UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 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

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 1, 2025, the registrant had 12,197,615 shares of common stock, $0.0001 par value per share, outstanding.

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 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.
- Our strategic refocus and the associated workforce reduction announced in February 2025 may not result in anticipated cost savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
- 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 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 Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission (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.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 evaluate and execute on strategic options for our tissue-targeted complement inhibitor platform, inclusive of ADX-097 and early-stage assets;
- our ability to implement and achieve cost savings 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 heightened and fluctuating interest rates and inflation and capital market disruptions, changes in governmental agencies, 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q in the section titled "Risk Factors" and in our periodic filings with 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, and we believe these industry publications and third-party research, surveys and studies are reliable.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 65,483	$ 77,965
Prepaid expenses and other current assets	3,149	3,912
Total current assets	68,632	81,877
Equity investment	2,526	2,600
Property and equipment, net	1,251	1,370
Right-of-use asset, operating leases	5,571	5,722
Restricted cash and restricted cash equivalents	647	647
Other noncurrent assets	444	116
Total assets	$ 79,071	$ 92,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,712	$ 2,989
Accrued expenses and other current liabilities	5,265	7,479
CVR liability	1,940	2,900
Venture debt, current portion	4,662	3,097
Total current liabilities	14,579	16,465
Lease liability, net of current portion	5,467	5,636
Venture debt, net of current portion	8,039	9,556
Other noncurrent liabilities	55,000	55,000
Total liabilities	83,085	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 March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 400,000,000 shares authorized, 12,197,615 shares issued and outstanding at March 31, 2025 and December 31, 2024	2	2
Additional paid-in capital	241,829	240,487
Accumulated other comprehensive loss	—	—
Accumulated deficit	(245,845)	(234,814)
Total stockholders' equity (deficit)	(4,014)	5,675
Total liabilities and stockholders' equity (deficit)	$ 79,071	$ 92,332

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

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development	7,124	9,841
General and administrative	5,104	5,002
Total operating expenses	12,228	14,843
Loss from operations	(12,228)	(14,843)
Change in fair value of convertible notes	—	15,890
Other income (expense), net	1,197	158
Total other income (expense), net	1,197	16,048
Income (loss) before provision for income taxes and loss from equity method investment	(11,031)	1,205
Provision for income taxes	—	—
Loss from equity method investment	—	(176)
Net income (loss)	$ (11,031)	$ 1,029
Net income (loss) per share—basic	$ (0.90)	$ 1.03
Net income (loss) per share—diluted	$ (0.90)	$ (6.33)
Weighted-average common shares—basic	12,197,615	995,280
Weighted-average common shares—diluted	12,197,615	2,334,180

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

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

	Three Months Ended March 31,	
	2025	2024
Net income (loss)	$ (11,031)	$ 1,029
Other comprehensive income (loss):		
Change in unrealized gain (loss) on available for sale securities, net	—	(5)
Total other comprehensive gain (loss)	—	(5)
Comprehensive income (loss)	$ (11,031)	$ 1,024

Q32 BIO INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(amounts in thousands, except share data)
(UNAUDITED)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Gain (Loss)	Deficit	(Deficit)
Balance as of December 31, 2023	2,286,873	$ 47,458	312,094	$ 4,132	2,625,896	$ 55	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)	(55)	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
Reverse recapitalization transaction costs	—	—	—	—	—	—	—	—	(10,013)	—	—	(10,013)
Issuance of CVR at fair value	—	—	—	—	—	—	—	—	(180)	—	—	(180)
Stock-based compensation expense	—	—	—	—	—	—	—	—	417	—	—	417
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(5)	—	(5)
Net income	—	—	—	—	—	—	—	—	—	—	1,029	1,029
Balance as of March 31, 2024	—	$ —	—	$ —	—	$ —	11,929,520	$ 2	$ 234,824	$ (5)	$ (186,052)	$ 48,769

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance as of December 31, 2024	12,197,615	$ 2	$ 240,487	$ —	$ (234,814)	$ 5,675
Stock-based compensation expense	—	—	1,342	—	—	1,342
Net loss	—	—	—	—	(11,031)	(11,031)
Balance as of March 31, 2025	12,197,615	$ 2	$ 241,829	$ —	$ (245,845)	$ (4,014)

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

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

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities:		
Net income (loss)	$ (11,031)	$ 1,029
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and issuance costs	48	29
Depreciation expense	119	123
Stock-based compensation expense	1,342	417
Non-cash lease expense	151	141
Loss from equity method investment	—	176
Loss on impairment of equity investment	74	—
Change in fair value of CVR liability	(960)	—
Change in fair value of convertible notes	—	(15,890)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	763	1,332
Other noncurrent assets	(328)	(600)
Accounts payable	(277)	928
Operating lease liability	(149)	(131)
Accrued expenses and other current liabilities	(2,234)	(2,218)
Other noncurrent liabilities	—	113
Net cash used in operating activities	(12,482)	(14,551)
Cash flows from investing activities:		
Maturities of short-term investments	—	97
Net cash provided by investing activities	—	97
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	—	(2,812)
Net cash provided by financing activities	—	99,346
Net increase (decrease) in cash, cash equivalents, restricted cash and restricted cash equivalents	(12,482)	84,892
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	$ 66,130	$ 116,156
Supplemental disclosure of non-cash operating, investing and financing activities:		
Interest payments on venture debt	$ 247	$ 115
Short-term investments acquired in connection with reverse recapitalization	$ —	$ 19,905
Issuance of CVR at fair value	$ —	$ 180
Transaction costs related to reverse recapitalization included in accounts payable and accrued expenses	$ —	$ 7,201

The accompanying notes are an integral part of these condensed 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.

