UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38433

Q32 Bio Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**47-3468154**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
830 Winter Street Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	QTTB	The Nasdaq Global Market

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market on June 30, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $136.4 million.

The number of shares of Registrant's common stock, par value $0.0001 per share, outstanding as of March 3, 2025 was 12,197,615.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the information required to be furnished pursuant to Part III of this Annual Report on Form 10-K will be set forth in, and incorporated by reference from, the Registrant's definitive proxy statement for the annual meeting of stockholders or an amendment to this Annual Report on Form 10-K which will be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended December 31, 2024.

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

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Annual Report on Form 10-K may include, for example, statements about:

- our ability to achieve and sustain profitability in the future;
- our strategies, prospects, plans, expectations or objectives of management for our future operations;
- estimates of our future expenses, revenues, capital requirements, 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 uncertainties related to economic downturns, public health crises, and other macroeconomic conditions;
- our reliance on third parties in the supply and manufacture of our product candidates;
- the impact of applicable laws and regulations, whether in the U.S. or foreign jurisdictions, and any changes thereto;
- the statements regarding our future economic conditions or performance, statements of belief and any statement of assumptions underlying any of the foregoing; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

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

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

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

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

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

- We have incurred significant 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.

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

PART I

Item 1. Business.

Merger with Homology

On March 25, 2024, Q32 Bio Inc., a Delaware corporation (previously named Homology Medicines, Inc., a Delaware corporation and our predecessor company, or Homology), consummated the previously announced merger pursuant to the terms of the Agreement and Plan of Merger, dated as of November 16, 2023, or the Merger Agreement, by and among Homology, Kenobi Merger Sub, Inc., or Merger Sub, and Q32 Bio Operations Inc. (previously named Q32 Bio Inc.), or Legacy Q32.

Pursuant to the Merger Agreement, on the Closing Date, (i) Homology effected a reverse stock split of Homology's issued common stock at a ratio of 1:18, or the Reverse Stock Split, (ii) Homology changed its name to "Q32 Bio Inc.," and (iii) Merger Sub merged with and into Legacy Q32, or the Merger, with Legacy Q32 as the surviving company in the Merger and, after giving effect to such Merger, Legacy Q32 becoming a wholly-owned subsidiary of Q32 Bio Inc., or together with its consolidated subsidiaries, Q32, the Company, we or us. As of the open of trading on March 26, 2024, our common stock began trading on the Nasdaq Global Market, or Nasdaq, under the symbol "QTTB."

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. To achieve this goal of restoring homeostasis to a dysregulated immune system, we are advancing antibody-based therapeutic candidates designed to target two central pathways of adaptive and innate immunity. The adaptive immune system is largely composed of T- and B-cell mediated cellular and antibody responses; while the innate immune system is a first line of defense employing leukocytes such as monocytes, macrophages, neutrophils, dendritic cells and natural killer cells that are responsible for clearing pathogens and cellular debris, and modulating T- and B-cell function. We believe that targeting these key pathways of immune dysregulation in autoimmune and inflammatory diseases will deliver therapeutics for indications with clear unmet medical need in the near term, while enabling us to build a broad and diverse pipeline in the long term. We have multiple product candidates across a variety of autoimmune and inflammatory diseases.

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

On December 10, 2024, we announced topline results from both of these trials, as well as our intention to advance bempikibart for the treatment of AA and enroll patients into Part B of the SIGNAL-AA trial in the first half of 2025. Patients in the SIGNAL Phase 2a clinical trials were dosed with 200mg subcutaneous, or SC, bempikibart every two weeks. In the SIGNAL-AA trial, 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, or RO, and observed favorable pharmacokinetics, or PK, / pharmacodynamic, or PD, properties, consistent with those from the Phase 1 clinical trial. Minimal anti-drug antibodies, or 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 additional AA patients through 36 weeks of treatment in a Part B expansion of the SIGNAL-AA Phase 2a clinical trial and report initial data from SIGNAL-AA Part B in the first half of 2026.

In February 2025, we announced a corporate restructuring to focus on the advancement of bempikibart for the treatment of patients with AA.

ADX-097, a Phase 2 asset and the lead product candidate from our complement inhibitor platform, is a humanized anti-C3d monoclonal antibody, or 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.

