone Event if such Development and Regulatory Milestone Event is achieved by Buyer or its Affiliates and *not* upon achievement of such Development and Regulatory Milestone Event by any other Buyer Party.

(v) For a given Product, if Development and Regulatory Milestone Event 2 becomes due and Development and Regulatory Milestone Event [**] has not been paid, then both Development and Regulatory Milestone Events [**] would be payable upon achievement of Development and Regulatory Milestone Event [**] by such Product. For a given Product, if the first of Development and Regulatory Milestone Event [**] becomes due and one of Development and Regulatory Milestone Event [**] have not been paid, then each unpaid Development and Regulatory Milestone Event [**], as applicable, would be payable upon the first achievement of Development and Regulatory Milestone Event [**]. For a given Product, if the first of Development and Regulatory Milestone Event [**] becomes due and Development and Regulatory Milestone Event [**] has not been paid,

then Development and Regulatory Milestone Event [**] would be payable upon the first achievement of Development and Regulatory Milestone Event [**].

(vi)Buyer shall notify Seller in writing of the achievement of a Development and Regulatory Milestone Event by a Buyer Party as promptly as practicable, but no later than within [**] following the date of the achievement thereof (or following Buyer becoming aware of achievement thereof by a Buyer Party that is not Buyer or its Affiliates). Following receipt of such notice, Seller will issue an invoice equal to the applicable Development and Regulatory Milestone Payment, and, subject to [**], Buyer will, within [**] following receipt thereof, pay the amount set forth in such invoice by wire transfer of immediately available funds.

(b) Commercial Milestone Payments.

(i) Following the Closing, subject to the remainder of this Section 1.4(b) (*Commercial Milestone Payments*), upon the first achievement by a Buyer Party of each milestone event set forth in the table below (each, a "**Commercial Milestone Event**"), Buyer shall pay, or cause to be paid, by wire transfer of immediately available funds to Seller an amount equal to the corresponding one-time payment set forth in the table below (each, a "**Commercial Milestone Payment**") in accordance with Section 1.4(b)(iv) and Section 1.4(b)(v).

Commercial Milestone Event	**Sales Milestone Payment**
1) [**]	$[**]
2) [**]	$[**]
3) [**]	$[**]
4) [**]	$[**]
5) [**]	$[**]
6) [**]	$[**]
7) [**]	$[**]
8) [**]	$[**]
Total	**$487,500,000**

(ii) For clarity, each Commercial Milestone Payment shall become due and payable only once upon the achievement of the corresponding Commercial Milestone Event regardless of the number of times it is achieved. Each Commercial Milestone Payment shall be noncreditable, nonrefundable and not subject to set-off, other than as set forth in [**].

(iii)Solely with respect to each of Commercial Milestone Events [**], the corresponding Commercial Milestone Payment shall only be payable upon the achievement of the applicable Commercial Milestone Event if such Commercial Milestone Event is achieved by Buyer or its Affiliates and *not* upon achievement of such Commercial Milestone Event by any other Buyer Party.

(iv)For clarity, the Commercial Milestone Payments shall be additive such that if multiple Commercial Milestone Events are achieved in the same Calendar Year, then the corresponding Commercial Milestone Payments shall be payable with respect to such Calendar Year.

(v) Buyer shall notify Seller in writing of the occurrence of a Commercial Milestone Event by a Buyer Party in the Royalty Report for the Calendar Quarter in which such Commercial Milestone Event was achieved. Following receipt of such notice, Seller will issue an invoice equal to the applicable Commercial Milestone Payment, and, subject to Section 1.4(e) (*Right to Offset*), Buyer will, within [**] following receipt thereof, pay the amount set forth in such invoice by wire transfer of immediately available funds.

(c) Royalties.

(i) Royalty Rates. Subject to the remainder of this Section 1.4(c)(i) (*Royalty Rates*), on a Product-by-Product and country-by-country basis, during the Royalty Term for such Product in such country, Buyer shall pay, or cause to be paid, to the Seller, royalties based on Annual Net Sales of such Product by the Buyer Parties (subject to Section 1.4(c)(iii) [**] in each Calendar Year, at the applicable rate(s) set forth in the table below (such payments, "**Royalties**"). The Royalty payable with respect to each particular Product shall be calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental Annual Net Sales of such Product [**] in the applicable Calendar Quarter.

Annual Net Sales	**Royalty Rate**
[**]	
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]

On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**]	[**]
[**]	
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**]	[**]

By way of example, if the total Annual Net Sales of a Product [**] in a particular Calendar Year is $[**], the Royalties payable hereunder shall be calculated as follows (subject to any applicable reductions under Section 1.4(c)(iv) (*Royalty Reductions*)): [**].

(ii) Royalty Term. Royalties shall be payable, on a Product-by-Product and country-by-country basis, during the period commencing on the First Commercial Sale of such Product in such country until the later to occur of: (i) the date on which the last-to- expire Valid Claim of a Transferred Patent Right or Patent Right licensed under the A&R License Agreement that Covers such Product, in each case, in such country; [**]; and (ii) the 10th anniversary of the First Commercial Sale of such Product in such country (such period, the "**Royalty Term**" for such Product in such country).

(iii)[**].

(iv)Royalty Reductions.

(A) Lack of Valid Claims. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), on a Product-by-Product and country-by-country basis, during the Royalty Term for such Product in such country, if such Product is not Covered by a Valid Claim of a Patent Right within the

Transferred Assets or Patent Right licensed under the A&R License Agreement in such country ([**]), then the royalty rates set forth in Section 1.4(c)(i) (*Royalty Rates*) with respect to Net Sales of such Product in such country will be reduced by [**]% for the remainder of the Royalty Term in such country.

(B) Biosimilar Competition. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), following the first Calendar Quarter in which there is a launch of a Biosimilar Product for a Product in any country in the Territory, if during the Royalty Term for such Product in a country in the Territory, the [**] of such Product in the relevant country in a Calendar Quarter decline by [**] or more relative to the [**] occurring during the [**] consecutive Calendar Quarters immediately preceding the launch of the Biosimilar Product, then, commencing upon the following Calendar Quarter and for so long as the [**] of such Product in such country in a Calendar Quarter continue to equal at least [**] less than the [**] occurring during the [**] consecutive Calendar Quarters immediately preceding the launch of the Biosimilar Product, the royalty rates set forth in Section 1.4(c)(i) (*Royalty Rates*) with respect to Net Sales of such Product in such country, will be reduced by [**].

(C) Third Party Payments. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), on a Product-by-Product basis, if a Buyer Party obtains, after the Closing Date, in an arms' length transaction a license under or other rights to any Patent Rights (or Know-How associated with such Patent Rights) owned or controlled by a Third Party that are reasonably necessary to develop, manufacture, commercialize, or otherwise exploit such Product, then the [**] payable by Buyer to Seller with respect to [**] such Product pursuant to this Section 1.4(c) (*Royalties*) may be reduced by [**] of any amounts actually paid by such Buyer Party to such Third Party in consideration for such license; provided that this Section 1.4(c)(iv)(C) (*Third Party Payments*) shall not apply [**]; provided, further, that to the extent Buyer reduces any [**] payable by Buyer to Seller for any amounts actually paid by a Buyer Party to a Third Party under this Section 1.4(c)(iv)(C) (*Third Party Payments*), such reduction shall be Buyer's sole and exclusive remedy with respect to such amounts and Buyer shall not be entitled to indemnification, or to sue for damages, or to assert any other right or remedy under this Agreement with respect to any such amounts.

(D) Inflation Reduction Act. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), if, on a Product-by-Product basis, if during any Calendar Quarter during the Royalty Term for such Product in the United States, such Product is designated as a "selected drug" by the Secretary of the U.S. Department of Health and Human Services pursuant to the Inflation Reduction Act of 2022 (or analogous legislation enabling the U.S. government to negotiate drug prices), and the Buyer Parties are required to negotiate, and are ultimately subject to, a "maximum fair price"

that will apply to sales of such Product in the United States, then the Royalties on Net Sales of Products in the United States otherwise payable by Buyer pursuant to this Section 1.4(c) (*Royalties*) will be reduced [**] by a [**] the price of such Product is decreased as a result of such designation and the ensuing maximum fair price (as defined in Section 1191(c)(3) of the Social Security Act) negotiation pursuant to the aforementioned Inflation Reduction Act or analogous legislation.

(E) Royalty Floor. Notwithstanding the foregoing in this Section 1.4(c)(iv) (*Royalty Reductions*), in no event shall the Royalties payable to Seller pursuant to Section 1.4(c)(i) (*Royalty Rates*) for a Product in a country in any given Calendar Quarter during the Royalty Term be reduced to less than [**] relative to what would otherwise have been due under Section 1.4(c)(i) (*Royalty Rates*) absent the reductions set forth in this Section 1.4(c)(iv) (*Royalty Reductions*); provided that if any reduction that Buyer would have otherwise been entitled to take under this Section 1.4(c)(iv) (*Royalty Reductions*) and the permitted deduction in Section 1.4(e) (*Right to Offset*) is not able to be fully deducted as a result of the application of this Section 1.4(c)(iv) (*Royalty Reductions*), then any remaining portion of such deduction may be carried forward and applied against future Royalties otherwise owed until exhausted (subject to the same [**] reduction floor).

(v) Calculation of Royalty Adjustments. [**].

(vi)Royalty Payments and Reports. Within [**] after the end of each Calendar Quarter during the Royalty Term, Buyer shall provide Seller with a royalty report providing a statement, on a Product-by-Product and country-by-country basis, of: (A) the amount of Net Sales of such Product in such country during the applicable Calendar Quarter calculated in U.S. dollars, (B) a calculation of the amount of Royalties due in U.S. dollars on such Net Sales of such Product for such Calendar Quarter, and (C) with respect to calculations applicable to countries outside of the United States, the exchange rate calculated in accordance with Section 1.4(c)(vii) (*Exchange*) and used to determine the foregoing amounts ((A)-(C)) (each such royalty report, a "**Royalty Report**"). Seller shall submit an invoice to Buyer with respect to the Royalty amount set forth therein, and Buyer will pay such amount within [**] after the receipt of such invoice.

(vii)Exchange. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. dollars, then such amounts will be converted to their U.S. dollar equivalent using Buyer's or its Affiliate's then-current standard procedures and methodology, including its then-current standard exchange rate methodology for the translation of foreign currency expenses into U.S. dollars or, in the case of (Sub)licensees, such similar methodology, consistently applied in accordance with GAAP or International Financial Reporting Standards (IFRS), as applicable. Calculation of Net Sales will exclude hedging and foreign exchange gain or loss realized through a hedging program.

(d) Sharing of (Sub)license Income. Buyer shall pay Seller [**] of (Sub)license Income within [**] following the end of the Calendar Quarter in which such (Sub)license Income is received by Buyer or any of its Affiliates. In the event the rights granted to a (Sub)licensee include a grant or other transfer of rights with respect to a Product along with a grant of rights or obligations with respect to other compounds or products that are owned or otherwise controlled by Buyer or any of its Affiliates, then [**].

(e) Right to Offset. Buyer may deduct from any Development and Regulatory Milestone Payment, Commercial Milestone Payment, Royalties, (Sub)license Income, or any other payment made by Buyer to Seller under this Section 1.4 (*Contingent Consideration*), [**], an "**Eligible Offset Amount**"). Notwithstanding the foregoing, Buyer must deduct any Eligible Offset Amount from Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or any other payments payable by Buyer to Seller under this Agreement at its earliest opportunity(ies) to do so [**]. To the extent Buyer deducts any Eligible Offset Amount actually paid to the Third Party licensor under an Upstream License Agreement against any payments due to Seller hereunder, such deduction shall be Buyer's sole and exclusive remedy with respect to any such Eligible Offset Amount and Buyer shall not be entitled to indemnification, or to sue for damages or to assert any other right or remedy under this Agreement, with respect to any such Eligible Offset Amount.

Section 1.5Late Payments. In the event Seller does not receive any payment from Buyer on or before the applicable date set forth this Agreement through no fault of the Seller (including, any Development and Regulatory Milestone Payment due in accordance with Section 1.4(a) (*Development and Regulatory Milestone Payments*), Commercial Milestone Payment due in accordance with Section 1.4(b) (*Commercial Milestone Payments*), Royalties due in accordance with Section 1.4(c) (*Royalties*), (Sub)license Income payments due in accordance with Section 1.4(d) (*Sharing of (Sub)license Income*) and payment as a result of an audit due in accordance with Section 1.7 (*Inspection of Buyer Records*)), simple interest shall accrue thereafter on such overdue amount at a rate equal to the lesser of: (a) [**] per month, or (b) the maximum rate permitted by applicable Laws, in each case calculated on the number of days such payment is delinquent, compounded monthly.

Section 1.6Records. Buyer shall keep, and shall cause the other Buyer Parties to keep, complete, true and accurate books of accounts and records sufficient to determine and establish the amounts payable incurred under this Agreement, and compliance with the other terms and conditions of this Agreement. Such books and records shall be kept reasonably accessible and shall be made available for inspection for a [**] period in accordance with Section 1.7 (*Inspection of Buyer Records*).

Section 1.7Inspection of Buyer Records. Upon reasonable prior written notice, Buyer shall permit, and shall cause its Affiliates to permit, an independent nationally recognized certified public accounting firm (subject to obligations of confidentiality to Buyer), appointed by Seller and reasonably acceptable to Buyer, to inspect the audited financial records of Buyer during regular business hours to the extent relating to payments to Seller under this Agreement; provided, that such inspection shall not occur (a) more often than [**], unless a material error is discovered as part of such inspection in which case Seller shall have the right to conduct a more thorough inspection for such period or (b) more frequently than [**] with respect to such records covering

any specific period of time. In addition, the Seller shall only be entitled to audit such records of Buyer and its Affiliates from the [**] in which the audit request is made. In addition, Buyer shall, and shall cause its Affiliates to ensure Buyer or its Affiliates have an audit right of each (Sub)licensee. Seller agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, which information shall constitute the confidential information of Buyer, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any applicable Laws. Any inspection conducted under this Section 1.7 (*Inspection of Buyer Records*) shall be at the cost and expense of Seller, unless such inspection reveals any underpayment of the amounts due hereunder for the audited period by at least [**], in which case the full costs of such inspection for such period shall be borne by Buyer. Any overpayment by Buyer, at Buyer's election, shall (i) by submission of an invoice to Seller, which shall be paid by Seller within [**] following receipt thereof or (ii) be offset by Buyer against future payments due by Buyer to Seller hereunder.

Section 1.8Commercially Reasonable Efforts.

(a) Diligence Obligations. From the Closing Date until [**] the "**Diligence Expiration Date**"), the Buyer Parties shall use (either directly or through its Affiliates and (Sub)licensees) Commercially Reasonable Efforts to obtain Regulatory Approval for one Product in the United States.

(b) Seller Acknowledgement. Seller (on behalf of itself and the Selling Affiliates) acknowledges that the development of the Products is uncertain and that the Buyer Parties may not achieve the results requiring payment of the Development and Regulatory Milestone Payments, Commercial Milestone Payments, or Royalties. Seller (on behalf of itself and the Selling Affiliates) also acknowledges and stipulates that:

(i) Buyer (A) has made no guarantees or promises and has provided no assurance that any Development and Regulatory Milestone Event or Commercial Milestone Event will be achieved at all or that any Product will generate any Net Sales upon which a Royalty will be due, and (B) has made no assessments or predictions regarding the likelihood of any such milestone being achieved or of any such sales occurring;

(ii) Buyer has not, prior to or after the date hereof, promised or projected any amounts to be received by Seller under this Agreement other than the Upfront Consideration and the Development and Regulatory Milestone 1;

(iii)none of the Seller or any Selling Affiliate is relying on or has relied on any promises, projections, representations, or warranties of any kind or other information, documents, or materials (or absence thereof) in respect of any payments described in this Agreement (other than those expressly set forth in this Agreement);

(iv)the Buyer Parties are not prohibited from developing or commercializing (or acquiring or in-licensing) assets or businesses related to other products that may compete with the Products; and

(v) except for the obligations set forth in Section 1.8 (*Commercially Reasonable Efforts*), the Buyer Parties shall have sole control and authority to operate the Business, develop Products, and otherwise use and exploit the Transferred Assets in any way that Buyer deems appropriate in its sole business judgment and in its sole and absolute discretion.

Section 1.9Development Updates.

(a) Development Plan. Within [**] following the Closing, Buyer will deliver to Seller a development plan (including [**]) that sets forth the planned development of the Products through [**] (the "**Development Plan**"). Buyer may, from time to time, make adjustments to the Development Plan as Buyer believes, in its good faith judgment, are appropriate under the then-current circumstances consistent with its diligence obligations set forth in Section 1.8 (*Diligence Obligations*).

(b) Development Reports. From and after the Closing until the earlier or the First Commercial Sale of Product in the United States or the Diligence Expiration Date, within [**] following the end of each Calendar Year beginning with the [**], Buyer shall provide to Seller a reasonably detailed written summary that describes material development activities for the Product(s) conducted by or on behalf of the Buyer Parties since the last report. In addition, from and after Closing until [**], within [**] following the end of each Calendar Year beginning with the [**], Buyer shall provide to Seller an updated Development Plan. In addition, upon the reasonable written request by Seller, Buyer will provide Seller with further details related to the foregoing.