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 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 they 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 condensed consolidated financial statements are issued.

As of March 31, 2025, the Company had an accumulated deficit of $245.8 million and cash and cash equivalents of $65.5 million. The Company expects that its cash and cash equivalents 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 unaudited condensed consolidated financial statements.

The Company has incurred recurring operating losses since its inception. During the three months ended March 31, 2025, the Company incurred a net loss of $11.0 million. 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 unaudited condensed consolidated financial statements have been prepared by the Company in conformity with GAAP and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2024, included in the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2025.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, including those adjustments that are normal and recurring in nature, which are necessary for a fair statement of the Company's financial position as of March 31, 2025, and consolidated results of operations for the three months ended March 31, 2025 and 2024, and cash flows for the three months ended March 31, 2025 and 2024. The results of operations for the three months ended March 31, 2025 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2025 or for any future period.

Principles of Consolidation

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

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 unaudited condensed 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 unaudited condensed 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.

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.

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. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale investments.

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):

	March 31,	
	2025	2024
Cash and cash equivalents	$ 65,483	$ 115,509
Restricted cash and cash equivalents	647	647
Total cash, cash equivalents, restricted cash and restricted cash equivalents	$ 66,130	$ 116,156

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 condensed 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.

At March 31, 2025, the Company accounted for its investment in Oxford Biomedica (US) LLC ("OXB (US) LLC") using the cost method (see Note 5).

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.

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 condensed consolidated financial statements were issued (see Note 20).

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.

Recently Issued Accounting Standards Not Yet Adopted

On December 14, 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 has determined that the effects of adopting the amendments in ASU 2023-09 will only impact its disclosures and not have a material impact on its consolidated financial position and the results of its operations when such amendment is adopted.

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 unaudited condensed 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:

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 unaudited condensed 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 unaudited condensed consolidated statements of stockholders' equity (deficit) for the three months ended March 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. will have an option to cause the Company to sell and transfer to Oxford Biomedica (US), Inc., and (ii) the Company will have 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 is 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. expect to finalize the transaction and pay the CVR holders by the end of the second quarter of 2025.

4. 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 March 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 March 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 and liabilities measured at fair value on a recurring basis as of March 31, 2025 are summarized as follows (in thousands):

Description	Balance as of March 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	$ 63,913	$ 63,913	$ —	$ —
Total cash equivalents	$ 63,913	$ 63,913	$ —	$ —
Total financial assets	$ 63,913	$ 63,913	$ —	$ —
Liabilities				
CVR liability	$ 1,940	$ —	$ —	$ 1,940
Total financial liabilities	$ 1,940	$ —	$ —	$ 1,940

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 is a derivative liability and is accounted for at fair value. The fair value of the CVR liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. For the portion of the CVR liability that is 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. At March 31, 2025, the Company utilized the purchase price for Homology's equity interest in OXB (US) LLC included in the call option execution notice obtained from Oxford Biomedica (US), Inc., less contractually reimbursable expenses pursuant to the CVR Agreement, to estimate the fair value of the CVR liability. 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, and in the case of one of the draft agreements, to certain milestones.

The CVR liability had an estimated fair value of $1.9 million as of March 31, 2025. The Company recorded in other income (expense), net, $1.0 million for the change in estimated fair value during the three months ended March 31, 2025.

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 Accounting Standards Codification ("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 condensed consolidated statement of operations until settlement. The Convertible Notes liability represents a Level 3 measurement within the fair value hierarchy as it was 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 unaudited condensed consolidated statement of operations for the three months ended March 31, 2024 (see Note 11).

During the three months ended March 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 three months ended March 31, 2025 and 2024.

5. 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 are embedded in the Company's ownership units of OXB (US) LLC because the Options are not legally detachable or separately exercisable. Accordingly, the equity method investment and the Options represent one unit of account and the fair value recorded reflects 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 has 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 qualifies 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 is required to make a qualitative assessment considering impairment indicators to evaluate whether the investment is impaired. If deemed impaired, the Company is 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. As of March 31, 2025, the Company performed an assessment to evaluate whether the investment is impaired and determined that the fair value of its investment in OXB (US) LLC was negatively impacted due to the projected payment to the Company as outlined in the call option exercise notice. The Company determined that the decline in value was deemed to be other than temporary and recorded an impairment charge of approximately $0.1 million to reduce its investment to fair value. The impairment charge is included in other income (expense), net in the Company's consolidated statements of operations. The Company and Oxford Biomedica (US), Inc. expect to finalize the transaction and pay the CVR holders by the end of the second quarter of 2025.