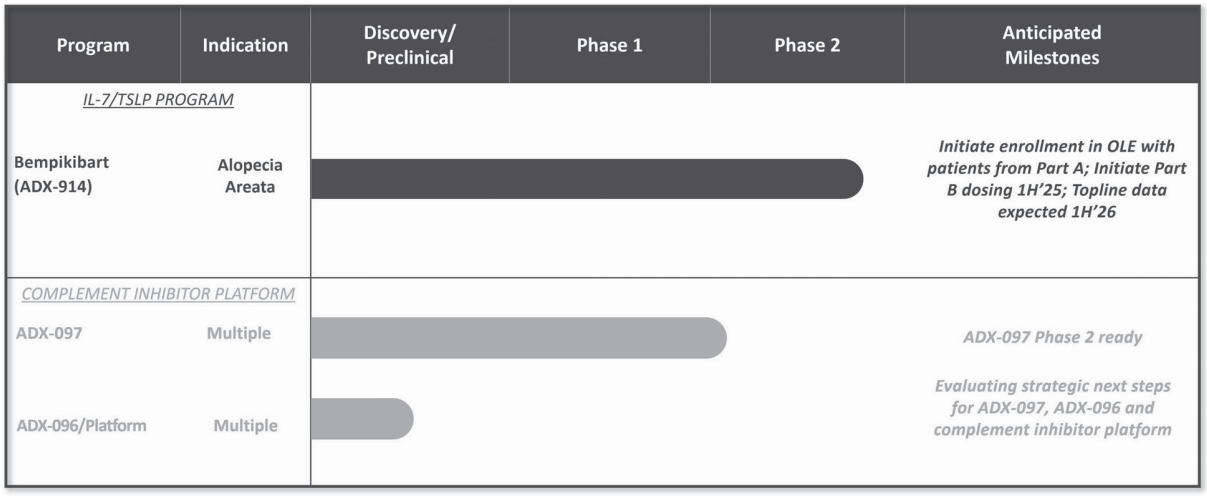
In preclinical studies, ADX-097 distributed to affected tissues/organs and demonstrated durable tissue PK and PD properties. We have completed a Phase 1 clinical trial of ADX-097 in healthy volunteers and observed circulating PK/PD consistent with preclinical studies, which established *in vivo* integrity 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 that we are discontinuing 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.

Our development pipeline is shown in the figure below.

Figure 1: Our Development Pipeline.



Bempikibart (ADX-914)

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

In October 2023, Amgen Inc., or Amgen, completed the acquisition of Horizon Therapeutics public limited company, or Horizon plc. Following the acquisition, Legacy Q32 agreed with Amgen to mutually terminate the Collaboration and Option

Agreement, or the Horizon Collaboration Agreement, and the Asset Purchase Agreement, or the Purchase Agreement, and together with the Horizon Collaboration Agreement, the Horizon Agreements, each between Legacy Q32 and Horizon Therapeutics Ireland DAC, or Horizon. In November 2023, Legacy Q32 entered into a termination agreement with Horizon, or 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. For more information see the section titled "*Business—Collaboration and License Agreements.*"

T cell pathology has been strongly implicated in AD and AA. Accumulating evidence suggests that multiple pathways are important in the pathogenesis of AD. This emerging view supports the belief that novel therapeutics, such as bempikibart, that more specifically address the underlying immune-phenotypic progression of the disease are needed. TH1 has long been implicated in the pathogenesis of AA supporting the potential for bempikibart to directly address the underlying driver of follicle damage and hair loss. In addition, given that AA is a disease often diagnosed in young adults, there is a critical need for effective novel treatments with a safety profile suitable for long-term, chronic treatment.

We own and have in-licensed various patents, patent applications, know-how and trade secrets relating to the development and commercialization of our IL-7Rα -targeted antagonistic antibody therapy candidates and platform technologies. Patents that have issued or may issue in the future protect composition of the bempikibart product candidate to the beginning of 2040, and protect methods of use to 2044, excluding any patent term adjustments and/or any patent term extensions.

We have completed two Phase 2a clinical trials and intend to advance bempikibart for the treatment of AA in the Phase 2a Part B clinical trial.

ADX-097

ADX-097 is an anti-C3d antibody linked to two moieties of a fragment of human factor H, or fH. C3d is a ubiquitous marker of complement activation, located adjacent to C3 convertase complexes. Factor H is an important negative regulator of the complement alternative pathway, or AP. While complement can be activated through three pathways, the AP is central to all because it amplifies signaling. This aspect of AP activation is commonly known as the "amplification loop" and is responsible for much of the damage observed in complement-mediated diseases.