Section 1.10Milestone Event Disputes. Buyer shall keep, and shall cause the Buyer Parties to keep, adequate books and records of accounting for the purpose of confirming whether a Development and Regulatory Milestone Event has occurred for a period of [**] following the end of the Calendar Year to which each pertains. If the Seller believes that any Development and Regulatory Milestone Event has occurred and Buyer has not yet provided notice to Seller of the occurrence of such Development and Regulatory Milestone Event, then the Seller shall deliver to Buyer written notice thereof (a "**Milestone Dispute Notice**"), in reasonable detail, within [**] following the date upon which the Seller alleges the applicable Development and Regulatory Milestone Event occurred. Following the delivery of a Milestone Dispute Notice, Buyer and Seller shall first attempt in good faith to resolve by negotiation and consultation between themselves, any dispute as to whether any Development and Regulatory Milestone Event has occurred and whether any Development and Regulatory Milestone Payment is payable. If Buyer and Seller do not reach agreement with respect to any dispute relating to any such matter within [**] after a Milestone Dispute Notice is delivered to Buyer by Seller, then the Parties shall submit for arbitration all matters that remain in dispute to a disinterested individual who has appropriate scientific, technical and regulatory expertise (as relevant) to resolve any disputes referred to him or her under this Section 1.10 (*Milestone Event Dispute*) (a "**Scientific Expert**") who is mutually agreed to by Buyer and Seller; provided, however, that such Scientific Expert shall not be or have been at any time within the previous [**] an Affiliate, employee, consultant, officer or director of Buyer, Seller or any of their respective Affiliates. If Buyer and Seller cannot agree on a mutually acceptable Scientific Expert within [**] after either Party has determined that the Parties cannot reach agreement with respect to a dispute, then within [**] after the expiration of such [**] period, each

of Buyer and Seller shall appoint one Scientific Expert who shall jointly select a third Scientific Expert within [**] after the last to occur of their respective appointments to arbitrate the referred matter. The Scientific Expert mutually agreed by the Parties or, if the Parties cannot agree, the third Scientific Expert selected by the Party-appointed Scientific Experts is referred to as the "**Selected Scientific Expert.**" Buyer and Seller shall instruct the Selected Scientific Expert to determine as promptly as practicable but in no event later than [**] after such person's appointment (the "**Determination Period**") whether the disputed Development and Regulatory Milestone Event or Commercial Milestone Event has occurred. The Selected Scientific Expert's determination shall be made based on the submission of documents and evidence by the Parties (including any such documentation or evidence reasonably requested by the Selected Scientific Expert, which Seller or Buyer shall provide upon request) and, upon the Selected Scientific Expert's request, by Third Parties, unless the Selected Scientific Expert determines that an oral hearing is necessary. The Selected Scientific Expert shall determine deadlines (which Buyer and Seller shall deem to be fair and appropriate) within the Determination Period for submitting documents and dates, if any, of oral hearings. The prevailing Party shall pay all of the expenses of arbitration, and the fees, costs and expenses of the Selected Scientific Expert.

Section 1.11Currency. Except as otherwise expressly provided in this Agreement, all payments under or in connection with this Agreement (including this Article 1) shall be in U.S. dollars.

Section 1.12Withholding. Buyer and any other applicable withholding agent shall be entitled to make all payments under this Agreement net of all deductions and withholdings in respect of Taxes required by Law. If any Taxes are required by Law in effect at the time of payment to be deducted from or in respect of any amount payable under this Agreement: (a) such amounts shall be deducted and withheld, and treated as paid to the person in respect of which such deduction or withholding was made, (b) Buyer shall make such deductions and timely pay the full amount deducted to the Governmental Authority in accordance with applicable Law and (c) Buyer shall use commercially reasonable efforts to provide any documentation or information reasonably requested by Seller to evidence such Tax payments. Notwithstanding the foregoing, other than withholding applied in respect of compensatory amounts or for failure to deliver an IRS Form W- 9, Buyer will provide written notice to Seller promptly upon any determination that withholding may be required on any payments under this Agreement and shall cooperate in good faith and use commercially reasonable efforts to take such steps as Seller may reasonably request to reduce or eliminate such deduction or withholding. Notwithstanding any provision to the contrary in this Agreement, the Parties acknowledge and agree that [**].

Section 1.13Transfer Taxes and Other Costs. All Transfer Taxes payable under applicable Law on or in connection with the transfer of the Transferred Assets to Buyer, if any, shall be paid by Buyer and Buyer shall indemnify Seller against any liability for such Transfer Taxes. Buyer shall prepare and file all necessary Tax Returns and other documentation required to be filed by it with respect to all Transfer Taxes, and, if required by applicable Law, the Parties will, and will cause their Affiliates to, join in the execution of any such Tax Returns and other documentation.

Section 1.14Allocation of the Consideration. Within [**] after the Closing, Buyer shall prepare and finalize an allocation of the purchase price paid (for Tax purposes) among the

Transferred Assets in accordance with Tax Law (including Section 1060 of the Code), the principles of Schedule 1.14, and in accordance with the remainder of this Section 1.14 (*Allocation of the Consideration*). Promptly following the Closing, Buyer shall deliver a proposed allocation of the purchase price in accordance with this Section 1.14 (*Allocation of the Consideration*) to Seller for Seller's review and comment, and Buyer shall consider any comments received from Seller in good faith. Seller shall provide Buyer with such evidence as Buyer may reasonably request to support the proposed allocation. The purchase price allocation, as finalized pursuant to the terms of this Section 1.14 (*Allocation of the Consideration*), shall be binding on the Parties, and the Parties shall (and shall cause their Affiliates to) file all Tax Returns and take all Tax positions in a manner consistent with the final purchase price allocation, unless otherwise required by a final determination within the meaning of Section 1313(a) of the Code or in connection with a good faith resolution of a Tax audit. Any adjustments to the purchase price (for Tax purposes) shall be allocated in accordance with the procedures and principles of this Section 1.14 (*Allocation of the Consideration*).

ARTICLE 2

REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the applicable section identified in the Seller Disclosure Letter, Seller represents and warrants to Buyer as follows:

Section 2.1Organization. Each of Seller and the Selling Affiliates is duly organized, validly existing and in good standing (to the extent such concept is recognized in the relevant jurisdiction) under the Laws of its respective jurisdiction of formation, and has full corporate or other applicable legal power and authority to enter into the transactions contemplated by this Agreement.

Section 2.2Corporate and Governmental Authorization.

(a) Seller has full corporate power and authority to enter into this Agreement and each of the Selling Affiliates have, or will have at Closing, full corporate or other applicable legal power and authority to enter into the Ancillary Agreements to which it is to be a party and to perform its obligations hereunder and thereunder (as the case may be). This Agreement has been, and the Ancillary Agreements to which the Selling Affiliates are to be a party will be by Closing, duly authorized and approved by all necessary corporate action.

(b) Seller has duly executed and delivered this Agreement and on the Closing Date will have duly executed and delivered the Ancillary Agreements.

(c) The transactions contemplated under this Agreement do not constitute a sale of all or substantially all of Seller's assets. Except as set forth on Section 2.2(c) of the Seller Disclosure Letter, no consent, approval, order or authorization of, action by or in respect of, or registration, declaration or filing with, any Governmental Authority is required by or with respect to Seller, the Business, or the Transferred Assets for, or in connection with, (i) the execution and delivery of this Agreement by Seller, (ii) the transfer of the Transferred Assets to Buyer or (iii) the consummation of transactions contemplated hereunder.

(d) Assuming the due authorization, execution and delivery of this Agreement by Buyer, this Agreement constitutes a legal, valid and binding obligation of Seller, enforceable against Seller in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles. Assuming the due authorization, execution and delivery of the Ancillary Agreements by Buyer, each Ancillary Agreement to be executed by any Selling Affiliate, when delivered hereunder, will be duly and validly executed and delivered, and will constitute a legal, valid and binding obligation of such Selling Affiliate, enforceable in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles.

Section 2.3Non-Contravention. The execution and delivery of this Agreement by Seller, the execution and delivery of the Ancillary Agreements by any Selling Affiliate thereto and the consummation of the transactions contemplated hereby or thereby, do not and will not

(a) violate in any material respect any provision of the Organizational Documents of Seller or any Selling Affiliate, (b) conflict with, result in the breach of, constitute a default under or result in the termination, cancellation or acceleration (whether after the giving of notice or the lapse of time or both) of any right or obligation of Seller or any Selling Affiliate under any Transferred Contract to which it is a party or to which its assets are subject, or result in the creation or the imposition of any Lien (other than a Permitted Lien) upon any of the Transferred Assets, or (c) violate, in any material respect, any Law of any Governmental Authority applicable to Seller or any Selling Affiliate, or any of the Transferred Assets or any Order against Seller or any Selling Affiliate or the Transferred Assets. Section 2.3 of the Seller Disclosure Letter sets forth a list of all Transferred Contracts that require a Transfer Approval to be assigned to Buyer.

Section 2.4Solvency. As of the date hereof and as of immediately after giving effect to the consummation of the transactions contemplated by this Agreement, Seller and its Affiliates will be Solvent.

Section 2.5Absence of Material Adverse Effect. Since December 31, 2024, there have not been any changes, effects, events, occurrences, states or facts or developments that, individually or in the aggregate, have resulted or would be reasonably likely to result in a Material Adverse Effect. Without limiting the generality of the foregoing, since December 31, 2024, the Seller and any of the Selling Affiliates have not, with respect to the Business:

(a) sold, assigned, pledged, hypothecated or otherwise transferred any assets, properties or rights related to the Product, except those which, when taken together with all assets, properties or rights disposed of, are immaterial to the Business taken as a whole;

(b) suffered any material damage, destruction or other casualty loss (whether or not covered by insurance);

(c) changed in any material way the manner in which accounts receivable related to the Product have been collected;

(d) materially and adversely modified or changed its relationship with its suppliers or customers; or

(e) entered into an agreement to do any of the foregoing.

Section 2.6Material Contracts.

(a) Except for the Contracts disclosed in the applicable subsection of Section 2.6 of the Seller Disclosure Letter (which is arranged in subsections to correspond to the subsections of this Section 2.6) and Contracts with employees, consultants, or advisors, as of the date hereof, there are no Contracts relating (whether solely or in part) to the operation and conduct of the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any of the Transferred Assets that constitute:

(i) any joint venture, partnership, limited liability company or other similar agreements or arrangements (providing for joint research, development or marketing of any of the Products);

(ii) any agreement or series of related agreements, including any option agreement, relating to the acquisition or disposition of any business or assets of any other Person or any material real property (whether by merger, sale of stock, sale of assets or otherwise related to the Business);

(iii)any agreement that (A) materially limits the freedom of Seller or its Affiliates to operate the Business or with any Person or in any area or that would so limit the freedom of Buyer or its Affiliates after the Closing (other than customary exclusive distribution agreements for the Products), (B) contains material exclusivity obligations or restrictions binding on Seller or the Selling Affiliates or that would be binding on Buyer or any of its Affiliates after the Closing, (C) contains any right of first refusal, right of first negotiation or right of first offer in favor of a party other than Sellers; or (D) otherwise restricts the research, development, manufacture, marketing, distribution, sale, supply, license or marketing of the products and services of Seller or that either Seller or any Selling Affiliate develops;

(iv)any agreement or series of related agreements for the purchase of materials, supplies, goods, services, equipment or other assets related to the Business that is reasonably expected to involve annual payments on the part of Seller or the Selling Affiliates in excess of $[**] from and after the Closing;

(v) any sales, distribution, agency or other similar agreement providing for the sale by the Business of Products, materials, supplies, goods, services, equipment or other assets that is reasonably expected to involve annual payments to Seller or the Selling Affiliates from and after the Closing over the remaining term of the agreement of $[**];

(vi)any agreement under which the Business has (A) granted a Lien on any material Transferred Asset, other than a Lien that will be released as of the Closing or (B) provided for the sale of any material Transferred Asset, or granted any preferential rights to purchase any material Transferred Asset, in each case outside the ordinary course of business;

(vii)any agreement providing any person or entity with pricing, discounts, or benefits that change based on the pricing, discounts, or benefits offered to other Third Parties, including any agreement containing "most favored nation";

(viii)any agreement in which either Seller has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a certain party;

(ix)any agreement providing for any royalty, milestone, or similar payments by the Seller or any Selling Affiliates; and

(x) any agreement between either Seller and a governmental authority.

(b) Section 2.6(b) of the Seller Disclosure Letter sets forth a true and complete list of all Contracts relating solely to the operation and conduct of the Business, to the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or to any of the Transferred Assets, in each case, as currently conducted. For the avoidance of doubt, such list does not include any Excluded Asset listed in clauses (i) through (xv) of Annex 9.1(b) attached hereto, any Shared Contract, or any Contracts with employees, consultants, or advisors, even if related to the operation and conduct of the Business as currently conducted, and includes Contracts that are no longer in effect.

(c) Section 9.1(b)(vi) of the Seller Disclosure Letter sets forth a true and complete list of all Shared Contracts.

(d) Seller has made available to Buyer true, correct, and complete copies of each of the Transferred Contracts and Shared Contracts.

(e) Each agreement, commitment, arrangement or plan disclosed in the Seller Disclosure Letter pursuant to this Section 2.6 (*Material Contracts*) or Section 2.9 (*Intellectual Property*) (each, a "**Material Contract**") is a valid and binding agreement of Seller or the Selling Affiliate thereto (subject to the effects of applicable bankruptcy, insolvency, fraudulent conveyance, or other Laws relating to or affecting creditors' rights generally and to general principles of equity, whether considered at law or in equity) and is in full force and effect, and neither Seller nor any of the Selling Affiliates or, to the Knowledge of Seller, any other party thereto is in default or breach in any material respect under (or is alleged to be in default or breach in any material respect under) the terms of, or has provided or received any notice of any intention to terminate, any such Material Contract, and, to the Knowledge of Seller, no event or circumstance has occurred since December 31, 2024 that, with notice or lapse of time or both, would constitute an event of default thereunder or result in a termination thereof or would cause or permit the acceleration of or other changes of or to any right or obligation or the loss of any benefit thereunder that has not been cured or waived.

Section 2.7Title to Transferred Assets. Seller or the Selling Affiliate has exclusive, good, marketable, title to all the Transferred Assets, and has the complete and unrestricted power and unqualified right to sell, assign, transfer and deliver to Buyer the Transferred Assets. There are no adverse claims of ownership to the Transferred Assets and neither Seller has received notice that any person or entity has asserted a claim of ownership or right of possession or use in or to

any of the Transferred Assets, nor are there any facts, circumstances or conditions on which, to the Knowledge of the Seller, such a claim could be brought in the future. At the Closing, Buyer will acquire from Seller sole and exclusive, good and marketable title to all of the Transferred Assets free and clear of all Liens (other than a Permitted Lien).

Section 2.8Completeness of Transferred Assets. Except for the Excluded Assets described on Annex 9.1(b) clause (i) through clause (xv) the Transferred Assets, together with any Unassigned Rights, the rights pursuant to the Ancillary Agreements, and Contracts with employees, consultants, or advisors, include all of the assets and rights in the possession and control of Seller or its Affiliates that are related to the Business or are used or held for use by Seller or the Selling Affiliates as of the Closing Date in connection with the operation or conduct of the Business, including the development, manufacture, or commercialization of Acquired Molecules and Acquired Products.

Section 2.9Intellectual Property.

(a) Section 9.1(a)(viii) of the Seller Disclosure Letter sets forth, as of the date hereof, a complete and accurate list of all Transferred Patent Rights, including the patent application or patent number, filing date, expiration date, country or territory, applicant and owner of record in respect of each such item of Transferred Patent Right, other than the Excluded Assets. No Person, including any Governmental Authority is making a written adverse claim of ownership or inventorship to the Transferred Patent Rights or is challenging the right, title or interest of Seller or any Selling Affiliate in, to or under any Transferred Patent Rights, or the validity or enforceability of any Transferred Patent Rights. The Transferred Patent Rights are not subject to any outstanding order of, judgment of, decree of or agreement with any Governmental Authority adversely affecting the use thereof by Seller or the Selling Affiliates or their rights thereto.

(b) Seller or a Selling Affiliate owns or has the right to use each item of Transferred IP free and clear of Liens. Immediately following the Closing, Buyer shall have the same rights, interest, and title in and to each item of the Transferred IP as held by Seller or the Selling Affiliates immediately prior to the Closing without the payment of any additional amounts or consideration other than fees, royalties or payments which Seller or the Selling Affiliates would otherwise have been required to pay had the transactions contemplated herein not occurred.

(c) The Transferred IP includes all of the IP Rights owned or controlled by Seller or its Affiliates used or held for use as of the Closing Date in the Business or the development, manufacture, or commercialization of Acquired Molecules and Acquired Products.

(d) Seller and the Selling Affiliates have taken commercially reasonable measures to protect and maintain the Transferred Know-How that constitutes trade secrets and other material confidential information included in the transferred Assets. To the Knowledge of Seller, (i) all current and former officers and employees of, and consultants, advisors and independent contractors to, Seller and the Selling Affiliates who have contributed to the creation, development or invention of any Transferred IP, while employed or engaged by the Seller or a Selling Affiliate, as applicable, have executed and delivered to Seller or a Selling Affiliate a valid and enforceable agreement regarding the protection of proprietary information and the present assignment to Seller or a Selling Affiliate, as applicable, of any Transferred IP arising from

services performed for Seller or a Selling Affiliate, by such persons, and (ii) no such officer, employee, consultant, advisor or independent contractors of Seller or any Selling Affiliate is in violation of any term of such agreement. No current or former officer, employee, consultant, advisor or independent contractors of Seller or any Selling Affiliate has made or threatened to make any claim or challenge against the Seller or any of its Affiliates in connection with his or her contribution to the creation, development or invention of any Transferred IP, and no circumstances exist which would reasonably be expected to lead to any such claim or challenge.

(e) [**]. There are no adverse Third Party actions or claims or any written allegations to the effect that the operation or conduct of the Business constitutes an infringement or violation of the Patent Rights or Know-How of any third Person.

(f) To the Knowledge of Seller, no Third Party has infringed, diluted, misappropriated or otherwise violated or is or are infringing upon, diluting, misappropriating or otherwise violating the Transferred IP.

(g) None of the Transferred IP is the subject of any written objection or claim received by Seller or any Selling Affiliate or published with respect to its ownership, validity, or enforceability thereof, and, to the Knowledge of Seller, there does not exist any valid basis for such an objection or claim.

(h) Except with respect to non-exclusive licenses granted in the ordinary course of business, agreements with distributors entered into in the ordinary course of business, other generally available commercial licenses, or Contracts otherwise included in Material Contracts, Section 2.9(h) of the Seller Disclosure Letter lists, as of the date of this Agreement, all of the written agreements (i) pursuant to which Seller and the Selling Affiliates obtained the right to use or practice rights under IP Rights owned by third Persons (excluding Copyright rights) that are used or held for use as of the Closing Date in the conduct of the Business or the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product or (ii) by which Seller or any of the Selling Affiliates has licensed or otherwise authorized a Third Party to use any Patent Right or Know-How included in the Transferred IP (collectively, the "**Licensed IP Contracts**"), including license agreements, settlement agreements, and covenants not to sue.

(i) There are no outstanding amounts payable by Seller or its Affiliates to [**] under the License Agreement to reimburse [**] for expenses incurred in the prosecution and maintenance of Patent Rights licensed to Seller or its Affiliates thereunder.

Section 2.10Litigation. As of the date hereof, except as set forth on Section 2.9 of the Seller Disclosure Letter, (a) no Litigation or investigation relating to the Business, the Transferred Assets, the Acquired Molecules, or Acquired Products is pending against or, to the Knowledge of Seller, threatened in writing against Seller or any Selling Affiliate and (b) neither Seller nor any Selling Affiliate, in connection with the Business, Transferred Assets, Acquired Molecule, or Acquired Product, is subject to any outstanding Order.