Prior to May 22, 2024, the Company was recording its share of income or losses from OXB (US) LLC on a quarterly basis under the equity method of accounting.

As of March 31, 2025, the carrying value of the equity investment was $2.5 million.

6. Property and Equipment, Net

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

	March 31, 2025	December 31, 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	(1,572)	(1,453)
Property and equipment, net	$ 1,251	$ 1,370

Depreciation expense for the three months ended March 31, 2025 and 2024 was approximately $0.1 million in each period. No impairment losses occurred in the three months ended March 31, 2025 and 2024. The Company had no losses on disposal of fixed assets for the three months ended March 31, 2025 and 2024.

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

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

	March 31, 2025	December 31, 2024
Prepaid external research and development	$ 1,653	$ 2,076
Prepaid expenses	848	885
Payroll tax credit	555	555
Other	93	396
Total prepaid expenses and other current assets	$ 3,149	$ 3,912

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

	March 31, 2025	December 31, 2024
Prepaid external research and development - long term	$ 444	$ 116
Other	—	—
Total other noncurrent assets	$ 444	$ 116

8. Accrued Expenses and Other Current Liabilities

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

	March 31, 2025	December 31, 2024
Accrued external research and development	$ 1,865	$ 2,611
Accrued compensation and related expenses	1,672	2,782
Accrued professional services and other	1,097	1,474
Operating lease liability, current	631	612
Total accrued expenses and other current liabilities	$ 5,265	$ 7,479

9. Restructuring Charges

On February 10, 2025, the Company notified its employees of a strategic restructuring plan adopted by the Company's board of directors to focus its resources on the advancement of bempikibart in patients with AA (the "Restructuring Plan"). In connection with the Restructuring Plan, the Company discontinued its Phase 2 renal basket clinical trial of ADX-097 and is evaluating strategic options for its tissue-targeted complement inhibitor platform, inclusive of ADX-097 and early-stage assets, in combination with other cost-saving measures. The Restructuring Plan included a reduction in force, which the Company expects to substantially complete by the end of the second quarter of 2025. As part of this Restructuring Plan, the Company recorded a restructuring charge for severance and related costs of approximately $0.9 million in the Company's condensed consolidated statements of operations during the three months ended March 31, 2025.

The Company's restructuring liability related to the Restructuring Plan, which is included in accrued compensation and related expenses, consisted of the following (in thousands):

	Employee-Related Costs
Accrued restructuring balance at January 1, 2025	$ —
Expenses incurred	924
Payments	(272)
Accrued restructuring balance at March 31, 2025	$ 652

10. Commitments and Contingencies

As of March 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 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 condensed consolidated balance sheet. As part of the agreement, the Company arranged for a letter of credit for $0.6 million as a security for lease, which is considered restricted cash and included as restricted cash and restricted cash equivalents in the condensed 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 March 31, 2025, the Company's headquarters lease had a weighted-average remaining lease term of 6.75 years and weighted average incremental borrowing rate of 7.5%.

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

	March 31, 2025	December 31, 2024
Assets:		
Operating lease right-of-use assets	$ 5,571	$ 5,722
Total operating lease right-of-use assets	$ 5,571	$ 5,722
Liabilities:		
Current:		
Operating lease liabilities	$ 631	$ 612
Noncurrent:		
Operating lease liabilities, net of current portion	5,467	5,636
Total operating lease liabilities	$ 6,098	$ 6,248

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

	March 31,	
	2025	2024
Fixed lease costs	$ 265	$ 257
Variable lease costs	230	137
Total lease costs	$ 495	$ 394

Variable lease costs were primarily related to operating expenses, taxes and insurances 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 unaudited condensed consolidated statements of operations. Future minimum lease payments under non-cancelable lease agreement as of March 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
2025	$ 795
2026	1,092
2027	1,124
2028	1,158
2029	1,193
Thereafter	2,494
Total minimum lease payments	7,856
Less imputed interest	(1,758)
Total lease liability	$ 6,098
Lease liability, current portion	631
Lease liability, net of current portion	5,467
Total	$ 6,098

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 March 31, 2025, all amounts under the sublease agreement have been paid and there are no accrued expenses or liabilities on the Company's condensed 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").

Unless earlier terminated by either party pursuant to its terms, the Colorado License Agreement will expire upon the expiration of the Royalty Term in all countries. The Company may terminate the Colorado License Agreement for convenience upon providing prior written notice to Colorado. Colorado may terminate the Colorado License Agreement or convert the Company's exclusive license to a non-exclusive license if the Company breaches certain obligations under the Colorado License Agreement and fails to cure such breach. The Colorado License Agreement will terminate automatically upon the Company's dissolution, insolvency, or bankruptcy.