We have evaluated ADX-097 in a Phase 1 clinical trial in healthy volunteers where we observed circulating PK/PD consistent with preclinical studies, which established *in vivo* ADX-097 integrity and informed our dosing strategy for next stage clinical testing. In addition, no severe or serious AEs were reported and minimal ADAs were observed in this Phase 1 clinical trial.

These Phase 1 data and our preclinical studies have enabled targeted indication selection for our Phase 2 program as well as informed our key Phase 2 dose.

In February 2025, we announced that we are discontinuing 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.

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

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

- **limited activity** due to reliance on systemic blockade for control of complement dysregulation at the tissue level;

- **high treatment burden**, including high doses and/or frequent administration due to high abundance and rapid turnover of most target complement proteins; and
- **infection risk** due to systemic blockade.

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

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

We own various patents, patent applications, know-how and trade secrets relating to the development and commercialization of our targeted complement inhibitor candidates and platform technologies. Patents that have issued or may issue in the future protect composition of the ADX-097 complement product candidate to the end of 2039, and protect methods of use to the end of 2044, excluding any patent term adjustments and/or any patent term extensions.

Our Team

We have assembled a team of industry-leading research, drug development, and operational experts, who have deep experience in advancing drug candidates in autoimmune and inflammatory diseases. The team is led by Jodie Morrison, our Chief Executive Officer, who brings extensive biopharma leadership experience from early stage through mid-size public biotech and pharmaceutical companies; Shelia Violette, Ph.D., Founder and Chief Scientific Officer, has more than 30 years of biotech experience in inflammatory and autoimmune diseases and served as an Entrepreneur in Residence at Atlas Venture; Jason Campagna, M.D., Ph.D., Chief Medical Officer, has more than 15 years of experience advancing all stages of clinical development pipelines; Lee Kalowski, President and Chief Financial Officer, has 20 years of life science industry experience and has previously served as CFO at multiple biotech companies and in equity research; and Saul Fink, Ph.D., Chief Technical Officer, has more than 25 years of experience leading manufacturing and nonclinical development of small molecules and biologics.

Our company was built upon the discoveries and findings from renowned researchers in immunology: Michael Holers, M.D. and Joshua Thurman, M.D., from the University of Colorado and Stephen Tomlinson, Ph.D. from the Medical University of South Carolina. They are pioneers in the field of tissue targeted regulation of complement system.

We are supported by leading biotechnology investors and pharmaceutical companies including OrbiMed, Atlas Venture, Abingworth, BMS, Acorn Bioventures, Osage University Partners, CU Healthcare Innovation Fund and Sanofi Ventures.

Our Strategy

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

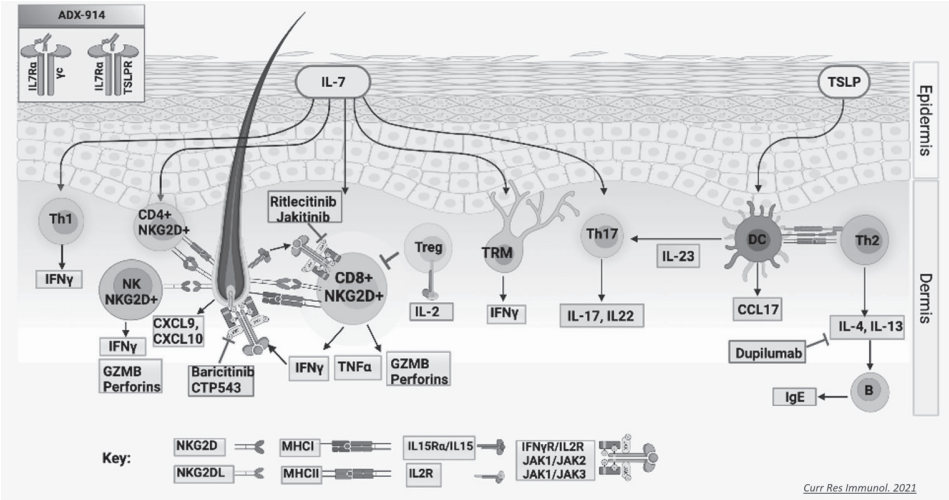
- ***Advance bempikibart for the treatment of AA in the SIGNAL-AA Phase 2a Part A open-label extension (OLE)***. We plan to initiate an open-label extension (OLE) following the same bempikibart dosing regimen leveraged in Part A to enable longer-term follow-up of patients and to further elucidate the durability of response and potential remittive effect. We plan to initiate the OLE in the first half of 2025;
- ***Advance bempikibart for the treatment of AA in the SIGNAL-AA Phase 2a Part B clinical trial.*** We plan to enroll approximately 20 additional patients in a Part B expansion of the SIGNAL-AA Phase 2a clinical trial to further evaluate bempikibart in AA, with data expected in the first half of 2026;
- ***Maximize value of ADX-097 and our tissue-targeted complement inhibitor platform.*** We believe that the tissue-directed approach to addressing complement dysregulation has the potential to drive improved efficacy and better safety across indications and we intend to maximize the value of ADX-097 and our tissue-targeted complement inhibitor platform as we evaluate our strategic options.