Section 2.11Transferred Materials. The Transferred Materials are usable in the ordinary course of business, subject to their respective shelf life and customary wear and tear, and with

respect to such Transferred Materials that is finished product inventory for use in Clinical Studies that complies with GMP, such Transferred Materials: (a) were manufactured, stored and to the extent packaged and labeled, packaged and labeled in accordance with the specifications for the Acquired Product, good manufacturing practices and applicable Law in all material respects; (b) are not adulterated or misbranded and, to the Knowledge of Seller, is not damaged or obsolete; (c) are not held on consignment; and (d) have been tested in accordance with established protocol sufficient to release the Acquired Product.

Section 2.12Compliance with Laws; Licenses and Permits.

(a) Since [**], Seller and the Selling Affiliates have conducted the Business in compliance with applicable laws, statutes, ordinances, rules, regulations, policies, mandates, guidelines, judgments, injunctions, requirements, orders and decrees of applicable Governmental Authorities ("**Laws**") and, to the Knowledge of Seller, are not under investigation by any Governmental Authority with respect to any violation of any Laws applicable to the Business or any Transferred Asset except, in each case, as would not reasonably be expected, individually or in the aggregate, to be material to the Business, the Transferred Assets, or the Development, Manufacture, or Commercialization of Acquired Molecule and Acquired Products.

(b) Seller (together with the Selling Affiliates) has all licenses, franchises, permits, certificates, approvals or other similar authorizations issued by applicable Governmental Authorities that are necessary for the operation of the Business (the "**Permits**") except, in each case, as would not reasonably be expected, individually or in the aggregate, to be material to the Business or the Transferred Assets, or the Development, Manufacture, or Commercialization of Acquired Molecule and Acquired Products. The Permits are valid and in full force and effect and none of the Permits will be terminated as a result of the transactions contemplated by this Agreement, except, in each case, as would not reasonably be expected, individually or in the aggregate, to be material to the Business or the Transferred Assets, or the Development, Manufacture, or Commercialization of Acquired Molecule and Acquired Products. No proceeding is pending or, to the Knowledge of Seller, threatened regarding the withdrawal, suspension, material modification or revocation of any such Permit. As of the date hereof, Seller has not received any written communication from any Governmental Authority threatening to withdraw, materially modify or suspend any Permit. Seller is not in violation of the terms of any Permit.

(c) Neither Seller or any Selling Affiliate, or, to the Knowledge of Seller, the Seller or any of the Selling Affiliate's officers, employees, or other representatives (i) has used or is using any funds for any unlawful contributions, unlawful gifts, unlawful entertainment or other unlawful expenses; (ii) has made any direct or indirect unlawful payments to any foreign or domestic Governmental Authority; (iii) has violated and is not violating any Anti-Corruption Laws; (iv) has established or maintained, or is maintaining, any unlawful or unrecorded fund of monies or other properties; (v) has made, or is making, any false or fictitious entries on its accounting books and records; (vi) has made, or is making, any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of any nature, or has paid, or is 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 (vii) has otherwise given or received anything of value to or from any official of any Governmental Authority, an intermediary for payment to any individual including officials of any Governmental Authority, any political party or customer for the purpose of obtaining or retaining business, in each case ((i) through (vii)), in connection with the Business or any Acquired Molecule or Acquired Product.

(d) All payments made by Seller or any Selling Affiliate to healthcare providers pursuant to any Transferred Contract or Shared Contract (i) were made for bona fide services actually rendered by such healthcare provider, (ii) were, in all material respects, consistent with fair market value for the services provided to the extent required by applicable Laws; (iii) were commercially reasonable based on the facts and circumstances known at the time the applicable arrangements were entered into, and (iv) were not structured in a manner that would, in any material respect, take into account the volume or value of referrals, prescriptions, orders, or other business generated in violation of applicable Laws.

(e) Notwithstanding the foregoing, Seller makes no representation or warranty in this Section 2.12 (*Compliance with Laws; Licenses and Permits*) with respect to Litigation matters, regulatory matters or Tax matters, which matters are exclusively addressed in Section 2.10 (*Litigation*) and Section 2.14 (*Tax Matters*), respectively.

Section 2.13Pre-clinical Development and Clinical Trials.

(a) The studies, tests, pre-clinical development, and Clinical Trials conducted by or on behalf of the Seller with respect to the Transferred Assets, and, to the Knowledge of the Seller, all activities related to the manufacture of compounds and products for use therein, have been conducted in all material respects in accordance with established protocols, procedures and controls pursuant to accepted professional and scientific standards for products or product candidates comparable to those being developed by the Seller and all applicable Laws, including the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. parts 50, 54, 56, 58 and 312. Neither Seller nor any Selling Affiliates or, to the Knowledge of Seller, any of their officer or employees, has received any written communication from FDA or any other Governmental Authority (including any warning letter or untitled letter) that alleges that the Business is not in compliance with any applicable requirements under Laws.

(b) The INDs included in the Transferred Assets are current and in full force and effect, and no suspension, revocation, or cancellation of such INDs is pending or threatened in writing. Seller has made available to Buyer true and complete copies of each such IND and all material governmental correspondence (including copies of official notices, citations or decisions) in the files of Seller or the Selling Affiliates relating to such INDs.

(c) There is no Clinical Trial currently being conducted with respect to any Acquired Molecule or Acquired Product or under any IND that is included in the Transferred Assets.

(d) Neither Seller, nor to the Knowledge of Seller, any of its officers, employees or Selling Affiliates has been, or is currently, subject to any enforcement proceedings by the FDA

or any other Governmental Authority as relates to the Business. Since November 1, 2021, there has not been and there is not now in effect any Form 483 observation, civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, untitled letter, proceeding or request for information pending regarding any Acquired Product against Seller or, to the Knowledge of Seller, any of its officers, employees or Selling Affiliates, and Seller has no current liability (whether actual or contingent) for failure to comply with the applicable Laws with respect to the operation of the Business.

(e) Neither Seller, nor to the Knowledge of Seller, any of its officers, employees, agents, or Selling Affiliates, has made an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority, or committed an act, made a statement, or failed to make a statement, including with respect to any scientific data or information, that, at the time such disclosure was made or failure to disclose occurred, would reasonably be expected to provide a basis for the FDA or any other Governmental Authority to invoke the FDA Application Integrity Policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities," set forth in FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09) or any similar policy, in each case as related to the Acquired Product.

(f) No studies, tests, pre-clinical development, or Clinical Trials conducted by or on behalf of the Seller with respect to the Transferred Assets have (i) been conducted using any clinical investigators who have (A) been debarred or have been convicted of any crime or engaged in any conduct that did result in debarment under 21 U.S.C. § 335a or disqualification as a clinical investigator under 21 C.F.R. § 312.70 or any similar Law or (B) been excluded or convicted of any crime which would reasonably be expected to result in being excluded from participating in the Federal health care programs under Section 1128 of the Social Security Act of 1935, as amended, or (ii) been terminated or suspended prior to completion. To the knowledge of Seller, no clinical investigator that has participated or is participating in, or institutional review board that has or has had jurisdiction over, any studies, tests, pre-clinical development, or Clinical Trials conducted by or on behalf of Seller has placed a clinical hold order on, or otherwise terminated, suspended, or materially delayed, such study, test, pre-clinical development, or Clinical Trial based on an actual or alleged lack of safety or efficacy or a failure to conduct such activity in compliance with applicable Laws.

(g) Seller has not received any notices or correspondence from the FDA or other Governmental Authority or any institutional review board or comparable authority requiring the termination, suspension or material modification of any studies, tests, pre-clinical development or Clinical Trials conducted by or on behalf of the Seller with respect to the Transferred Assets.

Section 2.14Tax Matters.

(a) All material Tax Returns that are required to be filed on or before the date of this Agreement in respect of the Transferred Assets or the operation of the Business have been filed (taking into account any applicable extensions). All such Tax Returns were correct and complete in all material respects and were prepared and filed in material compliance with all applicable Laws.

(b) All material Taxes in respect of the Transferred Assets or the operation of the Business that are due and payable with respect to Pre-Closing Tax Periods have been paid in full.

(c) There are no Liens for any Taxes upon any of the Transferred Assets.

(d) The representations and warranties set forth in this Section 2.14 (*Tax Matters*) are the sole representations and warranties relating to Taxes and no other representations or warranties contained in this Agreement shall be construed to cover any matter involving Taxes.

Section 2.15Finders' Fees. Except as set forth in Section 2.15 of the Seller Disclosure Letter, there is no investment banker, broker, finder or other intermediary retained by or authorized to act on behalf of Seller who might be entitled to any fee or commission from Buyer or any of its Affiliates upon consummation of the transactions contemplated by this Agreement.

Section 2.16[**].

Section 2.17No Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, (A) NONE OF SELLER OR ANY OF ITS AFFILIATES IS MAKING OR HAS MADE ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AT LAW OR IN EQUITY, WITH RESPECT TO THIS AGREEMENT, THE ANCILLARY AGREEMENTS, SELLER, THE SELLING AFFILIATES, THE TRANSFERRED ASSETS, THE ASSUMED LIABILITIES, THE BUSINESS, THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT (INCLUDING ANY CONSENTS OR APPROVALS REQUIRED IN CONNECTION THEREWITH) OR ANY INFORMATION PROVIDED OR MADE AVAILABLE TO BUYER IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT (INCLUDING ANY FORECASTS, PROJECTIONS, ESTIMATES, BUDGETS, PRESENTATIONS CONCERNING THE BUSINESS (INCLUDING WITHOUT LIMITATION, THE CONFIDENTIAL INFORMATION MEMORANDA AND ANY "TEASER" DOCUMENTS), OR DUE DILIGENCE OR OTHER "DATA ROOM" MATERIALS), INCLUDING ANY WARRANTY WITH RESPECT TO MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND ALL OTHER REPRESENTATIONS OR WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED AND SHALL NOT BE DEEMED TO BE OR TO INCLUDE REPRESENTATIONS OR WARRANTIES OF ANY OF THE FOREGOING PARTIES AND HAVE NOT BEEN RELIED UPON BY BUYER OR ANY OF ITS AFFILIATES IN EXECUTING, DELIVERING AND PERFORMING THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY; AND (B) ALL OF THE ASSETS AND LIABILITIES TO BE SOLD, CONVEYED, ASSIGNED, TRANSFERRED OR ASSUMED, AS APPLICABLE, IN ACCORDANCE WITH THIS AGREEMENT, SHALL BE SOLD, CONVEYED, ASSIGNED, TRANSFERRED OR ASSUMED ON AN "AS IS, WHERE IS" BASIS.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES OF BUYER

Except as set forth in the applicable section identified in the Buyer Disclosure Letter, Buyer represents and warrants to Seller as follows:

Section 3.1Organization. Buyer is a duly organized corporation, validly existing and in good standing (to the extent such concept is recognized in the relevant jurisdiction) under the Laws of its respective jurisdiction of formation, and has full corporate or other applicable legal power and authority to carry on its business in the places where such businesses are now being conducted, except where the absence of such power and authority would not be expected to be material to Buyer, taken as a whole.

Section 3.2Corporate and Governmental Authorization.

(a) Buyer has full corporate power and authority to enter into this Agreement and the Ancillary Agreements, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. This Agreement has been, and the Ancillary Agreements will be by Closing, duly authorized and approved by all necessary corporate action by Buyer. The performance of Buyer's obligations hereunder and thereunder and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite corporate action of Buyer. Buyer has duly executed and delivered this Agreement and on the Closing Date will have duly executed and delivered the Ancillary Agreements.

(b) Assuming the due authorization, execution and delivery of this Agreement by Seller, this Agreement constitutes a legal, valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles. Assuming the due authorization, execution and delivery of the Ancillary Agreements by Seller or such applicable Selling Affiliate, each Ancillary Agreement to be executed by Buyer, when delivered hereunder, will be duly and validly executed and delivered, and will constitute a legal, valid and binding obligation of Buyer, enforceable in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles.

Section 3.3Non-Contravention. The execution and delivery of this Agreement and the Ancillary Agreements by Buyer, and the performance of its obligations hereunder and thereunder do not (a) violate in any material respect any provision of the Organizational Documents of Buyer, (b) violate any Law of any Governmental Authority applicable to Buyer or any Order against Buyer or (c) require any consent, authorization, approval, waiver or other action by any Person under any provision of any material agreement or other instrument to which Buyer is a party.

Section 3.4Sufficiency of Funds. Buyer has, and at Closing will have, sufficient funds on hand to consummate the transactions contemplated by this Agreement and the Ancillary Agreements and to deliver the Upfront Closing Consideration and all fees and expenses related to the transactions contemplated by this Agreement and the Ancillary Agreements at Closing, and

thereafter to pay and discharge the Assumed Liabilities as they become due through the [**] anniversary of the Closing Date. Buyer acknowledges and agrees that its obligations under this Agreement, including its obligation to consummate the transactions contemplated by this Agreement are not contingent upon Buyer's ability to obtain financing.

Section 3.5Solvency. As of the date hereof and as of immediately after giving effect to the consummation of the transactions contemplated by this Agreement, Buyer and its Affiliates will be Solvent.

Section 3.6Litigation. There is no Litigation pending, or, to the knowledge of Buyer, threatened against or affecting Buyer before any court or arbitrator or any Governmental Authority that in any manner challenges or seeks to prevent, enjoin, alter, or materially delay the transactions contemplated by this Agreement or any Ancillary Agreement.

Section 3.7Finders' Fees. There is no investment banker, broker, finder or other intermediary retained by or authorized to act on behalf of Buyer who might be entitled to any fee or commission from Seller or any of the Selling Affiliates upon consummation of the transactions contemplated by this Agreement.

ARTICLE 4

CERTAIN COVENANTS

Section 4.1Access to Information; Books and Records.

(a) From and after the Closing, each Party shall promptly afford the other Party and such other Party's respective agents reasonable access to such Party's books and records, information, employees and auditors related to the Transferred Assets and Assumed Liabilities to the extent necessary or useful for such Party in connection with any audit, investigation, dispute or Litigation related to the Business unless it is related to an audit, investigation, dispute or Litigation between Buyer and Seller; provided that such Party agrees to reimburse the other Party promptly for all reasonable and documented out-of-pocket costs and expenses incurred in connection with any such request.

(b) Notwithstanding anything to the contrary in Section 4.1(a) (*Access to Information; Books and Records*), (i) access rights pursuant to Section 4.1(a) (*Access to Information; Books and Records*) shall be exercised in such manner as not to interfere unreasonably with the conduct of the Business or any other business of the Party granting such access, and (ii) the Party granting access to the other Party may withhold any document (or portions thereof) or information (A) that is subject to the terms of a non-disclosure agreement with a Third Party, (B) that may constitute privileged attorney-client communications or attorney work product and the transfer of which, or the provision of access to which, as reasonably determined by such Party's counsel, constitutes a waiver of any such privilege or (C) if the provision of access to such document (or portion thereof) or information, as determined by such Party's counsel, would reasonably be expected to conflict with applicable Laws.

Section 4.2Confidentiality.

(a) Each of Buyer and Seller acknowledges that the information provided to them in connection with this Agreement and the consummation of the transactions hereunder is subject to the terms of the Confidentiality Agreement. Effective upon, and only upon, the Closing, the Confidentiality Agreement shall terminate with respect to information included in or related to the Transferred Assets.

(b) From and after the Closing, Seller and Selling Affiliates shall, and shall cause their respective Affiliates and representatives to, maintain in confidence any written, oral, or other information relating to the Business (including all Transferred Know-How and Data included therein) ("**Confidential Business Information**"), and Seller and Selling Affiliates shall not disclose to any Third Party or use for any purpose such Confidential Business Information without the Buyer's prior written consent; provided, however, that Confidential Business Information will not include information that Seller or the applicable Selling Affiliate can demonstrate with documentary evidence that such information (i) is publicly available other than as a result of a disclosure by the Seller or Selling Affiliate or any of its officers, directors, managers, employees, agents or other representatives in violation of this Section 4.2 (*Confidentiality*), (ii) is obtained by the Seller or any Selling Affiliate or their respective representatives after the Closing from a Third Party that, at such time, was not under a legal, contractual or fiduciary duty of confidentiality with respect to such information, or (iii) was independently developed by the Seller or the Selling Affiliates after the Closing without reference to or use of any Transferred Know-How or other confidential information in relation to the Transferred Assets. Notwithstanding the foregoing, Seller and Selling Affiliates may disclose Confidential Business Information to the extent (x) it is required to be disclosed pursuant to Law or any listing agreement with or the rules of any applicable securities exchange, or (y) it is required to disclose such information by judicial order or administrative process or pursuant to applicable Law; provided that Seller (A) notifies Buyer of the disclosure requirement promptly after Seller becomes aware of the judicial order or other requirement (unless such notification would be unlawful); (B) cooperates with Buyer in seeking a protective order or similar relief to protect the confidentiality of the information to be disclosed (in each case at the expense of Buyer); and (C) limits the disclosure to what is requested by the judicial order or other requirement. Notwithstanding the foregoing, Seller may retain one (1) copy of Confidential Business Information in its confidential files for archival or compliance purposes and may retain such additional copies of or any computer records or files containing Confidential Business Information or any of its Affiliates' confidential information that have been created solely by automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Seller's standard archiving and back-up procedures, but not for any other use or purpose. All such Confidential Business Information shall continue to be subject to the terms of this Agreement.

(c) Subject to the foregoing, after the Closing and following transfer of the Transferred Assets and Assumed Liabilities in accordance with this Agreement, each Party shall, and shall cause its Affiliates and representatives to, promptly (and in any event within [**] after the Closing) remove, erase, delete or otherwise destroy (i) all information of or relating to the other Party (other than, with respect to Buyer, information relating to the Business, including any Transferred Assets or Assumed Liabilities) (whether in print, electronic or other forms) in the possession of any of its representatives and (ii) in the case of Selling Affiliates, all Confidential Business Information; in each case ((i) and (ii)), provided that, subject to Section 4.2(b) (*Confidentiality*), Seller and the Selling Affiliates shall have the right to retain copies of all books,

data, files, information and records of the Business in any media (including, for the avoidance of doubt, Tax Returns and other information and documents relating to Tax matters, provided that Tax Returns relating solely to the Transferred Assets or the Business will be Transferred Assets) (other than any trade secrets and technical or scientific information included in the Transferred Know-How) relating to periods ending on or prior to the Closing Date (i) as may be required by any Governmental Authority or (ii) as may be necessary for Seller or the Selling Affiliates to perform their respective obligations pursuant to this Agreement or any of the Ancillary Agreements, in each case subject to compliance with all applicable privacy Laws.

Section 4.3Public Announcement.