During the three months ended March 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 March 31, 2025 and December 31, 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 March 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, for a total of $12.5 million principal amount outstanding at March 31, 2025. 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 provides 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 March 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 was $0.3 million and $0.1 million for the three months ended March 31, 2025 and 2024, respectively. The effective rate on the Loan Agreement, including the amortization of the debt discount and issuance costs was 9.56% and 10.42%, respectively, at each of March 31, 2025 and December 31, 2024. The components of the long-term debt balance are as follows (in thousands):

	March 31, 2025	December 31, 2024
Principal amount of term loans	$ 12,500	$ 12,500
Unamortized debt discount and issuance costs	201	153
Carrying amount	12,701	12,653
Less current portion	(4,662)	(3,097)
Long-term debt, net	$ 8,039	$ 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. The Convertible Notes become due on demand of the Convertible Noteholders one year from the date of issuance. On April 27, 2023, the Company amended the maturity dates for the Convertible Notes. On May 20, August 5 and December 23, 2022, the Company received $8.3 million, $5.0 million, and $16.7 million, respectively, in exchange for issuance of the Convertible Notes. Interest expense was $0.4 million three months ended March 31, 2024. There was no interest expense recorded for the three months ended March 31, 2025, as 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 condensed 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 three months ended March 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 March 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:

	As of March 31, 2025	As of December 31, 2024
Shares available for future issuance under the 2024 Stock Incentive Plan	1,908,292	1,760,657
Shares available for future issuance under the 2024 Employee Stock Purchase Plan	242,813	120,836
Shares reserved for stock option exercises	1,938,015	1,942,920
Shares reserved for vesting of restricted stock units	467,150	—
Shares reserved for warrants	18,144	18,144
	4,574,414	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 March 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 March 31, 2025, there were 1,908,292 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 March 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 three months ended March 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 three months ended March 31, 2025:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2025	1,942,920	$ 12.93	8.33	$ 12
Granted	60,743	$ 2.54		
Exercised	—	$ —		
Cancelled	(65,648)	$ 14.10		
Outstanding at March 31, 2025	1,938,015	$ 2.54	7.93	$ —
Vested and expected to vest at March 31, 2025	1,938,015	$ 2.54	7.93	$ —
Exercisable at March 31, 2025	942,917	$ 2.54	7.03	$ —

The per share weighted-average grant date fair value of options granted in the three months ended March 31, 2025 was $2.42 prior to the Option Repricing (as defined below) in February 2025 and $1.73 after. The total fair value of options vested during the three months ended March 31, 2025 was $0.9 million. As of March 31, 2025, total unrecognized compensation costs to the unvested stock options were approximately $11.3 million, which is expected to be recognized over a weighted-average period of 2.4 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 three months ended March 31, 2025. An additional $0.2 million will be 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 three months ended March 31, 2025:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2025	—	$ —
Granted	467,150	$ 2.54
Vested	—	$ —
Forfeited	—	$ —
Outstanding at March 31, 2025	467,150	$ 2.54

As of March 31, 2025, total unrecognized compensation costs to the unvested RSUs were approximately $1.1 million, which is expected to be recognized over a weighted-average period of 2.9 years.

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 three months ended March 31, 2025 and 2024 were as follows:

	Three Months Ended March 31,	
	2025	2024
Risk-free interest rate range	4.46%	4.24%
Expected dividend rate	— %	— %
Expected term (years) range	5.23	5.88 – 6.11
Expected stock price volatility range	95.8%	92.0% – 92.2%

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 during the three months ended March 31, 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):

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 265	$ 157
General and administrative	1,077	260
Total stock-based compensation expense	$ 1,342	$ 417

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 or up to $20.1 million in excess of the cash received. 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 Topic 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.

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 three months ended March 31, 2025 and 2024 related to services provided by these investors and board members.

No amounts were due to related parties at March 31, 2025 or December 31, 2024.

17. Income Taxes

The Company did not record a tax provision or benefit for the three months ended March 31, 2025 and 2024.

The Company has evaluated the positive and negative evidence involving its ability to realize its deferred tax assets and has considered its history of cumulative net losses incurred since inception and its lack of any commercially ready products. The Company has concluded that it is more likely than not that it will not realize the benefits of its deferred tax assets. The Company reevaluates the positive and negative evidence at each reporting period.

18. 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.

For the three months ended March 31, 2025, the Company's potentially dilutive securities, which include stock options, RSUs 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.

For the three months ended March 31, 2024, 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 three months ended March 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 the period.

	Three Months Ended March 31,	
(in thousands, except per share amounts)	**2025**	**2024**
Numerator:		
Net income (loss)-basic	$ (11,031)	$ 1,029
Net income (loss)-diluted	$ (11,031)	$ (14,771)
Denominator:		
Weighted-average common shares outstanding-basic	12,197,615	995,280
Dilutive securities	—	1,338,900
Weighted-average common shares outstanding-diluted	12,197,615	2,334,180
Net income (loss) per share-basic	$ (0.90)	$ 1.03
Net income (loss) per share-diluted	$ (0.90)	$ (6.33)

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:

	Three Months Ended March 31,	
	2025	**2024**
Options to purchase common stock	1,938,015	2,028,820
Restricted stock units	467,150	—
Warrants to purchase common stock	18,144	18,144

19. 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 loss, including significant expenses regularly provided to the CODM, attributable to the Company's reportable segment for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,	
	2025	2024
	(in thousands)	
Direct research and development expense by program:		
Bempikibart	$ 2,764	$ 5,261
ADX-097	569	1,084
Discovery and other	43	225
Personnel-related costs (excluding stock-based compensation)	4,549	5,732
Other G&A expenses	2,706	1,849
Interest (income) expense, net	(371)	(180)
Other segment items (1)	771	(15,000)
Total segment net (gain) loss	$ 11,031	$ (1,029)

(1) Other segment items are included in order to reconcile to total segment net (gain) loss. Other segment items include non-cash items such as depreciation and amortization expense and stock-based compensation expense, gains and losses on the change in fair value of convertible notes, change in fair value of contingent value rights and loss from equity method investment.

20. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the date the financial statements are available to be issued for potential recognition or disclosure in the financial statements. The Company has completed an evaluation of all subsequent events after the balance sheet date of March 31, 2025 through the date the financial statements were issued to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of March 31, 2025 and events which occurred subsequently but were not recognized in the financial statements, and there were no material subsequent events requiring disclosure.

Item 2. 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 condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q.

Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Legacy Q32" refers to the business and operations of Q32 Bio Operations (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 autoimmune and inflammatory diseases driven by pathological immune dysfunction.

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 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 alopecia areata ("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. We expect to report topline data from SIGNAL-AA Part B trial in the first half of 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 off-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 130 patients to-date and has demonstrated a favorable safety and tolerability profile, with no Grade 3 or higher related adverse events. We plan to enroll approximately 20 evaluable severe or very severe AA patients through 36 weeks of treatment in a Part B expansion of the SIGNAL-AA Phase 2a clinical trial and report topline data from SIGNAL-AA Part B in the first half of 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, a Phase 2 asset and the lead product candidate from our complement inhibitor platform, is a humanized anti-C3d monoclonal antibody ("mAb") fusion protein. ADX-097 is designed to restore complement regulation – an integral part of the innate immune system – through a tissue targeted mechanism. ADX-097 is designed to inhibit alternative pathway complement activation locally in diseased tissues where complement-mediated pathology is actively manifest. We believe ADX-097 has the potential to drive improved clinical activity and address the limitations of the currently available systemic approaches to complement inhibition, including infection risk and the need for high drug doses and frequent administration, to achieve therapeutic levels of inhibition.

In preclinical studies, ADX-097 distributed to affected tissues/organs and demonstrated durable tissue PK and PD properties. We have completed a Phase 1 clinical trial of ADX-097 in healthy volunteers and observed circulating PK/PD consistent with preclinical studies, which established in vivo integrity of ADX-097. ADX-097 was also shown to be well-tolerated and demonstrated minimal ADAs.

Additional discovery and earlier development efforts from our complement inhibitor platform include ADX-096, a C3d mAb – CR1 fusion protein which demonstrated preclinical data supportive of its use in ophthalmologic indications, as well as other C3d mAb fusions and nanobodies designed for tissue-targeted complement inhibition.

In February 2025, we announced a corporate restructuring to focus on the advancement of bempikibart for the treatment of patients with AA. As part of the restructuring, we discontinued the Phase 2 renal basket clinical trial of ADX-097 and are evaluating strategic options for our tissue-targeted complement inhibitor platform, inclusive of ADX-097 and early-stage assets, to prioritize the clinical development of bempikibart (the "Restructuring Plan"). The Restructuring Plan included a reduction in force, which we expect to substantially complete by the end of the second quarter of 2025. As part of this Restructuring Plan, we incurred severance and severance-related charges of approximately $0.9 million. We may also incur other charges or cash expenditures not currently contemplated or that cannot be currently estimated due to events that may occur as a result of, or be associated with, the Restructuring Plan.

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 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, the Company accounts for consideration payable to Horizon as a reduction of the transaction price under the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). 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, 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. 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.

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 March 31, 2025, we had cash and cash equivalents of $65.5 million. We expect that our cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements to the second half of 2026. 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 Quarterly Report on Form 10-Q.

The expected use of proceeds represents current intentions based upon present plans and business conditions. As of the date of this Quarterly Report on Form 10-Q, 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 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 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, 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 or up to $20.1 million in excess of the cash received. These potential payments to the customer are not in exchange for a distinct good or service; therefore, we are accounting for 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. No amounts have been recognized related to the remaining potential payment to Horizon (up to $20.1 million) as it cannot be deemed probable that the respective milestones will be achieved at this time.

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 condensed 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 unaudited condensed 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 unaudited condensed consolidated statement of operation for the three months ended March 31, 2024.

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.