Our Programs

Bempikibart in AA and AD

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

Figure 2: Bempikibart Has the Potential to Block TH1-and TH2-Driven Disease Pathology in AA



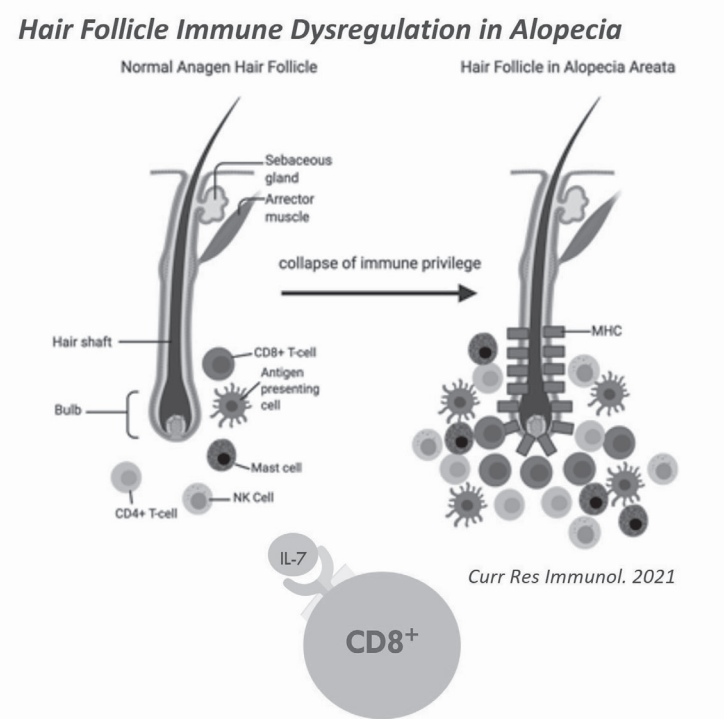
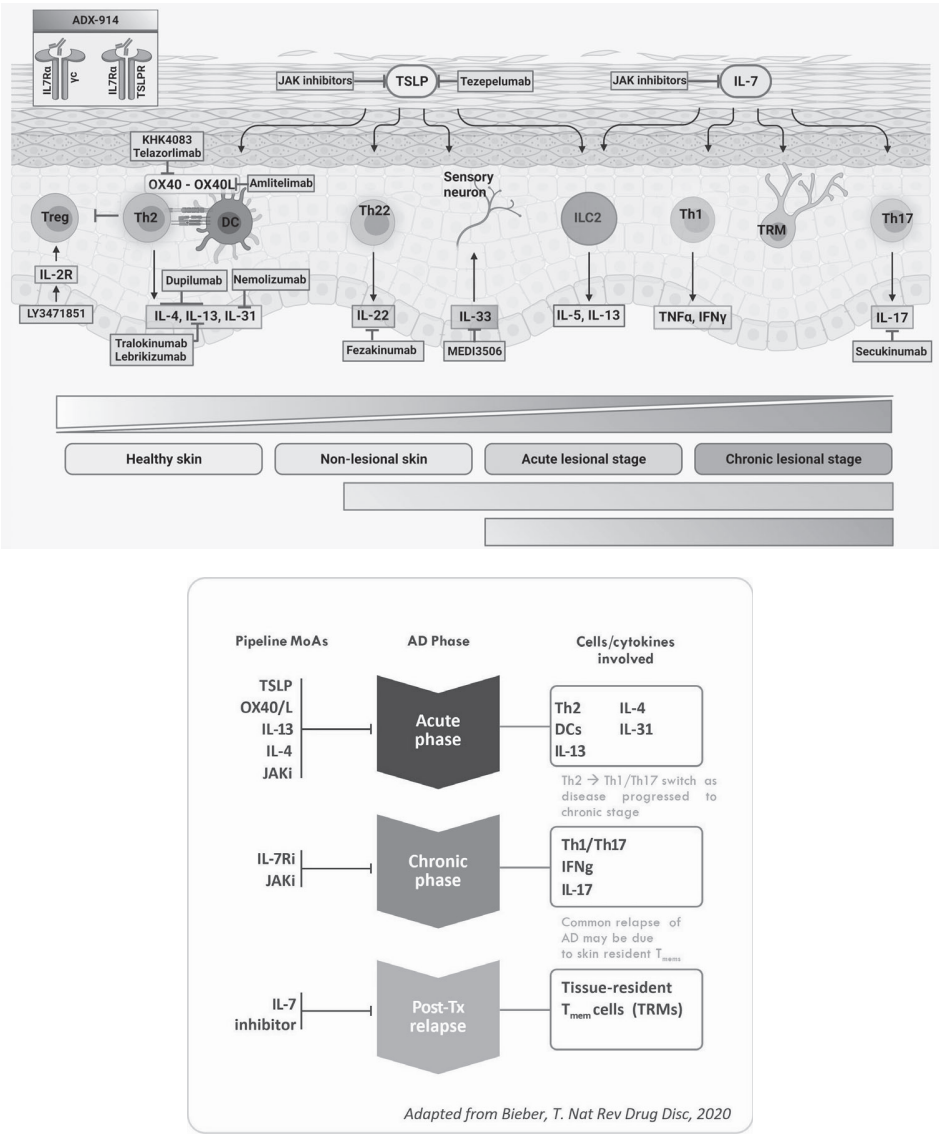