(a) No Party to this Agreement shall originate any publicity, news release or other similar public announcement or disclosure, written or oral, relating to this Agreement or any documents or transactions contemplated hereby or the existence of any arrangement between the Parties, without the prior written consent of the other Party (not to be unreasonably withheld, conditioned, or delayed) whether or not named in such publicity, news release or other similar public announcement, except (a) each Party may issue a press release to announce the execution of this Agreement in a form agreed to the other Party (such agreement not to be unreasonably, withheld, conditioned, or delayed) and (b) either Party may originate any such publicity, news release or other similar public announcement as may be required by Law or any listing or trading agreement concerning its publicly traded securities; provided that, in such event, the issuing Party shall still be required to consult with the other Party, whether or not named in such publicity, news release or other similar public announcement, at least [**] prior to its release (or such shorter period as may be reasonable under the circumstances) to allow the other Party to comment thereon; provided, further, that if such non-issuing Party shall not have provided its consent to the issuing Party's request for consent and/or consultation pursuant to the foregoing after [**] (or such shorter period as may be reasonable under the circumstances), then the issuing Party shall be deemed to have fulfilled its obligations pursuant to this Section 4.3 (*Public Announcement*) and shall be free to issue such publicity, news release or other similar public announcement, and each Party may each disclose to Third Parties any information contained in a previously approved press release without the need for further approval by the other Party.

(b) Without limiting the foregoing, following the Closing, if Buyer intends to issue any such public news release or other similar public announcement or disclosure, whether written or oral, with respect to (i) the achievement of any Development and Regulatory Milestone Event or Commercial Milestone Event, (ii) disclosure of top line data from a study conducted by Buyer or its Affiliates or (Sub)licensees that is intended to support initial regulatory approval of, or a new indication for, any Product, (iii) unknown adverse events related to any Products, (iv) the receipt of Regulatory Approval of any Product, (v) the commercial launch of any Product, or (vi) ceasing all development and commercialization activities related to any Product, in each case, solely with respect to the development, commercialization, or other exploitation of a Product in any of [**], then, in each case, Buyer will, to the extent legally permitted, notify Seller of such disclosure at least [**] prior to the anticipated date of such public disclosure. Notwithstanding the foregoing, Buyer will not be required to notify Seller of any public disclosure (A) set forth in any ordinary course registration statement, form, report, schedule, statement, exhibit or other document (including exhibits, financial statements and schedules thereto and all other information incorporated therein and amendments and supplements thereto, but for clarity excluding reports

on form 8-K) required to be filed or furnished by Buyer to the Securities and Exchange Commission pursuant to the Exchange Act or the Securities Act of 1933, as amended, or (B) contained in a previously approved public announcement or disclosure.

(c) If Buyer or Seller, based on the advice of its counsel, determines that this Agreement, or any of the Ancillary Agreements, must be publicly filed with a Governmental Authority, then Seller or Buyer, prior to making any such filing, shall provide the other Party and its counsel with a redacted version of this Agreement (and any other Ancillary Agreement) which it intends to file, and will give due consideration to 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 sections specified by such Party or its counsel.

Section 4.4Shared Contracts. The Parties desire for the benefit of Seller and Buyer, respectively, to have and obtain the rights and benefits under each Shared Contract set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter. Following the Closing, Buyer shall elect what Shared Contracts it desires to obtain the rights and benefits under, including, to the extent permissible and practicable, through partial assignment of the applicable portions of such Shared Contracts, and the Parties shall cooperate with each other to provide Seller and the Selling Affiliates and Buyer and its Affiliates with their applicable rights and benefits under each such Shared Contract *first*, by effecting a partial assignment of such Shared Contract; provided that Seller will use commercially reasonable efforts to obtain any required counterparty consent to effect such partial assignment, or, if unable to effect such partial assignment, *second*, by assisting Buyer in entering into a new Contract or Contracts with the applicable Third Party on substantially similar terms (a "**Separated Contract**"). Without limiting the foregoing, the Parties will reasonably cooperate to contact the Third Party counterparty to (A) each Shared Contract to the extent it is still in effect and has not been concluded with respect to the Transferred Assets, within [**] following the Closing, and (B) any other Shared Contract, including any Shared Contract that is no longer in effect or has been concluded with respect to the Transferred Assets, to the extent requested by Buyer, within [**] following Seller's receipt of such request, in each case, to notify such Third Party of Buyer's purchase of the Transferred Assets and to notify such Third Party that it may interact with the Buyer regarding such Shared Contract to the extent it relates to the Acquired Molecules, Acquired Products, or Transferred Assets, and only with respect to the applicable parts and provisions of such Shared Contract. Buyer acknowledges that, with respect to subclause (B) in the foregoing sentence, reasonable cooperation by Seller may be limited by the availability of current contact information for any applicable Third Party. The Third Party costs of entering into a new Contract or Contract(s) shall be borne by Buyer. If any Shared Contract set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter cannot be partially assigned or separated into a Separated Contract following Closing, then Seller and Buyer shall, and shall cause each of their respective Affiliates to, use their commercially reasonable efforts to cause, for the period after the Closing until such Shared Contract is separated into a Separated Contract, (i) the rights and benefits under each Shared Contract to the extent relating to the Business to be enjoyed by Buyer; (ii) the liabilities under each Shared Contract to the extent relating to the Business after Closing to be borne by Buyer; (iii) the rights and benefits under each Shared Contract to the extent relating to any business other than the Business to be enjoyed by Seller; and (iv) the liabilities under each Shared Contract to the extent relating to either (a) the Business before Closing or (b) any business other than the Business, in each case, to be borne by Seller. If and to the extent that a Shared Contract set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter contains a separate

and severable agreement, statement of work, purchase order, or other distinct component that (a) relates solely to the Acquired Molecules, Acquired Products, or Transferred Assets and (b) is capable of being independently assigned without breaching or otherwise affecting the remaining portions of such Shared Contract, then, upon the valid assignment of such separate and severable portion to Buyer, such portion shall be deemed a Transferred Contract for all purposes hereunder.

Section 4.5Further Assurances. From time to time after the Closing Date, at the reasonable request of a Party, without further consideration and at the expense of the Party so requesting, the other Party shall execute and deliver to such requesting Party, or shall cause to be executed and delivered to such requesting Party, such additional instruments or documents, and shall take or cause to be taken such other action, as such requesting Party may reasonably request in order to consummate more effectively the transactions contemplated by this Agreement. Seller shall, execute and deliver, or cause to be executed and delivered, to Buyer any confirmatory assignment, invention assignment, inventor's declaration, or other documentation, and provide, or cause to be provided, any good faith testimony (by affidavit, declaration, or in person), in each case, as reasonably necessary or desirable to complete the chain-of-title of the Transferred IP to Seller and then, in accordance with to this Agreement, to Buyer and to otherwise perfect, defend, or enforce Buyer's rights, title, and interests in and to the Transferred IP (including all inventions claimed or disclosed in the Transferred Patent Rights).

Section 4.6Insurance. The coverage under all insurance policies related to the Business and arranged or maintained by Seller or the Selling Affiliates following Closing is only for the benefit of Seller and the Selling Affiliates, and not for the benefit of Buyer or the Business. As of the Closing Date, Buyer agrees to arrange for its own insurance policies with respect to the Business and agrees not to seek, through any means, to benefit from any of Seller's or the Selling Affiliates' insurance policies which may provide coverage for claims relating in any way to the Business following the Closing.

Section 4.7Wrong Pockets. For a period of up to [**] after the Closing Date, if either Buyer or Seller becomes aware that (w) any of the Transferred Assets has not been transferred to Buyer, (x) any of the Excluded Assets has been transferred to Buyer, (y) any Contract relating solely to the operation and conduct of the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any of the Transferred Assets was not included in Section 9.1(a)(vi) of the Seller Disclosure Letter, or (z) any Shared Contract that has not been, or attempted to be, assigned-in-part to Buyer or separated into a Separated Contract, in each case, it shall promptly notify the other and the Parties shall, as soon as reasonably practicable and, subject to Section 1.1(e) (*Business Transfer Documents*), cause such property to be:

(a) upon the written request of the Buyer, and with any necessary prior Third Party consent or approval, transferred to Buyer, in the case of any Transferred Asset that was not transferred to Buyer at the Closing;

(b) with any necessary prior Third Party consent or approval, transferred to Seller, in the case of any Excluded Asset that was transferred to Buyer at or after the Closing;

(c) upon the written request of the Buyer, and with any necessary prior Third Party consent or approval, transferred to Buyer, in the case of any Contracts described in clause (y) above; or

(d) upon the written request of the Buyer, in the case of Contracts described in clause (z) above, assigned-in-part to Buyer or separated into a Separated Contract, in each case, in accordance with Section 4.4 (*Shared Contracts*).

Section 4.8Transfer Plan; Transition Assistance. Following the Closing, Seller shall (a) conduct certain transfer and transition activities to transfer the Transferred Assets to and transition the Acquired Program to Buyer as set forth in the transfer plan on Exhibit D the ("**Transfer Plan**"), and (b) upon Buyer's reasonable written request following Closing, provide reasonable assistance to Buyer and the other Buyer Parties in connection with understanding and using the Transferred Assets and conducting the Business, including making appropriate full-time employees of Seller available to assist Buyer or its designee from time to time as reasonably requested by Buyer (such assistance, the "**Transition Assistance**"). Seller shall provide Buyer with access to the Data Room for at least [**] following the Closing and allow Buyer to download all of the contents of the Data Room. If and to the extent Seller provides the Buyer Parties (i) more than [**] hours of Transition Assistance but not more than [**] hours of Transition Assistance, in the aggregate, pursuant to this Section 4.8 (*Transfer Plan; Transition Assistance*), then Buyer will reimburse Seller for the cost of its employees' performance of such additional Transition Assistance at [**], and (ii) more than [**] hours of Transition Assistance, in the aggregate, then Buyer will reimburse Seller for the cost of its employees' performance of such additional Transition Assistance at the Hourly Rate. The total hours of Transition Assistance provided by Seller pursuant to this Section 4.8 (*Transfer Plan; Transition Assistance*) shall not exceed [**] hours in the aggregate. If applicable, Seller shall invoice Buyer for any such additional Transition Assistance provided at [**] thereof, as applicable, and Buyer shall pay all such undisputed amounts within [**] after receipt of an applicable invoice from Seller. Notwithstanding anything herein to the contrary, Buyer shall reimburse Seller for any reasonable and documented out-of-pocket costs, including fees payable to consultants, that Seller incurs in connection with any Transition Assistance; provided, that Seller shall not incur any such out-of- pocket costs without the prior written consent of Buyer; and provided further that any such services provided by consultants and reimbursed by Buyer will not count towards the hourly limits in the third sentence of this Section 4.8 (*Transfer Plan; Transition Assistance*). Seller shall invoice Buyer for any such out-of-pocket costs, and Buyer shall pay all such undisputed amounts within [**] after receipt of an applicable invoice from Seller. If any Know-How is created by or on behalf of Seller or any Selling Affiliate, solely or jointly, in the conduct of activities set forth in the Transfer Plan or otherwise pursuant to this Section 4.8 (*Transfer Plan; Transition Assistance*), then, if such Know-How primarily relates to an Acquired Molecule or Acquired Product, such Know-How will be deemed to be Transferred Know-How for the purposes of this Agreement and will be owned by Buyer and, [**].

Section 4.9License. Effective as of the Closing and subject to the terms, conditions, and provisions of this Agreement, Buyer hereby grants to Seller, and Seller hereby accepts, a non- transferable, non-exclusive license, with the right to grant sublicenses solely to Seller's applicable Affiliates, under the Transferred Assets, solely for the purposes of during the applicable term of the Ancillary Agreements, performing Seller's obligations under such Ancillary Agreements and under the Transfer Plan.

Section 4.10[**].

[**].

Section 4.11Payments from Third Parties; Correspondence.

(a) Except as expressly provided in any Ancillary Agreement, in the event that, on or after the Closing Date, either Party receives from a Third Party any payments or other funds due to the other pursuant to the terms of this Agreement or of any Ancillary Agreement, then the Party receiving such funds shall promptly forward such funds to the other Party. The Parties acknowledge and agree there is no right of offset regarding any such payments, and a Party may not withhold any such funds received from a Third Party for the account of the other Party in satisfaction of any claim or dispute pursuant to this Agreement or any Ancillary Agreement. For purposes of this Agreement, any payments or other funds received by Buyer or any of its Affiliates from a Third Party in respect of any Product(s) shall first be applied against any outstanding receivable held by Seller or any applicable Selling Affiliate in respect of such Product(s) for any period prior to Closing and only after all such receivables have been satisfied shall any payments or other funds received by Buyer or any of its Affiliates from a Third Party in respect of any Product(s) be deemed in respect of receivables for any period after the Closing.

(b) From and after the Closing until the [**] of the Closing Date, (i) Seller shall use commercially reasonable efforts to cause to be delivered to Buyer any mail or other communications received by Seller or any of the Selling Affiliates from any Person in respect of any Product with respect to the period after the Closing and (ii) Buyer shall use commercially reasonable efforts to cause to be delivered to Seller or its applicable Selling Affiliate any mail or other communications received by Buyer or its Affiliates from any Person either intended for Seller or any of the Selling Affiliates and not related to any Product or Transferred Asset or regarding any Product or Transferred Asset with respect to the period prior to the Closing. The provisions of this Section 4.11(b) (*Payments from Third Parties; Correspondence*) are not intended to, and shall not be deemed to, constitute an authorization by any of Seller or Buyer to permit the other to accept service of process on its behalf and neither Seller nor Buyer are or shall be deemed to be the agent of the other for service of process purposes.

Section 4.12Use of Trademarks. Neither Party nor any of its Affiliates shall use in any manner any Trademark or trade dress of the other Party or any of its Affiliates.

Section 4.13Mutual Non-Solicitation. From and after the Closing Date, Seller and Buyer each agree that they shall not, and they shall each cause their respective Subsidiaries and Affiliates to not, for a period of [**] after the Closing Date, directly or indirectly, encourage, induce, or solicit (a) in the case of Seller, any employee of Buyer to leave employment with Buyer or any of its Affiliates or (b) in the case of Buyer, any employee of Seller or any of the Selling Affiliates who as of the Closing Date provided services to the Business; provided, that this clause shall not preclude Seller, Buyer or any of their respective Subsidiaries or Affiliates from (i) posting a general solicitation through a public medium or general or mass mailing by or on behalf of Seller, Buyer or any of their respective Subsidiaries or Affiliates, as applicable, that is not targeted at employees of such other Party or (ii) soliciting any former employee of such other Party.

Section 4.14Competition.

(a) Seller acknowledges and agrees that, subject to the remainder of this Section 4.14 (*Competition*), during the Exclusive Period, Seller and its Affiliates shall not, directly or indirectly, by itself or for or with any Third Party, research, develop, manufacture, or commercialize [**], in the Field in the Territory.

(b) The Parties hereby acknowledge and agree that Section 4.14(a) (*Competition*) shall not apply to any activities intended by Seller or any of its Affiliates to ensure its compliance with this Section 4.14 (Competition) (e.g., counter screening).

(c) Notwithstanding anything to the contrary in this Section 4.14 (*Competition*), if a Change of Control occurs with respect to Seller or any of its Affiliates with an Acquirer, and the Acquirer (or any of such Acquirer's successors or assigns, other than Seller and its Affiliates as of the Change of Control) [**] a program or product (or rights thereto) that would otherwise violate Section 4.14(a) (*Competition*) (each, an "**Seller COC Program**"), then (i) Section 4.14(a) (*Competition*) will not apply with respect to such Seller COC Program, and (ii) such Third Party, or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, as applicable, will be permitted to pursue, and continue such Seller COC Program after such Change of Control and such pursuit and continuation will not constitute a violation of Section 4.14(a) (*Competition*); provided that such Third Party or any of such Third Party's Affiliates (including Seller and Selling Affiliates) or any or any successors or assigns of such Third Party or such Third Party's Affiliates, as applicable, will (A) not use any Transferred Know-How or other confidential information of Buyer or the Buyer Parties, or otherwise practice, use, or exploit any Transferred Assets in connection with such Seller COC Program and (B) Segregate the Seller COC Program from the Transferred Assets.

(d) In addition, notwithstanding Section 4.14(a) (*Competition*), if (i) Seller or its Affiliate acquires a Third Party (by merger, sale, consolidation, reorganization, or otherwise) so that such Third Party becomes an Affiliate over which Seller or its Affiliate has control, or (ii) Seller or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (i) and (ii), a "**Seller Acquisition**"), and, in each case, the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Seller and its Affiliates as of the Seller Acquisition) already has, or the acquired assets contain, as applicable, a program or product that existed prior to the Seller Acquisition that would otherwise violate Section 4.14(a) (a "**Seller Acquisition Program**"), then Seller or such Affiliate will elect whether to (A) divest its rights to such Seller Acquisition Program, or (B) cease the development or commercialization of such Seller Acquisition Program, and will provide Buyer written notice of the existence of such Seller Acquisition Program and such decision within [**] after the closing of such Seller Acquisition. If Seller provides notice as described in clause (A) of the preceding sentence, then Seller, and its Affiliates if applicable, will divest such Seller Acquisition Program within [**] after the closing of the applicable Seller Acquisition, and if Seller provides notice that it will terminate such Seller Acquisition Program as described in clause (B) of the preceding sentence, then Seller, and its Affiliates if applicable, will (1) cease the development and commercialization of such Seller Acquisition Program as soon as reasonably practicable and in any event within [**] of the closing of the applicable Seller Acquisition, giving due consideration to ethical concerns and requirements

under applicable Law and any agreements with Third Parties and (2) until such Seller Acquisition Program can be divested or terminated, (x) not use any Transferred Know-How or other confidential information of Buyer or the Buyer Parties, or otherwise practice, use, or exploit any Transferred Assets in connection with such Seller Acquisition Program, and (y) Segregate the Seller Acquisition Program from the Transferred Assets.

(e) The restrictions set forth in Section 4.14(a) (*Competition*) shall no longer apply to Seller and its Affiliates upon the earliest to occur of (i) Buyer's public announcement that it is permanently abandoning all development and commercialization of all Products, and (ii) Seller's receipt of written notice from Buyer that, consistent with Buyer's use of Commercially Reasonable Efforts, Buyer has made the determination to permanently abandon all exploitation of all Products. Buyer shall promptly notify Seller in writing following any determination by Buyer to permanently abandon all exploitation of all Products. In addition, the restrictions set forth in Section 4.14(a) (*Competition*) shall cease to apply to Seller and its Affiliates in the event that Buyer's fails to perform and satisfy its undisputed payment obligations under this Agreement for as long as such breach remains uncured.

Section 4.15Transferred Patent Rights; Negative Covenant. Buyer acknowledges and agrees that the execution and delivery of this Agreement will provide the Buyer Parties with unrestricted rights to use and exploit the Transferred Patent Rights only in connection with the development, manufacture, promotion, marketing, distribution and/or sale of any Acquired Molecule or any Acquired Product and no other compound or product, including, for clarity, any [**]. Buyer hereby covenants and agrees not to, and shall cause the other Buyer Parties not to, practice any (a) Transferred Patent Right or (b) Patent Right licensed under the A&R License Agreement, in each case ((a) and (b)), to develop, manufacture, promote, market, distribute, or sell any compound or product other than an Acquired Molecule or Acquired Product.