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 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 three months ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,		
	2025	2024	Change
	(in thousands)		
Operating expenses:			
Research and development	7,124	9,841	(2,717)
General and administrative	5,104	5,002	102
Total operating expenses	12,228	14,843	(2,615)
Loss from operations	(12,228)	(14,843)	2,615
Change in fair value of convertible notes	—	15,890	(15,890)
Other income (expense), net	1,197	158	1,039
Total other income (expense), net	1,197	16,048	(14,851)
Income (loss) before provision for income taxes and loss from equity method investment	(11,031)	1,205	(12,236)
Provision for income taxes	—	—	—
Loss from equity method investment	—	(176)	176
Net income (loss)	$ (11,031)	$ 1,029	$ (12,060)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,		
	2025	2024	Change
	(in thousands)		
Direct research and development expense by program:			
Bempikibart	$ 2,764	$ 5,261	$ (2,497)
ADX-097	569	1,084	(515)
Discovery and other	43	225	(182)
Unallocated expenses:			
Personnel-related and consulting (including stock-based compensation)	2,985	2,682	303
Indirect research and development expense	763	589	174
Total research and development expenses	$ 7,124	$ 9,841	$ (2,717)

Research and development expenses were $7.1 million for the three months ended March 31, 2025, compared to $9.8 million for the three months ended March 31, 2024. The decrease of $2.7 million was primarily due to a decrease of $2.5 million in clinical spend related to our bempikibart program due to higher costs in the prior year as we were advancing clinical trials for AA and AD, a decrease in direct research and development expenses related to ADX-097 of $0.5 million as we discontinued the Phase 2 renal basket clinical trial of ADX-097 in the first quarter of 2025 and a decrease in toxicology costs of $0.2 million as compared to the prior year.

The increase in personnel-related and consultant costs was primarily related to severance expense associated with the restructuring in February 2025. Personnel-related and consultant costs for the three months ended March 31, 2025 and 2024 included stock-based compensation expense of $0.3 million and $0.2 million, respectively.

General and Administrative Expenses

General and administrative expenses were $5.1 million for the three months ended March 31, 2025, consistent with $5.0 million for the three months ended March 31, 2024.

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 convertible notes is reflected in the unaudited condensed consolidated statement of operation for the three months ended March 31, 2024.

Other Income (Expense), Net

Other income (expense), net was $1.2 million for the three months ended March 31, 2025, compared to $0.2 million for the three months ended March 31, 2024. Other income (expense), net for the three months ended March 31, 2025 includes a gain recorded for the change in fair value of the CVR liability of $1.0 million, as well as interest income of $0.7 million. These increases are partially offset by an other-than-temporary impairment charge of approximately $0.1 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 and interest expense of $0.3 million on our venture debt. The increase in other income (expense), net is due to the change in fair value of the CVR liability that was not present in the prior year, as well as a higher average cash balance resulting in higher interest income for the three months ended March 31, 2025.

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 three months ended March 31, 2024, we recorded a loss from equity method investment of $0.2 million, representing our share of OXB (US) LLC's net loss. See Notes 2 and 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q 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 from proceeds from the sales of our convertible preferred stock, convertible notes, venture debt, and proceeds from the Horizon Collaboration Agreement and from the Merger with Homology and accompanying Pre-Closing Financing. From inception through March 31, 2025, we raised $111.4 million in aggregate cash proceeds, net of issuance costs, from the sales of our Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock and received payments of $55.0 million in connection with the Horizon Collaboration Agreement. We also received $30.0 million from the sales of convertible notes, $12.5 million from our venture debt, $61.3 million, net of issuance costs, in connection with the Merger with Homology and $42.0 million pursuant to the Pre-Closing Financing. As of March 31, 2025, we had cash and cash equivalents of $65.5 million.

Going Concern

We have incurred significant operating losses since inception and, as of March 31, 2025, had an accumulated deficit of $245.8 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 March 31, 2025, we had cash and cash equivalents of $65.5 million. We expect that our cash and cash equivalents as of March 31, 2025, will be sufficient to fund our operations to the second half of 2026. 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:

	Three Months Ended March 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (12,482)	$ (14,551)
Net cash provided by investing activities	—	97
Net cash provided by financing activities	—	99,346
Increase/(decrease) in cash, cash equivalents and restricted cash	$ (12,482)	$ 84,892

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 three months ended March 31, 2025, net cash used in operating activities was $12.5 million, which was primarily utilized for the funding of our operating expenses of $12.2 million as we incurred expenses associated with research and development activities including clinical trial activities associated with our bempikibart program. Non-cash expenses include stock-based compensation expense of $1.3 million, non-cash lease expenses of $0.2 million and depreciation expense of $0.1 million, partially offset by a gain of $1.0 million recognized on the change in fair value of the CVR liability. The change in net operating assets and liabilities was primarily attributable to a decrease in accrued expenses and other current liabilities of $2.2 million, an increase in other noncurrent assets of $0.3 million and a decrease in accounts payable of $0.3 million, partially offset by a decrease in prepaid expenses and other current assets of $0.8 million.

For the three months ended March 31, 2024, net cash used in operating activities was $14.6 million, which was primarily utilized for the funding of our operating expenses of $14.8 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 $15.0 million. Non-cash expenses include a gain of $15.9 million recognized on the change in fair value prior to the conversion of convertible notes pursuant to the Merger with Homology on March 25, 2024, stock-based compensation expense of $0.4 million, loss from our equity method investment of $0.2 million, non-cash lease expenses of $0.1 million and depreciation expense of $0.1 million. The change in net operating assets and liabilities was primary attributable to a decrease in accrued expenses and other current liabilities of $2.2 million and an increase in other noncurrent assets of $0.6 million, partially offset by an increase in accounts payable of $0.9 million and a decrease in prepaid expenses and other current assets of $1.3 million.