Figure 3: Bempikibart Has the Potential to Modulate Immune Cells Important in Both Acute and Chronic AD Pathogenesis.



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

Bempikibart Preclinical and Clinical Data

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

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

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

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

Phase 1 Clinical Trial Results

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

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

The Role of IL-7 and TSLP in AA

AA

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

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

Current Treatment Landscape and Unmet Need in AA

AA is an autoimmune condition that affects hair follicles and leads to hair loss. This condition may develop at any age and in both sexes, and the incidence of this disease has been estimated to be 2% of the population worldwide. The disease most commonly affects scalp and facial hair and although some patients recover spontaneously, many patients progress to alopecia totalis (total scalp hair loss) or alopecia universalis (total body hair loss). The disease is associated with significant quality of life impairment and is associated with a high burden of psychosocial comorbidities, such as depression. Although pathophysiology has not been fully delineated, development of the condition is mediated by inflammatory mechanisms, and it is thought to have genetic and environmental components. IL-7 upregulation has been shown to be involved in the pathogenesis of AA, and evidence suggests that inhibition of IL-7Rα may be an effective modulator of the T-cell response driving injury in the disease.

Baricitinib and ritlecitinib, both JAK inhibitors, are the only current FDA-approved treatments for AA. Although JAK inhibitors have demonstrated hair regrowth in patients with severe disease (≥50% hair loss), increased risk of serious side effects may preclude this option for some patient populations. Other standard-of-care approaches for alopecia include topical corticosteroids, immunotherapy, and light therapy. Because hair loss can affect such disparate body locations, these treatments often have limited usefulness across the patient population.

Further Clinical Development of Bempikibart: Clinical Trial Plan

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

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

SIGNAL-AA Phase 2a Clinical Trial

SIGNAL-AA is a Phase 2a, randomized, double-blind, placebo-controlled, proof-of-concept clinical trial evaluating the efficacy, safety and tolerability of bempikibart in participants with severe and very severe AA, as defined by a baseline Severity of Alopecia Tool, or SALT, score of 50-100. In Part A of the trial, bempikibart or placebo was dosed SC for 24 weeks, with a follow-up period of 12 weeks.

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

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

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

We plan to enroll approximately 20 additional patients through 36 weeks of treatment in a Part B expansion of the SIGNAL-AA Phase 2a clinical trial to further evaluate bempikibart in AA. SIGNAL-AA Part B is an open-label clinical trial, dosing patients with bempikibart for 36 weeks, with follow-up out to 52 weeks, in approximately 20 evaluable patients with severe or very severe AA. Dosing will include an initial loading regimen of 200mg of bempikibart dosed weekly over four weeks, followed by a maintenance dose of 200mg every-other-week over a 32-week period for a total of 36 weeks. The primary efficacy endpoints include the proportion of patients achieving a 30% or greater reduction in SALT score and proportion of patients achieving a SALT-20 at week 36, with follow-up through week 52. The trial is intended to enable advancement into pivotal trials upon completion, pending review of the results. We expect to report initial data from SIGNAL-AA Part B in the first half of 2026.