Section 4.16Maintenance and Enforcement of the Transferred Patent Rights. Following the Closing, Buyer shall either (a) not disclaim, allow to lapse, abandon, or terminally disclaim or fail to take any action necessary or desirable to prevent the disclaimer, lapse or abandonment of, an issued Patent Right in the Transferred Patent Rights if such issued Transferred Patent Right is the only remaining Transferred Patent Right with a Valid Claim that Covers the sale of a Product in a country (except for good faith abandonment in the ordinary course of prosecution) or (b) if Buyer does disclaim, allow to lapse, abandon, or terminally disclaim or fail to take any action necessary or desirable to prevent the disclaimer, lapse or abandonment of such issued Transferred Patent Right (except for good faith abandonment in the ordinary course of prosecution), the Buyer will continue to pay Royalties on Net Sales of Products in such country as if such Transferred Patent Right continued to be issued until such time such Transferred Patent Right would have expired but for such action by Buyer.

Section 4.17Transferred Materials. At or as promptly as practicable following the Closing and as set forth under Annex 9.1(a)(v), Seller shall cause the Transferred Materials to be made available for delivery to Buyer from Seller's or its applicable vendor, by Buyer or its carrier and at Buyer's cost and expense.

ARTICLE 5

TAX MATTERS

Section 5.1Tax Allocation. In the case of any Taxes that are imposed on a periodic basis and are payable for a Straddle Period, the portion of such Tax that relates to the portion of the Straddle Period ending on the Closing Date shall (a) in the case of any Taxes other than Taxes based upon or related to income, gains or receipts, sales or use, employment, withholding, transaction-based Taxes, or similar items, be deemed to be the amount of such Tax for the entire Straddle Period multiplied by a fraction, the numerator of which is the number of calendar days from the beginning of such Straddle Period through the Closing Date and the denominator of which is the number of calendar days in the entire Straddle Period, and (b) in the case of any Tax based upon or related to income, gains or receipts, sales or use, employment, withholding, withholding- based Taxes, or similar items, be deemed equal to the amount of Tax which would be payable if the relevant Tax period ended on the Closing Date. Any Tax refunds or credits for overpayment for a Straddle Period shall be determined in a manner consistent with this Section 5.1 (*Tax Allocation*), and any such amounts that relate to a Pre-Closing Tax Period (or are otherwise described in Annex 9.1(b)(x)) shall be for the account of Seller. Buyer shall, or shall cause its Affiliates, to promptly remit to Seller the net amount of any such refund (or any other amounts described in Annex 9.1(b)(x)), net of any out of pocket costs or expenses of Buyer or its Affiliates on obtaining, receiving, or paying over any such refund.

Section 5.2Cooperation. Each of Buyer and Seller shall provide the other with such information and records, and make such of its officers, directors, employees and agents available, as may reasonably be requested by such other Party in connection with the preparation of any Tax Return or the conduct of any Tax Proceeding of the Transferred Assets for any Pre-Closing Tax Period or a Straddle Period.

Section 5.3Contingent Consideration. The Parties agree for all U.S. Tax purposes that the Contingent Consideration shall be treated as deferred contingent purchase price eligible for installment sale treatment under Section 453 of the Code and any corresponding provision of state and local or non-U.S. Law (subject to any imputation of interest under Section 483 or Section 1274 of the Code). The Parties shall file all Tax Returns consistent with the foregoing.

ARTICLE 6

INDEMNIFICATION

Section 6.1Survival. All representations and warranties made in this Agreement shall survive the Closing Date for a period of [**] after the Closing Date; provided that the representations and warranties of Seller set forth in [**] (collectively, the "**Fundamental Representations**") and [**] shall survive until [**] following the expiration of the applicable statute of limitations. The respective covenants and agreements of Seller and Buyer contained in this Agreement contemplated or required to be performed or complied with from and after the Closing (each, a "**Post-Closing Covenant**") shall survive the Closing Date hereunder for such period of time as may be specified therein, but in no event will Buyer be permitted to bring an indemnity claim with respect to any breach of a Post-Closing Covenant after the expiration of the

applicable statute of limitations. An Indemnifying Party shall have no indemnification obligation in respect of claims made pursuant to this Article 6 unless the Indemnified Party gives written notice of the claim to the Indemnifying Party in accordance with the procedures set forth in this Agreement on or prior to the expiration of the applicable survival period. If the Indemnified Party delivers such written notice of a claim on or prior to the expiration of the applicable survival period, then the Indemnifying Party's indemnification obligations shall continue with respect to such claim until the final resolution and satisfaction of such claim in accordance with the provisions of this Article 6.

Section 6.2Indemnification by Seller. From and after the Closing, and subject to this Article 6, Seller shall defend, indemnify and hold harmless Buyer, and each of its Subsidiaries and Affiliates, and their respective officers, directors, employees, agents, successors and assigns (collectively, the "**Buyer Indemnitees**") from and against, and pay or reimburse the Buyer Indemnitees for all Losses resulting from (a) any inaccuracy in or breach of any representation or warranty by Seller set forth in this Agreement, (b) any breach or default in performance by Seller of any Post-Closing Covenant of Seller, (c) the ownership and operation of the Transferred Assets and the Business prior to the Closing Date, and (d) any Excluded Liability. Notwithstanding that a claim for Losses may fall into multiple categories of this Section 6.2 (*Indemnification by Seller*), Buyer Indemnitees may recover such Losses only one time.

Section 6.3Indemnification by Buyer. From and after the Closing, and subject to this Article 6, Buyer shall defend, indemnify and hold harmless Seller and each of its Subsidiaries and Affiliates and their respective officers, directors, employees, agents, successors and assigns (collectively, the "**Seller Indemnitees**") from and against, and pay or reimburse the Seller Indemnitees for, any and all Losses resulting from (a) any inaccuracy in or breach of any representation or warranty by Buyer set forth in this Agreement, (b) any breach or default in performance by Buyer of any Post-Closing Covenant of Buyer, (c) the ownership and operation of the Transferred Assets and the Business after the Closing and (d) the Assumed Liabilities. Notwithstanding that a claim for Losses may fall into multiple categories of this Section 6.3 (*Indemnification by Buyer*), Seller Indemnitees may recover such Losses only one time.

Section 6.4Limitations on Indemnity. Buyer and Seller agree, for themselves and on behalf of the Buyer Indemnitees and the Seller Indemnitees, respectively, that:

(a) Except in the case of fraud, no Buyer Indemnitee will assert any claims for, nor shall any Buyer Indemnitee be entitled to, indemnification under Section 6.2(a) (*Indemnification by Seller*) until such time as the aggregate of all Losses that Buyer Indemnitees may have under Section 6.2(a) (*Indemnification by Seller*) exceeds $[**] (*i.e.,* [**]) (the "**Indemnity Threshold**"), at which time the Buyer Indemnitees may assert claims for all Losses. The aggregate liability of Seller in respect of claims for indemnification pursuant to Section 6.2(a) (*Indemnification by Seller*) will not exceed $[**] (*i.e.,* [**]) (the "**Upfront Cap**"). Notwithstanding the foregoing, to the extent that Buyer Indemnitees have Losses for which it is entitled to indemnification under Section 6.2(a) (*Indemnification by Seller*) in excess of the Upfront Cap up to a total of $[**] (*i.e.,* [**]) (such excess the "**Excess Indemnifiable Losses**"), any Buyer Indemnitee may assert a claim against Seller for such Excess Indemnifiable Losses and/or may offset or recover from Seller such Excess Indemnifiable Losses against any Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalty, or

(Sub)license Income owed by Buyer to Seller under this Agreement after, with respect to the Royalties, the application of all other reductions applicable pursuant to Section 1.4(c)(iv) (*Royalty Reductions*), but in each case, only to the extent provided in Section 6.4(b) (*Limitations on Indemnity*).

(b) To the extent a Buyer Indemnitee asserts a claim against Seller for Excess Indemnifiable Losses, Seller will not be required to pay or reimburse any Excess Indemnifiable Losses to the extent that such Excess Indemnifiable Losses exceed an amount equal to [**] actually received by Seller as of the time such Excess Indemnifiable Losses are payable to the Buyer Indemnitees. To the extent any Excess Indemnifiable Losses are not paid or reimbursed by Seller, whether as a result of the foregoing limitation or otherwise, Buyer may offset them in accordance with this Section 6.4(b) (*Limitations on Indemnity*) against subsequent future Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or (Sub)license Income payments owed by Buyer to Seller until exhausted; provided, that, no Development and Regulatory Milestone Payment, Commercial Milestone Payment, Royalty, or (Sub)license Income payment will be reduced by more than [**] relative to what it otherwise would have been absent the reductions in this Section 6.4(b) (*Limitations on Indemnity*). If and to the extent that any Excess Indemnifiable Losses are not either paid by Seller or offset against any Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or (Sub)license Income payment as a result of the foregoing limitation, then Buyer may carry forward and offset such amounts against future Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or (Sub)license Income payments otherwise owed by Buyer to Seller (subject to the foregoing [**] per-payment reduction limit) until exhausted.

(c) Notwithstanding anything to the contrary set forth herein, the provisions of Section 6.4(a) (*Limitations on Indemnity*) will not apply in respect of claims for breach of any Fundamental Representation or fraud; provided that in no event shall the aggregate liability of Seller in respect of claims for indemnification pursuant to Section 6.2(a), Section 6.2(b) and Section 6.2(c) (*Indemnification by Seller*) exceed the Purchase Price actually received by Seller, other than for fraud.

(d) No Buyer Indemnitee shall be entitled to indemnification, to sue for damages or to assert any other right or remedy under this Agreement with respect to any Loss, cause of action or other claim to the extent it (i) is a potential Loss that may be asserted rather than an actual Loss that has, in fact, been incurred by such Party or (ii) is a Loss with respect to which such Party or any of its Affiliates has taken action (or caused action to be taken) to accelerate the time period in which such matter is asserted or payable. Notwithstanding the foregoing, pursuant to Section 6.1 (*Survival*) above, if a written notice of any claim for indemnification hereunder has been delivered in accordance with this Agreement prior to the expiration of the applicable survival period set forth above, the indemnification obligations of Buyer Indemnitee shall continue with respect to such claim until the final resolution and satisfaction of such claim in accordance with the provisions of this Article 6.

(e) No Buyer Indemnitee shall be entitled to recover any amount relating to any matter arising under one provision of this Agreement to the extent such Buyer Indemnitee has already recovered such amount with respect to such matter pursuant to such provision or any other provisions of this Agreement.

(f) With respect to each indemnification obligation in this Agreement: (i) in no event shall an Indemnifying Party have liability to the Indemnified Party for damages that are waived pursuant to Section 8.4(c) (*Waiver of Certain Damages*); and (ii) the Parties shall treat any indemnification payment made under this Agreement as an adjustment to the Upfront Consideration, or Development and Regulatory Milestone Payments, Commercial Milestone Payments, or Royalties, or (Sub)license Income (as applicable).

(g) If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Losses pursuant to Section 6.2 or Section 6.3 and the Indemnified Party could have recovered all or a part of such Losses from a Third Party (a "**Potential Contributor**") based on the underlying claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against the Potential Contributor as are necessary to permit the Indemnifying Party to recover from the Potential Contributor the amount of such payment.

(h) Any Indemnified Party shall take all commercially reasonable steps under applicable Law to mitigate any Losses incurred by such Party upon and after becoming aware of any event or condition that would reasonably be expected to give rise to any indemnification rights hereunder.

Section 6.5Notification of Claims; Third Party Claims.

(a) A Person that may be entitled to be indemnified under this Agreement (the "**Indemnified Party**") shall promptly notify the Party or Parties liable for such indemnification (the "**Indemnifying Party**") in writing of any claim in respect of which indemnity may be sought under this Article 6 (*Indemnification*), describing in reasonable detail the facts and circumstances with respect to the subject matter of such claim; provided, however, that (i) the failure to provide such notice shall not release the Indemnifying Party from any of its obligations under this Article 6 (*Indemnification*) except to the extent the Indemnifying Party is prejudiced by such failure and (ii) the Indemnified Party will not be permitted to deliver a such notice (and will not be entitled to indemnification pursuant to this Article 6 (*Indemnification*)) with respect to breaches of a representation and warranty unless such notice is delivered prior to the expiration of any applicable survival period specified in Section 6.1 (*Survival*) for such representation or warranty.

(b) Upon receipt of notice of a claim for indemnity from an Indemnified Party pursuant to this Section 6.5 (*Notification of Claims; Third Party Claims*) in respect of a pending or threatened claim or demand by a Third Party that the Indemnified Party has determined has given or could reasonably give rise to a right of indemnification under this Agreement (such claim or demand being a "**Third Party Claim**" and including a pending or threatened claim or demand asserted by a Third Party against the Indemnified Party), the Indemnifying Party may, by notice to the Indemnified Party delivered within [**] of the receipt of notice of such Third Party Claim, assume the defense and control of such Third Party Claim, with its own counsel and at its own expense, but shall allow the Indemnified Party a reasonable opportunity to participate in the defense of such Third Party Claim with its own counsel and at its own expense. The Indemnified Party may take any actions reasonably necessary to defend such Third Party Claim prior to the time that it receives notice from the Indemnifying Party as contemplated by the preceding sentence. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party (which shall not be unreasonably withheld, conditioned, or delayed), consent to a settlement,

compromise or discharge of, or the entry of any judgment arising from, any Third Party Claim. Without limitation, the Parties stipulate and agree that it would be reasonable for the Indemnified Party to withhold such consent if (i) the Indemnifying Party does not pay or cause to be paid all amounts arising out of such settlement, compromise, or judgment concurrently with its effectiveness, (ii) the settlement, compromise, or discharge judgment involves any finding or admission of any violation of Law or admission of any wrongdoing by the Indemnified Party, encumbers any asset of any Indemnified Party, or requires the Indemnified Party agree to any restriction or condition that would apply to or materially adversely affect any Indemnified Party, or (iii) the settlement, compromise, or judgment does not contain a complete and unconditional release of each Indemnified Party from any and all liability in respect of such Third Party Claim. The Indemnified Party shall not settle, compromise or consent to the entry of any judgment with respect to any claim or demand for which it is seeking indemnification from the Indemnifying Party or admit to any liability with respect to such claim or demand without the prior written consent of the Indemnifying Party.

(c) Notwithstanding anything to the contrary in this Article 6 (*Indemnification*) (including Section 6.2 (*Indemnification by Seller*) and Section 6.3 (*Indemnification by Buyer*)), no Indemnifying Party shall have any liability under this Article 6 (*Indemnification*) for any Losses arising out of or in connection with any Third Party Claim that is settled or compromised by an Indemnified Party without the prior written consent of such Indemnifying Party.

(d) In the event any Indemnifying Party receives notice of a claim for indemnity from an Indemnified Party pursuant to this Section 6.5 (*Notification of Claims; Third Party Claims*) that does not involve a Third Party Claim, the Indemnifying Party shall notify the Indemnified Party within [**] following its receipt of such notice whether the Indemnifying Party disputes its liability to the Indemnified Party under this Article 6 (*Indemnification*). The Indemnified Party shall reasonably cooperate with and assist the Indemnifying Party in determining the validity of any such claim for indemnity by the Indemnified Party.

Section 6.6Exclusive Remedy. Notwithstanding any provision to the contrary in this Agreement, Seller and Buyer hereby agree that following the Closing, subject to Section 8.10 (*Specific Performance*), the sole and exclusive financial remedy of a Party for any breach or inaccuracy of any representation, warranty, covenant, or agreement contained in this Agreement shall be the indemnification rights set forth in this Article 6 (*Indemnification*), regardless of the legal theory under which any liability or obligation may be sought to be imposed, whether sounding in contract or tort, or whether at law or in equity, or otherwise. The Parties hereto agree that the provisions of this Agreement relating to indemnification, and the limits imposed on Buyer's and the Buyer Indemnitees' and Seller's and Seller Indemnities' rights and remedies with respect to this Agreement and the transactions contemplated hereby (including this Article 6 (*Indemnification*)) were specifically bargained for between sophisticated parties and were specifically taken into account in the determination of the amounts to be paid to Seller hereunder. Without limiting the generality of the foregoing, the Parties to this Agreement hereby irrevocably waive any right of rescission they may otherwise have or to which they may become entitled with respect to this Agreement and the transactions contemplated hereby.

ARTICLE 7

DEFINITIONS

Section 7.1Certain Terms. The following terms have the respective meanings given to them below:

"**[**]**" means, [**].

"**[**]**" means, [**].

"**A&R License Agreement**" means that certain Amended and Restated Exclusive License Agreement between [**] and Buyer, dated as of the Closing Date.

"**Acquired Backup Molecule**" means each molecule described on Part C of Exhibit E.

"**Acquired Molecule**" means (a) ADX-097, (b) the Acquired Backup Molecules, or (c) any other molecule that includes, comprises or contains (i) an Antibody that directly binds to C3d, or a fragment or portion thereof and (ii) CFH (ENSG00000000971), or a fragment or portion thereof.

"**Acquired Product**" means, as of the applicable time, any product, in all forms, presentations, formulation, methods of administration and dosage forms, that includes, comprises or contains (a) ADX-097 or (b) any other Acquired Molecule that is owned or controlled by Seller or its Affiliates, in each case (a)-(b), including its peptide and nucleic acid sequences, and any fragments, variants and derivatives of, and modified (including post-translationally modified) forms of, the foregoing (in each case, alone or in combination with other active ingredients).

"**Acquired Program**" means the Seller's and the Selling Affiliates' program of research and development related to Acquired Molecules and Acquired Products.

"**Acquirer**" means, collectively, with respect to the acquisition of a Party by a Third Party, a Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates (determined as of immediately prior to the closing of such Change of Control).

"**[**]**" means [**]

"**ADX-097**" means the molecule described on Part B of Exhibit E.

"**Affiliate**" means, with respect to any Person, any other Person that now or hereinafter controls, is controlled by, or is under common control with, such Person. For purposes of this definition, "control" shall mean direct or indirect ownership of at least fifty percent (50%) of the

shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, status as a general partner in any partnership or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to direct the management and policies of a corporation or other entity. The Parties acknowledge that, in the case of entities organized under the laws of certain countries where the maximum percentage ownership permitted by law for a foreign investor is less than fifty percent (50%), such lower percentage shall be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management and policies of such entity.

"**Agreement**" has the meaning set forth in the Preamble.