Investing Activities

For the three months ended March 31, 2024, net cash provided by investing activities consisted of maturities of short-term investments during the period since the Merger. There was no net cash used in or provided by investing activities for the three months ended March 31, 2025.

Financing Activities

For the three months ended March 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 and $7.0 million of proceeds from the borrowings under a new loan and security agreement, slightly offset by payments of $2.8 million of transaction costs related to the Merger. There was no net cash used in or provided by financing activities for the three months ended March 31, 2025.

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 to the second half of 2026. 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. In addition, 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.

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

	Payments Due by Period			
	Total	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligation	$ 7,856	$ 3,011	$ 3,580	$ 1,265

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.

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.

Unless earlier terminated by either party pursuant to its terms, the Colorado License Agreement will expire upon the expiration of the Royalty Term in all countries. We may terminate the Colorado License Agreement for convenience upon providing prior written notice to Colorado. Colorado may terminate the Colorado License Agreement or convert our exclusive license to a non-exclusive license if we breach certain obligations under the Colorado License Agreement and fail to cure such breach. The Colorado License Agreement will terminate automatically upon our dissolution, insolvency, or bankruptcy. 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.

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 condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of our condensed 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 condensed 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 condensed 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.

Our critical accounting policies are described under the heading "*Critical Accounting Policies and Significant Judgments and Estimates*" in our Annual Report on Form 10-K for the year ended December 31, 2024. There were no material changes to our critical accounting policies during the three months ended March 31, 2025 from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2024.

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 unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We have determined that the effects of any such pronouncements will not have a material impact on our condensed consolidated financial position and results of operations.

Item 3. 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 4. 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 March 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 March 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 quarter ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings 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. We are not currently party to any material legal proceedings.

Item 1A. Risk Factors.

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q.

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. Our net loss for the three months ended March 31, 2025 was $11.0 million. On March 25, 2024, Legacy Q32 closed the Merger with Homology and as part of that transaction, recorded a gain of $15.9 million due to the change in fair value prior to the conversion of the Legacy Q32 Convertible Notes which resulted in net income of $1.0 million for the three months ended March 31, 2024. 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 also incur additional 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, cash equivalents and short-term investments should be sufficient to fund our operations to the second half of 2026. 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 and ADX-097 programs) 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 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 February 2025, we announced that we were discontinuing the Phase 2 clinical trial of ADX-097 to focus our resources on the bempikibart clinical development program.

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, or 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. We currently have only data from our Phase 1 clinical trial and our Phase 2 Part A AA and AD clinical trials related to bempikibart, and only data from our Phase 1 clinical trial regarding properties of ADX-097, 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 and ADX-097 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 study. An open-label study is one where both the patient and investigator know whether the patient is receiving the investigational product candidate. Such studies may test only the investigational product candidate and sometimes may do so at different dose levels. Open-label studies are subject to various limitations that may exaggerate any therapeutic effect as patients in such studies are aware when they are receiving treatment. Open-label studies 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 studies may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the studies 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 study 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 study, 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 announced in February 2025 that we were discontinuing our ongoing clinical trial of ADX-097 to focus on the bempikibart clinical development program. 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, study 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 study 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"), and The Regents of the University of Colorado (the "Colorado Agreement"), under which we in-license patent rights and know-how relating to ADX-097. For more information regarding the BMS Agreement and Colorado Agreement, please see the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations– Collaboration and License Agreements*" in this Quarterly Report on Form 10-Q. 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 both the BMS License Agreement and Colorado Agreement, the counterparties may terminate the agreements 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 counterparties may have the right to terminate these agreements. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology 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 their 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.

Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025, and the current U.S. administration is focused on reducing costs of the federal government generally, including significantly reducing the number of government employees. 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 also could result in 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 or at all.

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 is substantial uncertainty as to whether and how the Trump administration will seek 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 new 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.

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.

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, tariffs 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.

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.

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*" in our Annual Report on Form 10-K for the year ended December 31, 2024 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.

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. 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*" in our Annual Report on Form 10-K for the year ended December 31, 2024 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*" in our Annual Report on Form 10-K for the year ended December 31, 2024 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 studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 (the "FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies 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 studies, 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 studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies 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 study 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 studies 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 condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same 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 and ADX-097. 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. If the BIOSECURE Act or similar legislation is passed in the future, it could prohibit the U.S. government from entering contracts or providing grants or loans to procure biotechnology equipment and services provided or produced by so-called "biotechnology companies of concern." It also could prohibit the U.S. government from entering contracts or providing grants or loans to entities who use biotechnology equipment or services provided or produced by "biotechnology companies of concern" in connection with such contracts, grants, or loans. WuXi Biologics, along with several other entities, was identified in the legislation as a "biotechnology company of concern." Even though the final version of the BIOSECURE Act considered by Congress did include 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 WuXi Biologics, and our agreement with them. In addition, foreign CDMOs may be subject to sanctions, 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 strategic refocus and the associated workforce reduction announced in February 2025 may not result in anticipated cost savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In February 2025, we announced a reduction in workforce in connection with the strategic refocus of our business to prioritize and focus on the advancement of bempikibart in patients with alopecia areata. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our results of operation and financial condition would be adversely affected. We expect to incur additional costs as we recognize one-time employee termination-related charges. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our strategic restructuring plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support which may result in unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, and clinical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

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 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. 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, 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*" in our Annual Report on Form 10-K for the year ended December 31, 2024 for a more detailed description of the laws that may affect our ability to operate.