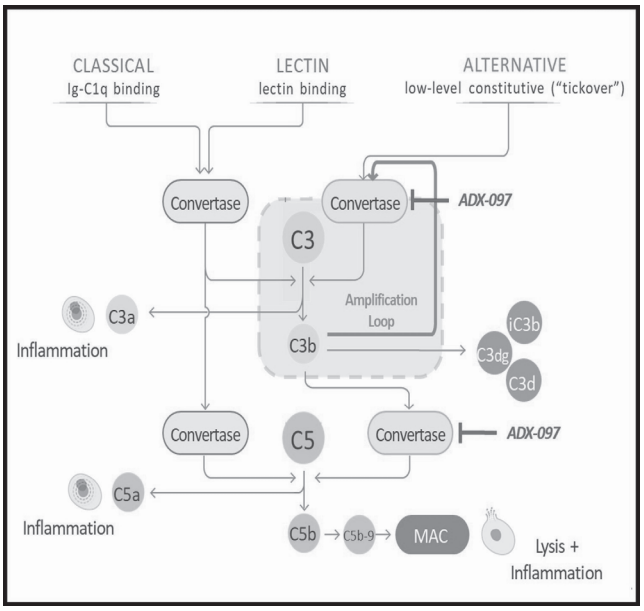
ADX-097 in LN, IgAN, C3G and AAV

Complement is an integral part of the innate immune system used as a first line of defense for removing bacteria and other pathogens, as well as damaged cells, and for modulating an adaptive immune response. In spite of these beneficial functions, when the complement system becomes dysregulated it can be a critical driver of chronic inflammatory and autoimmune diseases.

There are three main branches of the complement system: the classical, or CP, the lectin, or LP, and the AP. These pathways can lead to the generation of cellular/tissue bound protein complexes, called convertases, the gatekeepers that catalyze the cleavage of the complement component 3 and 5 proteins, or C3 and C5, respectively. This cleavage, predominantly happening on the cellular/tissue surface, ultimately leads to the formation of C3a and C5a, chemotactic factors that recruit inflammatory immune cells, and the assembly of C5b-9 forming the membrane attack complex, or MAC, on cell membranes. Uncontrolled and persistent production of these complement activation products ultimately leads to pathological tissue inflammation and cellular damage.

The AP is central to the complement system. It provides for amplification of complement signaling downstream of all 3 complement pathways, commonly referred to as the "amplification loop" (see figure below). Consequently, sustained overactivation of the complement system in many diseases is driven by AP activation.

Figure 4: Schematic of the Complement System Showing Critical Elements of the Three Pathways.



MAC: Membrane attack complex.

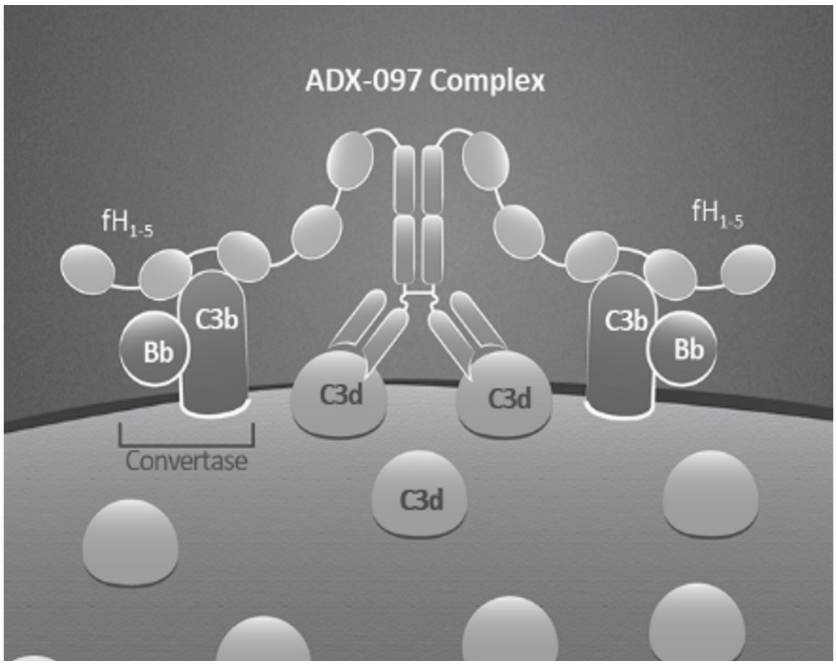
Under normal conditions, inactivation of convertases, to maintain proper balance of the complement system, is endogenously controlled by several complement negative regulatory proteins. Among these is fH, a protein that binds and inactivates AP convertases. Factor H both catalyzes dissociation of AP C3 and C5 convertases and, in combination with Factor I, leads to irreversible catalytic degradation.