"**Ancillary Agreements**" means the (a) Business Transfer Documents, (b) the Assignment and Assumption Agreement, (c) the Bill of Sale, (d) the Patent Assignment, (e) the License Agreement Novation Agreement, and (f) all other agreements, documents and instruments executed and delivered in connection with the transactions contemplated by this Agreement.

"**Annual Net Sales**" means, on a Product-by-Product basis, the total Net Sales of such Product in a given Calendar Year.

"**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 and published interpretations thereunder.

"**Antibody**" means an antibody or immunoglobulin molecule (whether human, murine, humanized, chimeric, monoclonal, polyclonal, full-length, functional fragment, or any other type of antibody or antibody derivative), whether multiple or single chain, recombinant or naturally occurring or a combination of the foregoing, whole or fragment.

"**Assignment and Assumption Agreement**" means that certain assignment and assumption agreement entered into by the Parties substantially in the form as attached as Exhibit A assigning the Assumed Liabilities to the Buyer.

"**Assumed Liabilities**" means the obligations and liabilities set forth or described on Annex 9.1(c).

"**Bill of Sale**" means that certain bill of sale entered into by the Parties substantially in the form as attached as Exhibit B transferring the tangible personal property included in the Transferred Assets to the Buyer.

"**Biosimilar Product**" means, with respect to a Product in a country, biologic product (a) whose licensing, approval, or marketing authorization relies in whole or in part on (i) a prior Regulatory Approval granted for such Product or (ii) any clinical data related to such Product generated for evidence of the safety and efficacy of such product, or (b) is determined by the applicable Regulatory Authority in such a country to be a biosimilar to or have no clinically meaningful differences from a Product, as set forth in 42 U.S.C. § 262(k)(4) in the United States, Section 10 of Directive 2001/83/EC in the European Union, or other applicable Law.

"**Business**" has the meaning set forth in the Recitals.

"**Business Day**" means any day that is not (a) a Saturday, (b) a Sunday or (c) any other day on which commercial banks are authorized or required by law to be closed in New York, New York or Boston, Massachusetts.

"**Business Transfer Documents**" has the meaning set forth in Section 1.1(e) (*Business Transfer Documents*).

"**Buyer**" has the meaning set forth in the Preamble.

"**Buyer Disclosure Letter**" means the letter, dated as of the date hereof, delivered by Buyer to Seller prior to the execution of this Agreement and identified as the Buyer Disclosure Letter.

"**Buyer Indemnitees**" has the meaning set forth in Section 6.2 (*Indemnification by Seller*).

"**Buyer Party**" means Buyer and its Affiliates and any (Sub)licensee.

"**Calendar Quarter**" means each of the three-month periods ending March 31, June 30, September 30 and December 31; provided that the first Calendar Quarter under this Agreement will extend from the Closing Date to the end of the then-current Calendar Quarter.

"**Calendar Year**" means the one (1) year period beginning on January 1 and ending on December 31; provided that the first Calendar Year under this Agreement will extend from the Closing Date to the end of the then-current Calendar Year.

"**Change of Control**" means, with respect to a Party (on a consolidated basis), that: (a) any Third Party acquires directly or indirectly the legal or beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the legal or beneficial owner of voting securities representing more than fifty (50%) of the total voting power of all of the then outstanding voting securities of such Party or its ultimate parent, other than through issuances by Party of securities of such Party in a financing transaction or series of

related financing transactions, (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which results in shareholders or equity holders of such Party (or its ultimate parent) immediately prior to such transaction, no longer owning at least fifty (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction, or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole or substantially all of such Party's business or assets relates, through one or more related transactions.

"**Clinical Trial**" means any clinical investigation conducted on human subjects, as that term is defined in FDA regulations at U.S. 21 C.F.R. § 312.3, or a similar clinical investigation conducted on human subjects, as defined under applicable Law outside the United States, that is designed to generate data in support on an application or submission for a product filed with a Regulatory Authority in a country or group of countries to obtain Regulatory Approval for such product in such country or group of countries.

"**Closing**" has the meaning set forth in Section 1.2 (*Closing*).

"**Closing Date**" has the meaning set forth in Section 1.2 (*Closing*).

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**Commercial Milestone Event**" has the meaning set forth in Section 1.4(b) (*Commercial Milestone Payments*).

"**Commercial Milestone Payment**" has the meaning set forth in Section 1.4(b) (*Commercial Milestone Payments*).

"**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Buyer Party with respect to the development of the Products, that level of efforts and resources commonly applied by biotechnology companies [**]. Seller acknowledges that [**].

"**Confidential Business Information**" has the meaning set forth in Section 4.2(b) (*Confidentiality*).

"**Confidentiality Agreement**" means the Confidential Disclosure Agreement, dated as of February 27, 2025, between Seller and Buyer.

"**Contract Expiration Date**" means, with respect to any Contract, the expiration date of the current term of such Contract, subject to any extensions pursuant to (iii) (*Transferred Assets Subject to Third-Party Consent*).

"**Contracts**" has the meaning set forth in clause (iv) of Annex 9.1(a).

"**Copyrights**" means copyrights and copyrightable works, including all rights of authorship, use, publication, reproduction, distribution, performance, transformation, moral rights and rights of ownership of copyrightable works, and all registrations and rights to register and obtain renewals and extensions of registration, together with all other interests accruing by reason of international copyright.

"**Cover**" or "**Covered by**" means, with respect to a Patent Right and a compound or product in a country, that, in the absence of ownership of or a license under such Patent Right, the manufacture, making, use, sale, offer for sale, or import of such compound or product in such country would infringe one or more Valid Claims of such Patent Right.

"**Data**" means all scientific data of any kind, including clinical and non-clinical data and data relating to chemistry, manufacturing, and controls.

"**Data Room**" means the electronic data room hosted by Progress Share File and entitled "[**]" that was provided by or on behalf of Seller to Buyer, which contains documents and materials relating to the Business, Acquired Molecules, and Acquired Products, as constituted as of 11:00 p.m. (Eastern time) [**] prior to of the Closing Date, the index of which is attached hereto as Exhibit I.

"**Determination Period**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**Development and Regulatory Milestone Event**" has the meaning set forth in Section 1.4(a) (*Development and Regulatory Milestone Payments*).

"**Development and Regulatory Milestone Payment**" has the meaning set forth in Section 1.4(a) (*Development and Regulatory Milestone Payments*).

"**Development Plan**" has the meaning set forth in Section 1.9(a) (*Development Plan*).

"**Diligence Expiration Date**" has the meaning set forth in Section 1.8(a) (*Diligence Obligation*s).

"**Divested Assets**" has the meaning set forth in Section 8.6 (*Divestitures*).

"**Divestiture**" has the meaning set forth in Section 8.6 (*Divestitures*).

"**Eligible Offset Amount**" has the meaning set forth in Section 1.4(e) (*Right to Offset*).

"**Environmental Law**" means any present and future applicable federal, state, and local laws, statutes, ordinances, rules, regulations and the like, as well as common law, (a) relating to

(i) protection of human health (as it relates to Hazardous Substances) or the environment, (ii) Hazardous Substances, or (iii) liability for or costs of actual or threatened danger to the environment, (b) conditioning transfer of property upon a negative declaration or other approval of a Governmental Authority of the environmental condition of any individual property, (c) requiring notification or disclosure of releases of Hazardous Substances or other environmental condition of any individual property to any Governmental Authority or other Person, whether or not in connection with the transfer of title to or interest in such individual property, (d) imposing conditions or requirements in connection with permits or other authorization for lawful activity associated with Hazardous Substances, and (e) related to a nuisance or trespass related to any individual property and associated with Hazardous Substances.

"**EU Approval**" means, with respect to a Product, receipt of Regulatory Approval from the European Commission for such Product in the EU under the centralized EMA filing procedure; provided, however, that if the centralized EMA filing procedure is not used, EU Approval will be achieved upon receipt of Regulatory Approval from the applicable Governmental Authority for such Product in any [**] of the following countries: [**].

"**Excess Indemnifiable Losses**" has the meaning set forth in Section 6.2(a) (*Indemnification by Seller*).

"**Excluded Assets**" means the property of Seller and the Selling Affiliates set forth or described on Annex 9.1(b), which property is not to be transferred to Buyer hereunder.

"**Excluded Contracts**" has the meaning set forth in clause (vi) of Annex 9.1(b).

"**Excluded Liabilities**" means all liabilities and obligations of Seller and the Selling Affiliates set forth or described on Annex 9.1(d), which are not to be assumed by Buyer hereunder.

"**Exclusive Period**" means the period commencing on the Closing Date and ending on the Diligence Expiration Date; provided that, [**].

"**Expert**" has the meaning set forth in Exhibit H.

"**FDA**" means the U.S. Food and Drug Administration or any successor entity thereto.

"**Field**" means the treatment, prevention or diagnosis of any disease or condition in humans.

"**First Commercial Sale**" means, on a country-by-country and Product-by-Product basis, the first sale of such Product by a Buyer Party for end use or consumption in such country following receipt of Regulatory Approval of such Product in such country; provided, however, that none of the following shall constitute a "First Commercial Sale": (a) any sale, transfer, or use

of such Product in clinical trials or non-clinical development activities with respect to such Product; (b) disposal or transfer of such Product for compassionate use or a *bona fide* charitable purpose; or (c) sales of such Product made on a named patient basis, in early access programs, or for similar uses.

"**Fundamental Representations**" has the meaning set forth in Section 6.1 (*Survival*).

"**GAAP**" means generally accepted accounting principles in the United States.

"**Governmental Authority**" means any nation or government, any state or other political subdivision thereof, any entity, authority or body exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, any court, tribunal or arbitrator and any self-regulatory organization.

"**Hazardous Substance**" means any and all material or substance (whether solid, liquid, or gas) defined, listed, regulated or otherwise classified as toxic or hazardous, or as a pollutant or containment, under any applicable Environmental Law.

"**Hourly Rate**" means the rate of $[**] per hour.

"**IND**" means an investigational new drug application, Clinical Trial application, Clinical Trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to initiate human clinical testing of a pharmaceutical product in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312, as well as all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

"**Indemnified Party**" has the meaning set forth in Section 6.5(a) (*Notification of Claims; Third Party Claims*).

"**Indemnifying Party**" has the meaning set forth in Section 6.5(a) (*Notification of Claims; Third Party Claims*).

"**Indemnity Threshold**" has the meaning set forth in Section 6.4(a) (*Limitations on Indemnity*).

"**Indication**" means any distinct disease or condition. For purposes of determining whether a given disease or condition is distinct from another disease or condition so as to constitute a separate Indication and be eligible to trigger a Development and Regulatory Milestone Event based on its being a distinct Indication, the applicable disease or condition must be clearly distinct from any other disease or condition, which means that each applicable disease or condition must bear a distinct reference number under the International Statistical Classification of Diseases and Related

Health Problems codes, such as ICD-11 or any successor thereto, as defined by the World Health Organization, to the left of the decimal point.

"**Initiation**" means, with respect to a Clinical Trial of a Product, the administration of the first dose of such Product to the first patient participating in such Clinical Trial.

"**IP Rights**" means (a) Patent Rights, (b) Trademarks, (c) Copyrights and (d) trade secrets, Know-How and Data and databases.

"**Know-How**" means (a) any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including non-public inventions, discoveries, databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, trade secrets, skill, experience, test data (including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data), analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data, and (b) any biological, chemical, or physical materials. Know-How expressly excludes Patent Rights.

"**Knowledge of Seller**" means the actual knowledge, as of the date hereof, of the Persons specified in Section 7.1(a) of the Seller Disclosure Letter and the knowledge such Persons would be expected to have after reasonably inquiry.

"**Laws**" has the meaning set forth in Section 2.11(a) (*Litigation*).

"**License Agreement Novation Agreement**" means that certain Novation Agreement among the Seller, Buyer, and [**], dated as the date hereof, substantially in the form as attached as Exhibit G.

"**Licensed IP Contracts**" has the meaning set forth in Section 2.9(h) (*Intellectual Property)*.

"**Lien**" means, with respect to any property or asset, any mortgage, lien, pledge, charge, security interest, lease, encumbrance or other adverse claim of any kind in respect of such property or asset.

"**Litigation**" means any action, demand, suit, arbitration proceeding, administrative or regulatory proceeding, citation, summons or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity.

"**Losses**" means any and all damages, judgments, Taxes, awards, liabilities, losses, obligations, claims of any kind or nature, fines and costs and expenses (including reasonable fees and expenses of attorneys, auditors, consultants and other agents).

"**Material Adverse Effect**" means any material adverse change in, or effect on, the Transferred Assets or the financial condition, results of operations, or prospects of the Business, taken as a whole; provided that any such change or effect resulting from any of the following, individually or in the aggregate, shall not be considered when determining whether a Material Adverse Effect has occurred: [**].

"**Material Contract**" has the meaning set forth in Section 2.6(e) (*Material Contracts*).

"**Milestone Dispute Notice**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**Net Sales**" means the [**].

"**Order**" means any order, writ, judgment, injunction, decree, ruling, assessment, stipulation, determination or award entered by or with any court or other Governmental Authority or arbitrator.

"**Organizational Documents**" means the articles of incorporation, constitution, certificate of incorporation, charter, bylaws, articles of formation, certificate of formation, regulations, operating agreement, certificate of limited partnership, partnership agreement and all other similar documents, instruments or certificates executed, adopted or filed in connection with the creation, formation or organization of a Person, including any amendments thereto.

"**[**]**" means [**].

"**Party**" and "**Parties**" has the meaning set forth in the Preamble.

"**Patent Assignment**" means that certain patent assignment between the Parties substantially in the form as attached as Exhibit C.

"**Patent Rights**" means patents (as well as the relevant complementary protection certificates where applicable) and patent applications (including any divisions, continuations, continuations-in-part, provisional applications, reexamined versions or reissues thereof) whether or not patents are issued on any such applications and whether or not any such applications are modified, withdrawn or resubmitted.

"**Permits**" has the meaning set forth in Section 2.11(b) (*Compliance with Laws; Licenses and Permits*).

"**Permitted Liens**" means (a) mechanics', carriers', workers', repairers' and similar statutory liens arising or incurred in the ordinary course of business or in connection with construction contracts for amounts that are not delinquent or are being contested in good faith and

that would not individually or in the aggregate be materially adverse to the Business, and (b) any liens arising or incurred by the terms and conditions of the Transferred Contracts set forth on Annex 9.1(a)(vi).

"**Person**" means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

"**Phase 2 Clinical Trial**" means any Clinical Trial of the effectiveness of a product for a particular indication or indications in patients with the disease or condition under study and to determine the short-term side effects and risks associated with such product and with the purpose to obtain sufficient information about the Product's efficacy to permit the design of Phase 3 Clinical Trials, and which is consistent with 21 C.F.R. § 312.21(b) or a comparable clinical study requested by the relevant Regulatory Authority in a country other than the United States, including a phase 2a Clinical Trial, phase 2b Clinical Trial, the second portion of a phase 1/2 Clinical Trial or the first portion of a phase 2/3 Clinical Trial.

"**Phase 3 Clinical Trial**" means a Clinical Trial of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular Indication in a manner with the aim to obtain Regulatory Approval for such Product in any country, as described in 21 C.F.R. § 312.21(c) or a comparable clinical study requested by the relevant Regulatory Authority in a country other than the United States, including the second portion of a phase 2/3 Clinical Trial.

"**Post-Closing Covenant**" has the meaning set forth in Section 6.1.

"**Post-Closing Tax Period**" means any taxable period beginning after the Closing Date and the portion of a Straddle Period beginning after the Closing Date.

"**Potential Contributor**" has the meaning set forth in Section 6.4(g).

"**Pre-Closing Accounts Payable**" has the meaning set forth in clause (i) of Annex 9.1(d).

"**Pre-Closing Accounts Receivable**" has the meaning set forth in clause (i) of Annex 9.1(b).

"**Pre-Closing Tax Period**" means any Tax period ending on or before the Closing Date and the portion of the Straddle Period ending at the completion of the Closing Date.

"**Product**" means any Acquired Product that incorporates, constitutes or contains an Acquired Molecule that is either (a) ADX-097, including its peptide and nucleic acid sequences, and any fragments, variants and derivatives, and modified (including post-translationally

modified) forms thereof or (b) Covered by [**], in each case ((a) and (b)), in any formulation or dosage strength. For clarity, any [**] is not a Product.

"**Proposal**" has the meaning set forth in Exhibit H.

"**Purchase Price**" means the aggregate of all consideration paid or payable to Seller pursuant to Section 1.3 (*Purchase Price*).

"**Regulatory Approval**" means approval of a Regulatory Approval Application by the applicable Regulatory Authority.

"**Regulatory Approval Application**" means: (a) a New Drug Application (as more fully defined in 21 CFR 314.5, et seq.) filed with the FDA, or any successor application thereto in the U.S. ("**NDA**") or a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act ("**BLA**"); (b) an application for authorization to market or sell a pharmaceutical or biological product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including, with respect to the EU, a marketing authorization application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition procedure, or any national approval procedure ("**MAA**"); or (c) with respect to any product for which a NDA, BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such NDA, BLA or MAA to expand the approved label for such pharmaceutical or biological product to include use of such pharmaceutical or biological product for an additional indication.

"**Regulatory Authority**" means with respect to a country in the Territory, any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in assessing or granting Regulatory Approvals (including pricing approvals) for pharmaceutical products in such country, including the FDA in the United States, the European Commission (and any successor entity thereto) in the European Union, [**] and any corresponding national or regional regulatory authorities in any country that is a counterpart to the foregoing agencies.

"**Royalties**" has the meaning set forth in Section 1.4(c) (*Royalties*).

"**Royalty Report**" has the meaning set forth in Section 1.4(c)(vi) (*Royalty Payments and Reports*).

"**Royalty Term**" has the meaning set forth in Section 1.4(c)(ii) (*Royalty Term*).

"**Scientific Expert**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**Securitization Transaction**" has the meaning set forth in Section 8.5(b) (*Securitization*).

"**Security Interest Release**" means evidence provided by Seller, in a form reasonably acceptable to Buyer, that First-Citizens Bank and Trust Company releases its security interest in all rights, title, and interests in and to the Transferred Assets.

"**Segregate**" means, with respect to any Seller COC Program or Seller Acquisition Program, systems and safeguards to segregate the use of Transferred Know-How or other confidential information of Buyer or the Buyer Parties and the practice, use, or exploitation of any Transferred Assets from the activities conducted under any Seller COC Program or Seller Acquisition Program, including ensuring that: [**]. When used as a noun, "Segregation" means any and all activities involved in Segregating any Seller COC Program or Seller Acquisition Program.

"**Selected Scientific Expert**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**[**]**" means that certain [**], which will be assigned by Buyer to Seller as a Transferred Contract in accordance with this Agreement.