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.

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 March 31, 2025, we had 28 full-time employees, including 4 who hold Ph.D. degrees and 2 who hold M.D. degrees, and one part-time employee; 18 employees are engaged in research and development and 10 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, geopolitical events, such as the conflict between Russia and Ukraine and the conflict in Israel and Gaza, 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 has raised interest rates multiple times in response to concerns about inflation 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, the U.S. has recently 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. On April 9, 2025, the U.S. announced a temporary pause on its tariffs applicable to many countries, while increasing the tariffs applicable to imports from China. The Trump administration has threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Similarly, global geopolitical disruptions, including the military conflict between Russia and Ukraine, the conflict 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, 2024 and December 31, 2023, we had federal and state NOLs of $233.4 million and $119.3 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 2044. As of December 31, 2024, we had federal research and development tax credit carryforwards of $6.2 million that expire at various dates from 2041 through 2044. In addition, as of December 31, 2024, we had state research and development tax credit carryforwards of $2.3 million that expire at various dates from 2038 through 2044.

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. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U.S. policy occurred and 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 March 31, 2025, we had 12,197,615 shares of common stock outstanding. Certain of these shares are subject to lock-up agreements between Homology and Legacy Q32 on the one hand and certain securityholders of Homology and Legacy Q32 on the other hand. Following the expiration of these lock-up agreements, the relevant stockholders will not be restricted from selling shares our common stock held by them, other than by applicable securities laws. Stockholders not subject to these lock-up agreements will not be 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 February 2025 Option Repricing, 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 March 31, 2025, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 57.9% 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 Quarterly 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.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum share price requirement, 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.

Risks Related to Our Operations Following the Merger

If any of the events described in "Risks Related to Our Business" occur, those events could cause potential benefits of the Merger not to be realized. To the extent any of the events in the risks described in that section occurs, the potential benefits of the Merger may not be realized and our results of operations and financial condition could be adversely affected in a material way. This could cause the market price of our common stock to decline.

We may be unable to successfully integrate Homology's and Legacy Q32's businesses and realize the anticipated benefits of the Merger.

The Merger involved the combination of two companies that operated as independent companies. Following the Merger, we are required to devote significant management attention and resources to integrating our business practices and operations. We may fail to realize some or all of the anticipated benefits of the Merger if the integration process takes longer than expected or is more costly than expected. Potential difficulties we may encounter in the integration process include the following:

- the inability to successfully combine our businesses in a manner that permits us to achieve the anticipated benefits from the Merger, which would result in the anticipated benefits of the Merger not being realized partly or wholly in the time frame currently anticipated or at all;
- creation of uniform standards, controls, procedures, policies and information systems; and
- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the Merger.

In addition, prior to the Merger, we operated independently. It is possible that the integration process also could result in the diversion of our management's attention, the disruption or interruption of, or the loss of momentum in our ongoing businesses or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain our business relationships or the ability to achieve the anticipated benefits of the Merger, or could otherwise adversely affect our business and financial results.

Stockholders could file lawsuits relating to the Merger.

Potential plaintiffs may file lawsuits relating to the Merger. The outcome of any future litigation is uncertain. Such litigation, if not resolved, could result in substantial costs to us, including any costs associated with the indemnification of directors and officers.

We will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will continue to incur significant legal, accounting and other expenses as a public company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Legacy Q32 prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of such requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. As an emerging growth company, Homology took advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Homology ceased to qualify as an emerging growth company effective December 31, 2023. We qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, which allows us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Quarterly Report on Form 10-Q and in our other periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we identify, or if our independent auditor

identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. If we are unable to successfully remediate any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our common stock may decline as a result.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

Provided we continue to be listed on the Nasdaq Stock Market LLC, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market LLC. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluations and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, Legacy Q32 was never required to test its internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by the Nasdaq Stock Market LLC, the SEC or other regulatory authorities.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c)

No Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements 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 quarter ended March 31, 2025.

Item 6. 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	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)).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibits 101).

* 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 (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.

+ 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Q32 BIO INC.

Date: May 8, 2025

By: /s/ Jodie Morrison
Jodie Morrison
Chief Executive Officer and Director

Date: May 8, 2025

By: /s/ Lee Kalowski
Lee Kalowski
Chief Financial Officer and President

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 Quarterly Report on Form 10-Q for the quarter ended March 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(s) 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(s) 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: May 8, 2025

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 Quarterly Report on Form 10-Q for the quarter ended March 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(s) 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(s) 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: May 8, 2025

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 Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2025 (the "Report") fully complies with the requirements of Section 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.

May 8, 2025

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 Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2025 (the "Report") fully complies with the requirements of Section 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.

May 8, 2025

By: /s/ Lee Kalowski

Lee Kalowski
Chief Financial Officer and President
(principal financial officer)