Given the central role of the AP in driving complement activity, gaining control of this pathway provides a mechanism to restore proper regulation of the complement system when it becomes dysregulated in disease.

ADX-097

ADX-097 is a C3d mAb recombinantly linked to 2 moieties of human fH1-5. ADX-097 was designed to provide a unique tissue targeted therapeutic approach to restore proper complement regulation on the surfaces of cells in diseased tissue where AP convertase assembly occurs and the amplification loop magnifies complement activation. The fH1-5 component of ADX-097 consists of the first five N-terminal domains of fH, which catalyzes the dissociation and irreversible proteolytic degradation of the AP C3/C5 convertases. When C3 is cleaved as a consequence of complement activation it leads to the generation of high-density surface bound C3d deposits positioned adjacent to the AP C3/C5 convertases. Our preclinical studies demonstrate that the binding of the antibody portion of ADX-097 to C3d brings the human fH1-5 protein into proximity with surface-bound C3/C5 AP convertases, allowing fH1-5 to interrupt complement activation. Thus, we believe, based on preclinical studies, that ADX-097 has the potential to durably restore control of the complement system at specific sites of ongoing injury and at doses where complement surveillance is maintained in circulation. See Figure 5 for a depiction of ADX-097's targeted mechanism of action.

Figure 5: Schematic of ADX-097 Targeted Mechanism of Action



fH1-5: first 5 N-terminal short consensus repeats of human factor H; mAb: monoclonal antibody

Given the ubiquitous nature of C3d deposition in tissue where complement is activated, and the importance of the AP in maintaining complement activation, we believe ADX-097 has therapeutic potential for multiple diseases. We also believe that by inhibiting complement in a tissue-directed manner, a greater potential for clinical activity is possible.

We have completed a robust preclinical and translational package and have also completed a Phase 1 clinical trial in healthy volunteers.

In February 2025, we announced that we are discontinuing 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.

ADX-097 Preclinical and Clinical Data

Preclinical pharmacology, PD, PK, and toxicology of ADX-097 were assessed in a wide range of in vitro experiments and in vivo nonclinical studies in mice, rats and NHPs. Three non-GLP and two GLP PK, PD and toxicology studies were completed to support clinical development of ADX-097.

These studies have provided compelling evidence for the therapeutic potential of ADX-097. These studies have demonstrated that ADX-097 or a pharmacologically equivalent mouse homolog, ADX-118, which contains the parent mouse anti-C3d antibody used in ADX-097 recombinantly linked to mouse fH1-5, were able to:

- Bind C3d and inhibit complement in *in vitro* assays;
- Distribute and bind C3d present in rodent kidney, liver, and skin and to NHP skin;
- Provide durable anti-complement activity in rodent and NHP tissue, with limited and transient systemic inhibition: durable (>7 days) tissue PD after 1-3 mg/kg SC dosing;
- Reduce glomerular C3 fragment deposition, proteinuria/albuminuria, and additional biomarkers of renal injury in rodent models of kidney disease; and
- Demonstrate increased functional potency compared to similar non-targeted fH1-5 in a passive Heymann nephritis, or PHN, model of kidney disease.

The ADX-097 preclinical toxicology studies were conducted in pharmacologically relevant species, mice and cynomolgus monkeys. It included a cross-reactivity study using human tissues to identify any potential off-target tissue binding, repeat-dose non-GLP studies of 28-day duration in mice and cynomolgus monkeys by SC or intravenous, or IV, administration, and a 29-day GLP repeat-dose toxicology study in cynomolgus monkeys by SC or IV administration. It also included a non-GLP 28-day study and a GLP 3-month study with ADX-118, a mouse homolog protein of ADX-097 with equivalent pharmacological activity, to minimize immunogenicity with long-term dosing. No ADX-097-mediated pharmacological adverse effects were observed in up to 29-day repeat-dose studies in either mice or monkeys. All adverse effects were attributable to an immune-mediated response to a humanized/human fusion protein in NHPs and mice. Consistent with all ADX-097 adverse events being mediated by an immune response to the humanize/human protein, no ADX-118-mediated adverse effects were observed in the 3-month repeat dose studies in mice. The NOAEL was determined at 250 mg/kg by IV weekly dosing (QW), the highest dose tested in the 3-month mouse study, providing support for chronic administration of ADX-097. Overall, the ADX-097 preclinical toxicology analysis provided a > 40x safety margin.