"**Seller**" has the meaning set forth in the Preamble.

"**Seller Acquisition**" has the meaning set forth in Section 4.14(d) (*Competition*).

"**Seller Acquisition Program**" has the meaning set forth in Section 4.14(d) (*Competition*).

"**Seller COC Program**" has the meaning set forth in Section 4.14(b) (*Competition*).

"**Seller Disclosure Letter**" means the letter, dated as of the date hereof, delivered by Seller to Buyer prior to the execution of this Agreement and identified as the Seller Disclosure Letter.

"**Seller Indemnitees**" has the meaning set forth in Section 6.3 (*Indemnification by Buyer*).

"**Selling Affiliates**" means all of the Affiliates of Seller that own any Transferred Assets or have obligations or liabilities in respect of any Assumed Liabilities.

"**Separated Contract**" has the meaning set forth in Section 4.4 (*Shared Contracts*).

"**Shared Academic Contracts**" means the Shared Contracts listed on Section 9.1(b)(vi)(4) of the Seller Disclosure Letter.

"**Shared Academic Contract Know How**" means, with respect to a given Shared Academic Contract, any Know How licensed or otherwise made available to Seller under such Shared Academic Contract.

"**Shared Contract**" means each Contract that relates to both (a) the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any Transferred Assets and (b) one or more other businesses or products of Seller or any Selling Affiliate, including the Contracts listed on Section 9.1(a)(vi) of the Seller Disclosure Letter and clearly labeled as "Shared Contracts".

"**Solvent**" means, with respect to any Person, that:

(a) the fair saleable value (determined on a going-concern basis) of the assets of such Person shall be greater than the total amount of such Person's liabilities (including all liabilities, whether or not reflected in a balance sheet prepared in accordance with GAAP and whether direct or indirect, fixed or contingent, secured or unsecured, disputed or undisputed);

(b) such Person shall be able to pay its debts and obligations in the ordinary course of business as they become due; and

(c) such Person shall have adequate capital to carry on its businesses and all businesses in which it is about to engage.

"**Straddle Period**" means any Tax period that includes, but does not end on, the Closing Date.

"**(Sub)license Income**" means consideration in any form received by Buyer or its Affiliates from or on behalf of any (Sub)licensee that is granted rights [**] in return for the grant of such license or sublicense outside the United States, including (a) upfront payments, regulatory approval milestone payments, commercial sales milestone payments, and royalties or profit share payments, and (b) payments for options for a license or sublicense or for the exercise of such options. (Sub)license Income shall not include [**]. For the avoidance of doubt, (Sub)license Income shall not apply to any sale of all or substantially all of Buyer's assets related to the Business, whether by merger, sale of assets, or otherwise or to a Change of Control of Buyer.

"**(Sub)licensee**" means any Third Party to which Buyer or an Affiliate of Buyer, directly or indirectly, grants a license the right to develop, use, import, promote, offer for sale, sell, have sold, and/or otherwise commercialize any Product. For clarity,

"**(Sub)licensee**" excludes wholesalers, distributors, contract research organizations, contract manufacturing organizations, contract development and manufacturing organizations, and other service providers.

"**Subsidiary**" means, with respect to any Person, any entity of which securities or other ownership interests (a) having voting power to elect a majority of the board of directors or other persons performing similar functions or (b) representing more than fifty percent of such securities or ownership interests are at the time directly or indirectly owned by such Person.

"**Support Memo**" has the meaning set forth in Exhibit H.

"**Tax**" means any federal, state, local or foreign income, alternative, minimum, accumulated earnings, personal holding company, franchise, capital stock, profits, windfall profits, gross receipts, sales, use, goods and services, value added, transfer, registration, stamp, premium, excise, severance, real property, personal property, ad valorem, occupancy, license, occupation, employment, payroll, social security, disability, unemployment, workers' compensation, withholding, estimated or other charge, assessment, or other expense in the nature of or similar to a tax (including all interest and penalties thereon and additions thereto).

"**Tax Proceeding**" means any audit, request for information, investigation, hearing, litigation, legal action, or judicial contest relating to Taxes.

"**Tax Return**" means any federal, state, local or foreign tax return, declaration, statement, report, schedule, form or information return or any amendment to any of the foregoing relating to Taxes.

"**Taxing Authority**" means any Governmental Authority exercising any authority to collect, impose, regulate or administer the imposition of Taxes.

"**Territory**" means anywhere in the world.

"**Third Party**" means, after the Closing, any Person other than Buyer or an Affiliate of Buyer.

"**Third Party Claim**" has the meaning set forth in Section 6.5(b) (*Notification of Claims; Third Party Claims*).

"**Trademarks**" means trademarks, service marks, trade names, trade dress, logos, slogans, and other similar designations of source or origin, together with the goodwill associated with any of the foregoing, and all applications, registrations and renewals therefor.

"**Transfer Approval**" has the meaning set forth in Section 1.1(g)(i) (*Transferred Assets Subject to Third-Party Consent*).

"**Transfer Plan**" has the meaning set forth in Section 4.8 (*Transfer Plan; Transition Assistance*).

"**Transfer Taxes**" mean any federal, state, county, local, foreign and other sales, use, transfer, goods and services, value added, conveyance, documentary transfer, stamp duty, recording or other similar Tax, fee or charge imposed on or in connection with the transactions contemplated by or the instruments executed under or in connection with this Agreement or the recording of any sale, transfer, or assignment of property (or any interest therein) effected pursuant to this Agreement.

"**Transferee**" has the meaning set forth in Section 8.6 (*Divestitures*).

"**Transferred Academic Contracts**" means the Transferred Contracts listed on Section 9.1(a)(vi)(3) of the Seller Disclosure Letter.

"**Transferred Academic Contract Know How**" means, with respect to a given Transferred Academic Contract, any Know How licensed or otherwise made available to Buyer under such Transferred Academic Contract.

"**Transferred Assets**" means the assets and other personal property of Seller and the Selling Affiliates related to the Business set forth or described on Annex 9.1(a).

"**Transferred Contracts**" has the meaning set forth in clause (v) of Annex 9.1(a).

"**Transferred IP**" has the meaning set forth in clause (vii) of Annex 9.1(a).

"**Transferred Know-How**" has the meaning set forth in clause (vii) of Annex 9.1(a).

"**Transferred Materials**" has the meaning set forth in clause (vi) of Annex 9.1(a).

"**Transferred Patent Rights**" has the meaning set forth in clause (vii) of Annex 9.1(a).

"**Transition Assistance**" has the meaning set forth in Section 4.8 (*Transfer Plan; Transition Assistance*).

"**Unassigned Right**" has the meaning set forth in Section 1.1(g)(i) (*Transferred Assets Subject to Third-Party Consent*).

"**Upfront Cap**" has the meaning set forth in Section 6.4(a) (Limitations on Liability).

"**Upfront Closing Consideration**" has the meaning set forth in Section 1.3(a)(i) (*Purchase Price*).

"**Upfront Consideration**" has the meaning set forth in Section 1.3(a)(ii) (*Purchase Price*).

"**Upfront Second Consideration**" has the meaning set forth in Section 1.3(a)(i) (*Purchase Price*).

"**Upstream License Agreement**" means each of the A&R License Agreement or the [**], as applicable.

"**Valid Claim**" means a claim of (a) an issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) any patent application that has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction; provided that a patent application pending for more than [**] from the priority date with respect thereto will not be considered to have any Valid Claim for purposes of this Agreement, unless and until a patent that meets the criteria set forth in clause (a) above issues from such application.

Section 7.2Construction. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles, Sections and Exhibits are to Articles, Section and Exhibits of this Agreement unless otherwise specified. All Exhibits and Disclosure Letters annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized term used in any Exhibit or the Seller's Disclosure Letter but not otherwise defined therein shall have the meaning given to such term in this Agreement. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. "Writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively. Any reference to "days" means calendar days unless Business Days are expressly specified. If any action under this Agreement is required to be done or taken on a day that is not a Business Day, then such action shall be required to be done or taken not on such day but on the first succeeding Business Day thereafter.

ARTICLE 8

MISCELLANEOUS

Section 8.1Notices. All notices, requests and other communications to any Party hereunder shall be in writing and will be (a) delivered by hand or by overnight courier with tracking capabilities, or (b) mailed postage prepaid first class, registered, or certified mail, and, in either case ((a) or (b)), may also be delivered electronically via email, in each case, addressed as set forth below unless changed by written notice so given:

if to Buyer,

Akebia Therapeutics, Inc.
245 First Street, Suite 1400
Cambridge, Massachusetts 02142
Attention: General Counsel
Telephone: 617-871-2098
E-mail: [**]

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600
Attention: David McIntosh
Telephone: [**]
E-mail: [**]

if to Seller,

Q32 Bio Inc.
830 Winter St.
Waltham, MA 02451
Attention:
Telephone:
E-mail:

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP

100 Northern Avenue
Boston, MA 02210
Attention: Jacqueline Mercier and Erini Svokos
Telephone: [**]
E-mail: [**]

or such other address or e-mail address as such Party may hereafter specify for the purpose by notice to the other Parties hereto. All such notices, requests and other communications shall be deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. on a Business Day in the place of receipt. Otherwise, any such notice, request or communication shall be deemed to have been received on the next succeeding Business Day in the place of receipt.

Section 8.2Amendment; Waivers, etc. No amendment, modification or discharge of this Agreement, and no waiver hereunder, shall be valid or binding unless set forth in writing and duly executed by the Party against whom enforcement of the amendment, modification, discharge or waiver is sought. Any such waiver shall constitute a waiver only with respect to the specific matter described in such writing and shall in no way impair the rights of the Party granting such waiver in any other respect or at any other time. Neither the waiver by any of the Parties hereto of a breach of or a default under any of the provisions of this Agreement, nor the failure by any of the Parties, on one or more occasions, to enforce any of the provisions of this Agreement or to exercise any right or privilege hereunder, shall be construed as a waiver of any other breach or default of a similar nature, or as a waiver of any of such provisions, rights or privileges hereunder. The rights and remedies herein provided are cumulative and none is exclusive of any other, or of any rights or remedies that any Party may otherwise have at law or in equity.

Section 8.3Expenses. Except as otherwise provided herein, all costs, fees and expenses incurred in connection with this Agreement, the Ancillary Agreements and the transactions contemplated hereby and thereby, whether or not consummated, shall be paid by the Party incurring such cost or expense.

Section 8.4Governing Law, etc.

(a) Governing Law and Jurisdiction. THIS AGREEMENT SHALL BE GOVERNED IN ALL RESPECTS, INCLUDING AS TO VALIDITY, INTERPRETATION AND EFFECT, BY THE LAWS OF THE STATE OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO ITS PRINCIPLES OR RULES OF CONFLICT OF LAWS, TO THE EXTENT SUCH PRINCIPLES OR RULES ARE NOT MANDATORILY APPLICABLE BY STATUTE AND WOULD PERMIT OR REQUIRE THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION. Buyer and Seller hereby irrevocably submit to the jurisdiction of the courts of the State of New York and the federal courts of the United States of America located in the State of New York solely in respect of the interpretation and enforcement of the provisions of this Agreement and in respect of the transactions contemplated hereby. Each of Buyer and Seller irrevocably agrees that all claims in respect of the interpretation and enforcement of the provisions of this Agreement and in respect of the transactions contemplated hereby, or with respect to any such action or proceeding, shall be heard and determined in such a New York state or federal court,

and that such jurisdiction of such courts with respect thereto shall be exclusive, except solely to the extent that all such courts shall lawfully decline to exercise such jurisdiction. Each of Buyer and Seller hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding for the interpretation or enforcement hereof or in respect of any such transaction, that it is not subject to such jurisdiction. Each of Buyer and Seller hereby waives, and agrees not to assert, to the maximum extent permitted by law, as a defense in any action, suit or proceeding for the interpretation or enforcement hereof or in respect of any such transaction, that such action, suit or proceeding may not be brought or is not maintainable in such courts or that the venue thereof may not be appropriate or that this Agreement may not be enforced in or by such courts. Buyer and Seller hereby consent to and grant any such court jurisdiction over the person of such Parties and over the subject matter of any such dispute and agree that service of process or other papers in connection with any such action or proceeding in the manner provided in Section 8.1 (*Notices*) or in such other manner as may be permitted by law, shall be valid and sufficient service thereof. Notwithstanding anything in this Section 8.4 (*Governing Law, etc.*) to the contrary, each Party to this Agreement may bring an action to seek equitable relief as provided in Section 8.10 (*Specific Performance*) in such jurisdiction as it may deem appropriate to enforce its rights hereunder and each Party hereby consents to each such applicable jurisdiction for purposes of such equitable relief.

(b) Waiver of Jury Trial. EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

(c) Waiver of Certain Damages. IN CONNECTION WITH ANY DISPUTE HEREUNDER, EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT, SPECULATIVE, TREBLE OR PUNITIVE DAMAGES, LOSS OF BUSINESS REPUTATION OR OPPORTUNITY, LOST REVENUE, INCOME OR PROFITS, DIMINUTION IN VALUE OR SIMILAR ITEMS FROM THE OTHER PARTY HERETO (OR ANY AFFILIATE OF SUCH OTHER PARTY HERETO), EXCEPT THAT THE COURT SHALL HAVE THE POWER TO AWARD ANY RELIEF PROVIDED BY GOVERNING STATUTE. NOTWITHSTANDING THE FOREGOING, THIS WAIVER WILL NOT APPLY TO LIMIT ANY CLAIM FOR (A) CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT DAMAGES, LOST PROFITS, DIMINUTION IN VALUE, OR SIMILAR ITEMS PAYABLE TO ANY THIRD PARTY BY AN INDEMNIFIED PARTY PURSUANT TO A THIRD PARTY CLAIM, OR (B) CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES WHICH ARE A REASONABLY FORESEEABLE RESULT OF THE FACTS AND CIRCUMSTANCES GIVING RISE TO THE CLAIM, ARISING FROM (I) EITHER PARTY'S BREACH OF SECTION 4.2 (*CONFIDENTIALITY*), SECTION 4.5 (*FURTHER ASSURANCES*), OR SECTION 4.10 (*[**]*), OR (II) SELLER'S OR ITS AFFILIATES' BREACH OF THE RESTRICTIONS SET FORTH IN SECTION 4.14 (*COMPETITION*) OR ITS OBLIGATIONS SET FORTH IN SECTION 4.8 (*TRANSFER PLAN; TRANSITION ASSISTANCE*) OR (III) ANY INACCURACY OR BREACH OF REPRESENTATION BY SELLER SET FORTH IN THIS AGREEMENT.

(d) Neither this Agreement nor any right or obligation of any of the Parties under this Agreement shall be governed by the U.N. Convention on Contracts for the International Sale of Goods, and the Parties to this Agreement expressly waive or disclaim, as the case may be, any right or obligation they may have under this Agreement pursuant to the U.N. Convention on Contracts for the International Sale of Goods.

Section 8.5Successors and Assigns.

(a) General. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns; provided that neither Party to this Agreement may assign any of its rights or obligations under this Agreement, including by sale of stock, operation of Law in connection with a merger or sale of substantially all the assets, without the prior written consent of the other Party, except that (i) either Party may, without such consent, assign its rights to, or have its obligations discharged by, an Affiliate, and (ii) subject to Section 8.6 (*Divestitures*), Buyer may, without such consent, assign its rights or obligations hereunder, in whole or in part, to a successor of all or substantially all of its business or assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets, or any other transaction. With respect to an assignment to an Affiliate, the assigning Party will remain responsible for the performance by such Affiliate of the rights and obligations hereunder. All validly assigned and delegated rights and obligations of the Parties hereunder will be binding and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Seller or Buyer, as the case may be. The permitted assignee or transferee will assume all obligations of its assignor or transferor under this Agreement. Any attempted assignment or transfer in violation of this Section 8.5(a) (*General*) shall be null and void.

(b) Securitization. Notwithstanding anything to the contrary in Section 8.5(a) (General) or elsewhere in this Agreement, Seller may assign to a Third Party its right to receive the payments owed under Section 1.4 (*Contingent Consideration*) (such assignment, a "**Securitization Transaction**") without the prior written consent of any Buyer Party. Seller shall notify Buyer in writing if it initiates a competitive process to enter into a Securitization Transaction with any Third Party, and Buyer shall be permitted to participate in such process to the extent as any other Third Party. Further, in connection with a contemplated Securitization Transaction, Seller may disclose to such Third Party the Royalty Reports contemplated under Section 1.4(c)(vi) (*Royalty Payments and Reports*) (without the prior written consent of any Buyer Party), to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (provided that such Third Party is under written obligations of confidentiality and non- use with respect to such confidential information that are no less stringent than the terms of the Confidentiality Agreement), and to allow such Third Party to exercise its rights under this Section 8.5(b) (*Securitization*). As part of any consummated Securitization Transaction, Seller may assign, without the prior written consent of any Buyer Party, its right to receive the Royalty Reports under Section 1.4(c)(vi) (*Royalty Payments and Reports*) and to conduct audits under Section 1.7 (*Inspection of Buyer Records*) to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such Section.

Section 8.6Divestitures. If at any time after the Closing until all Development and Regulatory Milestone Payments have been received by Seller, a Buyer Party divests or transfers (by way of merger, consolidation, asset acquisition or sale, exclusive license, exclusive sublicense,

assignment or other similar transfer) (a "**Divestiture**") to a Third Party all of Buyer Parties' right, title and interest in and to all Products and the IP Rights related to the same (collectively, "**Divested Assets**" and the Third Party receiving any Divested Assets, the "**Transferee**"), Buyer will: (i) make provision for the Transferee to assume and succeed to the obligations of Buyer set forth in Section 1.4 (*Contingent Consideration*); and (ii) prior to or simultaneously with the consummation of any such Divestiture, cause such Transferee to provide to the Seller an instrument of assumption of the Transferred Liabilities in a form substantially similar to the form of assignment and assumption agreement as attached as Exhibit A effecting the assumption and succession described in the foregoing clause (i). Buyer will only remain liable to the Seller for the obligations set forth in Section 1.4 (*Contingent Consideration*) following any such Divestiture if, at the time of such Divestiture, such Transferee has a lesser ability than Buyer to satisfy its payment obligations as they become due and payable, as indicated by the balance sheets of such Transferee and Buyer at the time of the Divestiture.

Section 8.7Entire Agreement. This Agreement, the Ancillary Agreements (when executed and delivered) and the Confidentiality Agreement constitute the entire agreement and supersede all prior agreements, understandings and representations, both written and oral, between the Parties with respect to the subject matter hereof.

Section 8.8Severability. If any provision, including any phrase, sentence, clause, section or subsection, of this Agreement is determined by a court of competent jurisdiction to be invalid, inoperative or unenforceable for any reason, such circumstances shall not have the effect of rendering such provision in question invalid, inoperative or unenforceable in any other case or circumstance, or of rendering any other provision herein contained invalid, inoperative or unenforceable to any extent whatsoever. Upon any such determination, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

Section 8.9Counterparts; Effectiveness; Third Party Beneficiaries. This Agreement may be executed in several counterparts, each of which, including those received via facsimile transmission or email (including in PDF format), shall be deemed an original and all of which shall together constitute one and the same instrument. This Agreement shall become effective when each Party shall have received a counterpart hereof signed by all of the other Parties. Until and unless each Party has received a counterpart hereof signed by the other Party, this Agreement shall have no effect and no Party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication). Except as provided under Article 6, no provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any Person other than the Parties and their respective successors and assigns.

Section 8.10Specific Performance. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof in any court specified in Section 8.4 (*Governing Law, etc.*), in addition to any other remedy to which they are entitled at law or in equity. The Parties hereby waive, in any action for specific performance,

the defense of adequacy of a remedy at law and the posting of any bond or other security in connection therewith.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date first above written.

Q32 BIO INC.

By: /s/ Jodie Morrison
Name: Jodie Morrison
Title: Chief Executive Officer

Q32 BIO OPERATIONS INC.

By: /s/ Jodie Morrison
Name: Jodie Morrison
Title: Chief Executive Officer

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler
Name: John P. Butler
Title: President and Chief Executive Officer

Annex 9.1(a)
Transferred Assets

The Transferred Assets consist only of Seller's and the Selling Affiliates' right, title and interest in, to and under the following assets as they exist at the time of the Closing, but in each case specifically excluding any assets described in clauses (i) through (xv) of Annex 9.1(b) (*Excluded Assets*):

(i) Regulatory Approvals. The INDs exclusively related to the sale of the Product in the Territory, including the INDs set forth on Section 9.1(a)(i) of the Seller Disclosure Letter, all pre-clinical data, clinical data and laboratory data relating to the Products and referenced in such INDs.

(ii)Books and Records. All books and records related to the Acquired Program or any Acquired Molecule, or Acquired Product including lab notebooks, invention disclosures, any relevant training materials or product presentations, market research data, market intelligence reports, and Clinical Trial-related assets, including data, databases, clinical study reports (if any) and ongoing patient management, pertaining to Clinical Trials of any Acquired Product, including those that were made available by Seller in the Data Room.

(iii)Regulatory Documentation. All (A) periodic safety reports or benefit risk evaluation reports, (B) correspondence between Seller or any of Seller's Affiliates, on the one hand, and any Governmental Authority, on the other hand, relating to any Acquired Molecule or Acquired Product, including any correspondence related to Clinical Trial design, safety reports or updates, complaint files and product quality reviews, (C) other governmental reports, inspectional notices, Form 483 observations and customs notices, (D) medical inquiries, standard response or non-standard letters or talking points, (E) complaints, investigations and corrective and preventive actions, (F) documents, reports, records, information and materials relating to any post-marketing requirements and post-marketing commitments, (G) Trial Master Files related to any Clinical Trials for any Acquired Product conducted by or on behalf of Seller, and (H) any outstanding or ongoing regulatory item, in each case ((A) through (H)), to the extent owned or controlled by Seller or its Affiliates as of the Closing Date.

(iv)Safety Database. Any safety database maintained by Seller or its Affiliates as of the Closing Date for the Products (or any other Acquired Molecule or Acquired Product).

(v)Goodwill. The goodwill generated by or associated with the Business.

(vi)Transferred Contracts. All leases, licenses, bids, tenders, purchase orders, consulting and other service agreements, supply agreements, distribution contracts, manufacturing contracts, maintenance contracts, agreements, commitments, and other contracts (collectively, "**Contracts**") relating solely to the operation and conduct of the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any of the Transferred Assets as set forth on Section 9.1(a)(vi) of the Seller Disclosure Letter, (collectively, the "**Transferred Contracts**").

(vii)Transferred Materials. (a) All inventory of Acquired Molecules and Acquired Products, (b) all inventory of all raw materials and lab supplies specific to making the Acquired Molecules and Acquired Products, all work-in-progress related thereto, and all clinical samples and packaging materials specifically related to the Acquired Molecules and Acquired Products, (c) the non-clinical samples related to the Acquired Molecules and Acquired Products as agreed to by the Parties in accordance with the Transfer Plan, and (d) [**], in each case ((a) through (d)), in Seller's possession or control (including such items held by contract manufacturers or other contractors), including all materials set forth on Section 9.1(a)(vii) of the Seller Disclosure Letter (the "**Transferred Materials**").

(viii)Intellectual Property. All Know-How (including Data) related to the Acquired Program or any Acquired Molecule or Acquired Product, and all intellectual property rights therein (including trade secret rights) (the "**Transferred Know-How**"), all Copyrights related to the Acquired Program or any Acquired Molecule or Acquired Product (the "**Transferred Copyrights**"), and any Patent Right that claims or discloses any Acquired Molecule or Acquired Product or any method of manufacturing or using any Acquired Molecule or Acquired Product, including the Patent Rights set forth on Section 9.1(a)(viii) of the Seller Disclosure Letter and all Patent Rights that claim priority thereto or share common priority therewith throughout the world (the "**Transferred Patent Rights**" and together with the Transferred Know-How and Transferred Copyrights the "**Transferred IP**"), and all claims and causes of action related thereto, including for past, present, and future infringement or misappropriation. For clarity, Transferred Know-How does not include Know-How (including Data) related to [**].

(ix)Domain Names. The Internet domain names set forth on Section 9.1(a)(ix) of the Seller Disclosure Letter (the "**Transferred Domain Names**").

Annex 9.1(b)
Excluded Assets

The Excluded Assets consist of any assets of Seller or any of the Selling Affiliates that do not constitute Transferred Assets as described on Annex 9.1(a), including without limitation, the following:

(i) Accounts Receivable. All accounts receivable, notes receivable and similar rights to receive payments of Seller or any of the Selling Affiliates existing on the Closing Date and arising out of the operation or conduct of the Business prior to the Closing Date (the "**Pre-Closing Accounts Receivable**").

(ii)Cash and Cash Equivalents. All cash, cash equivalents and deposits (including marketable securities and other investment assets and all monies received in respect of the sale of warranty programs) held by Seller or any of the Selling Affiliates on the Closing Date.

(iii)Hedging or Other Currency Exchange Agreements. All rights to receive payments of Seller or any of the Selling Affiliates pursuant to a hedging or other currency exchange agreement existing on the Closing Date.

(iv)Benefit Plans. All the assets of and all the assets relating to and all rights under any employee compensation, benefit or welfare plan or any related contract between any Person and Seller or any of the Selling Affiliates (including Business employee benefit plans).

(v)Certain Records. Any records and files not related to the Acquired Program or any Acquired Molecule or Acquired Product, including, but not limited to, (A) the personnel records maintained by Seller or any of the Selling Affiliates, (B) Tax Returns (except for Tax Returns relating solely to the Transferred Assets or the Business), (C) records (including accounting records) relating to Taxes paid or payable by Seller or any of the Selling Affiliates and all financial and Tax records relating to the Business that form part of Seller's or any of the Selling Affiliates' general ledger or otherwise constitute accounting records not relating solely to the Transferred Assets or the Business, and (D) records prepared in connection with the transactions contemplated by this Agreement or the Ancillary Agreements, including bids received from other Persons and analyses relating to the Business communications among Seller and its advisors.

(vi)Certain Contracts and Contract Rights. All rights of Seller and the Selling Affiliates under (A) this Agreement and the Ancillary Agreements, (B) any Shared Contract, including the Contracts set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter, (C) any Contracts related to shared services and systems provided by Seller or the Selling Affiliates to the Business, other than Buyer's rights under the Ancillary Agreements, and (D) any contracts between or among Seller and any of the Selling Affiliates or between or among the Selling Affiliates, whether arising before or after the Closing Date (collectively, the "**Excluded Contracts**").

(vii)Insurance. All current and prior insurance policies arranged or maintained by Seller or any of the Selling Affiliates and all rights of any nature with respect thereto, including all rights to insurance recoveries thereunder and to assert claims with respect to any such insurance recoveries, whether arising before or after the Closing Date.

(viii)Corporate Organizational Records. The organizational documents, qualifications to do business as a foreign corporation, arrangements with registered agents relating to foreign qualifications, taxpayer and other identification numbers, seals, minute books, stock transfer books, blank stock certificates and other documents relating to the organization, maintenance and existence of Seller and each of the Selling Affiliates as a corporation or other entity.

(ix)Capital Stock. All shares of capital stock of Seller and the Selling Affiliates.

(x)Tax Claims. (A) Refunds and credits, claims for refunds or credits and rights to receive refunds or credits from any Taxing Authority with respect to Taxes arising out of, relating to or in respect of the Business or the Transferred Assets for any Pre-Closing Tax Period and (B) all VAT credits, refunds, or reclaim rights held by Seller or any of the Selling Affiliates on the Closing Date.

(xi)Real Property. Each of the following: (A) any real property and any buildings, improvements and fixtures thereon; and (B) any leasehold interests, including any prepaid rent, security deposits and options to renew or purchase in connection therewith, of Seller or any of the Selling Affiliates.

(xii)Intellectual Property. Except for Transferred IP, all other IP Rights.

(xiii)Domain Names. All Internet domain names other than the Transferred Domain Names.

(xiv)Excluded IT Systems. All property in the nature of databases, software programs, computer hardware, source code and object code owned or licensed by Seller or any of the Selling Affiliates, in each case that is not otherwise specifically set forth on Section 9.1(a) of the Seller Disclosure Letter.

(xv)Furniture, Equipment, and Supplies. All furniture and office and laboratory equipment and supplies (other than Transferred Materials).

Annex 9.1(b)

Annex 9.1(c)
Assumed Liabilities

The Assumed Liabilities consist of the following liabilities and obligations of Seller or any of the Selling Affiliates, but, in each case, specifically excluding any liabilities described in clause (i) through clause Annex 9.1(d)(ix) of Annex 9.1(d) (*Excluded Liabilities*):

(i) Accounts Payable. All accrued receipts and accounts payable arising out of or relating to the operation or conduct of the Business after the Closing Date.

(ii)Transferred Contract Liabilities. All liabilities and obligations arising out of or relating to the Transferred Contracts arising after the Closing Date or relating to any period after the Closing Date, but excluding those in respect of the Pre-Closing Accounts Payable; provided, however, that the Shared Contracts shall be subject to the provisions of Section 4.4 (*Shared Contracts*). All liabilities arising under the A&R License Agreement will be Assumed Liabilities.

(iii)Taxes and Transfer Taxes. (A) All Taxes directly arising out of the Transferred Assets for all Post-Closing Tax Periods and (B) all Taxes apportioned to the Buyer pursuant to Section 1.13 (*Transfer Taxes and Other Costs*) and Section 5.1 (*Tax Allocation*) of this Agreement.

(iv)Asset Ownership. All liabilities and obligations arising out of or relating to any Transferred Asset or the ownership by Buyer and its Affiliates of any Transferred Asset, in each case, to the extent arising after the Closing Date.

(v)Product Claims. All liabilities and obligations arising after the Closing Date from or relating to lawsuits or other claims, regardless of when commenced or made and irrespective of the legal theory asserted, arising from or relating to the design, manufacture, testing, advertising, marketing, distribution or sale of the Products, including all liabilities and obligations arising from or relating to (A) warranty obligations, (B) infringement, dilution, misappropriation or other violation of IP Rights, (C) alleged or actual hazard or defect, physical injury, death, medical care or medical monitoring or loss or damage to property, arising out of or in connection with the design, manufacture, materials or workmanship, testing, advertising, marketing, distribution, sale or use of the Products in the Territory, including any failure to warn or alleged or actual breach of express or implied warranty or representation; or (D) any recall, withdrawal, retrieval or post-sale warning, in each case ((A) through (D)), with respect to Products (or any other Acquired Molecule or Acquired Product) sold or distributed after the Closing Date by or on behalf of Buyer or its Affiliates.

(vi)Business Claims. Except as otherwise set forth in this Agreement and except for the matters specifically identified as Excluded Liabilities, all obligations and liabilities in respect of any criminal, civil or administrative suit, action or proceeding, pending or threatened, and claims, whether or not presently asserted, arising out of or relating to the operation or conduct of the Business after the Closing Date.

(vii)Clinical Trials. All liabilities and obligations arising from or relating to Clinical Trials for the Products after the Closing Date.

Annex 9.1(c)

Annex 9.1(d)
Excluded Liabilities

The Excluded Liabilities consist of the liabilities and obligations of Seller or any of the Selling Affiliates, other than the Assumed Liabilities described in Annex 9.1(c) (*Assumed Liabilities*), including the following:

(i) Accounts Payable. All accrued receipts and accounts payable arising out of the ordinary course operation or conduct of the Business before the Closing Date (the "**Pre-Closing Accounts Payable**").

(ii)Transferred Contract Liabilities. All liabilities and obligations arising out of or relating to the Transferred Contracts arising prior to the Closing Date or relating to any period prior to the Closing Date, including those in respect of the Pre-Closing Accounts Payable; provided, however, that the Shared Contracts shall be subject to the provisions of Section 4.4. All liabilities arising under the Exclusive License Agreement dated as of [**] between Seller and [**] (as amended prior to the Closing Date) will be Excluded Liabilities, including any amounts due by Seller or its Affiliates to [**].

(iii)Taxes. All Taxes (A) of Seller or the Selling Affiliates relating to the Transferred Assets or the Business for Pre-Closing Tax Periods, and (B) of any other Person (including as a transferee, or successor, or as a result of being a member of an affiliated, consolidated, combined or unitary group), in each case, as a result of a transaction occurring or circumstance existing prior to the Closing, but, excluding any Transfer Taxes that are Assumed Liabilities pursuant to Annex 9.1(c)(iii) (*Taxes and Transfer Taxes*).

(iv)Employment Matters. All employment, labor, compensation, pension, retirement savings plans (including 401-Ks), employee welfare and employee benefits related liabilities, obligations, commitments, claims and losses relating to each employee of Seller and its Affiliates, including all former employees of the Business (or any dependent or beneficiary of any such employee), in each case, that arise out of an event or events that occur at any time prior to, on, or after the Closing Date.

(v)Excluded Asset Liabilities. Each liability, obligation or commitment that relates exclusively to, or that arises exclusively out of, any Excluded Asset, or that arises out of the distribution to, or ownership by, Seller or any of the Selling Affiliates of any Excluded Asset or associated with the realization of the benefits of any Excluded Asset, whether arising before or after the Closing Date.

(vi)Real Estate Liabilities; Environmental Liabilities. All liabilities and obligations in respect of any real property, including, without limitation, those arising under or relating to any Environmental Law or Hazardous Substances, whether arising prior to, on, or after the Closing Date.

(vii)Asset Ownership. All liabilities and obligations arising out of or relating to any Transferred Asset or the ownership by Buyer and its Affiliates of any Transferred Asset to the extent arising, or relating to the period, prior to the Closing Date.

(viii)Product Claims. All liabilities and obligations arising from or relating to lawsuits or other claims, regardless of when commenced or made and irrespective of the legal theory asserted, arising from or relating to the design, manufacture, testing, advertising, marketing, distribution or sale of the Products, including all liabilities and obligations arising from or relating to (A) warranty obligations, (B) infringement, dilution, misappropriation or other violation of IP Rights, (C) alleged or actual hazard or defect, physical injury, death, medical care or medical monitoring or loss or damage to property, arising out of or in connection with the design, manufacture, materials or workmanship, testing, advertising, marketing, distribution, sale or use of the Products in the Territory, including any failure to warn or alleged or actual breach of express or implied warranty or representation; or (D) any recall, withdrawal, retrieval or post-sale warning, in each case ((A) through (D)), with respect to Products (or any other Acquired Molecule or Acquired Product) sold or distributed prior to the Closing Date by or on behalf of Seller or its Affiliates.

(ix)Business Claims. Except as otherwise set forth in this Agreement and except for the matters specifically identified as Assumed Liabilities, all obligations and liabilities in respect of any criminal, civil or administrative suit, action or proceeding, pending or threatened, and claims, whether or not presently asserted, arising out of or related to the operation or conduct of the Business prior to the Closing Date.

(x)Clinical Trials. All liabilities and obligations arising from or relating to the Clinical Trials for a Product conducted by or on behalf of the Seller or its Affiliates prior to the Closing Date.

Annex 9.1(d)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-1 No. 333-278829) of Q32 Bio Inc., as amended by Post-Effective Amendment No. 1 to Form S-1 on Form S-3 Registration Statement (No. 333-278829),

(2) Registration Statement (Form S-3 No. 333-286491) of Q32 Bio Inc.,

(3) Registration Statement (Form S-8 No. 333-285699) pertaining to Q32 Bio Inc. 2024 Stock Option and Incentive Plan and Q32 Bio Inc. 2024 Employee Stock Purchase Plan,

(4) Registration Statement (Form S-8 No. 333-279877) pertaining to Q32 Bio Inc. 2017 Stock Option and Grant Plan, Q32 Bio Inc. 2024 Stock Option and Incentive Plan, Q32 Bio Inc. 2024 Employee Stock Purchase Plan,

(5) Registration Statement (Form S-8 No. 333-270398) pertaining to the Homology Medicines, Inc. 2018 Incentive Award Plan and Homology Medicines, Inc. 2018 Employee Stock Purchase Plan, and

(6) Registration Statement (Form S-8 No. 333-224030) pertaining to the Homology Medicines, Inc. 2015 Stock Incentive Plan, as amended, Homology Medicines, Inc. 2018 Incentive Award Plan and Homology Medicines, Inc. 2018 Employee Stock Purchase Plan;

of our report dated March 10, 2026, with respect to the consolidated financial statements of Q32 Bio Inc. included in this Annual Report (Form 10-K) of Q32 Bio Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2026

Exhibit 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

I, Jodie Morrison, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Q32 Bio 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 10, 2026

By: /s/ Jodie Morrison

Jodie Morrison
Chief Executive Officer and Director
(principal executive officer)

Exhibit 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

I, Lee Kalowski, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Q32 Bio 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 10, 2026

By: /s/ Lee Kalowski

Lee Kalowski
Chief Financial Officer and President
(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, Jodie Morrison, Chief Executive Officer of Q32 Bio 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, 2025 (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 10, 2026

By: /s/ Jodie Morrison
Jodie Morrison
Chief Executive Officer and Director
(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, Lee Kalowski, Chief Financial Officer of Q32 Bio 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, 2025 (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 10, 2026

By: /s/ Lee Kalowski
Lee Kalowski
Chief Financial Officer and President
(principal financial officer)