Phase 1 Clinical Trial Data

ADX-097 has been evaluated in a completed Phase 1 study conducted in healthy volunteers, study ADX-097-101.

This was a randomized, double-blind, placebo-controlled, single ascending dose, or SAD, and multiple dose study to assess the safety, tolerability, PK, and PD of ADX-097. Data from this study provided initial characterization of the safety, PK, PD, and immunogenicity profile of ADX-097 across a wide range of dose levels, using both IV and SC routes of administration.

In total, 56 healthy volunteers were dosed (randomized 2:1; n=4 ADX-097 and n=2 placebo per cohort): 49 volunteers in the SAD portion of the study and 7 participants in the multiple dose portion. The SAD portion of the study included Cohort 1 (0.1 mg/kg IV), Cohort 2 (0.3 mg/kg IV), Cohort 3 (1 mg/kg IV), Cohort 4a (3 mg/kg IV), Cohort 4b (3 m/kg [actual: 3.75 mg/kg] SC), Cohort 6a (10 mg/kg IV), Cohort 6b (10 mg/kg SC), and Cohort 8 (30 mg/kg IV). The multiple dose portion of the study included multiple ascending dose, or MAD, Cohort 1 (450 mg SC fixed weekly dose).

Blinded safety data indicated that ADX-097 was generally well tolerated across all dose levels with single or repeat dosing with no observed clinically significant drug-related safety findings or trends. All observed treatment-emergent adverse events, or TEAEs, were mild or moderate in severity. There were no observed serious adverse events, no severe TEAEs, no discontinuations due to study drug, and no dose-related trends in TEAEs. Except for one observed TEAE of blood creatine phosphokinase increase in SAD Cohort 1 that was deemed mild by the investigator, there were no observed clinically significant drug-related laboratory findings or trends. In addition, there were no observed clinically significant findings related to vital signs or electrocardiograms, no TEAEs related to immunogenicity, and SC administration was generally well tolerated with only mild injection site reactions observed.

In the PK analysis, ADX-097 demonstrated dose-dependent PK and the minimum drug concentration at a dose of 450 mg SC weekly dosing at steady state is estimated to achieve a target threshold associated with tissue pharmacological activity in over 90% of patients. The PD analysis demonstrated increasing inhibition of circulating AP activity and more sustained inhibition with increasing doses. No apparent change in circulating AP activity was observed following 450mg SC weekly dosing. No clinically significant ADA was identified in the ADX-097-101 study, consistent with low immunogenicity potential of ADX-097 in humans. See Figure 6 and Figure 7 for a summary of ADX-097-101 PK and PD data.

Figure 6: ADX-097-101: Plasma ADX-097 Concentrations and % of Baseline Wieslab AP Activity After Single Dose IV of ADX-097

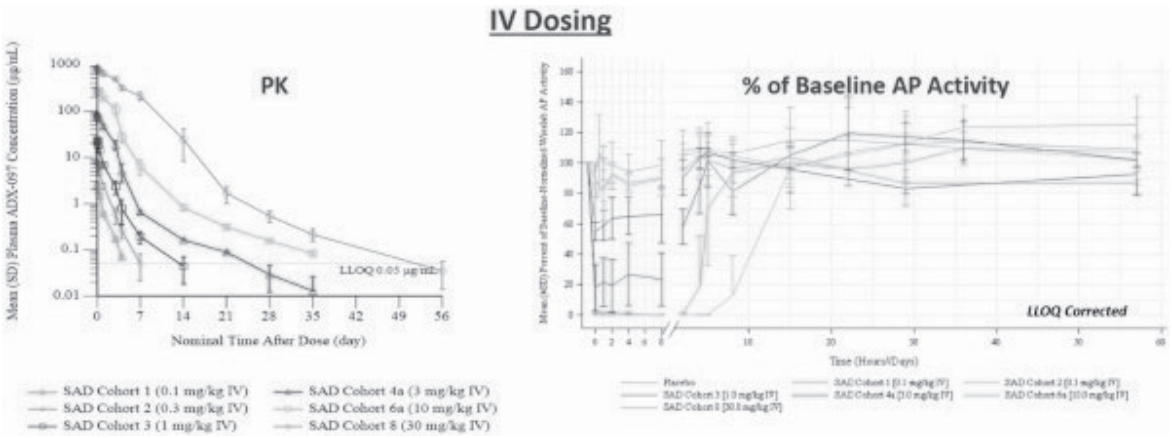
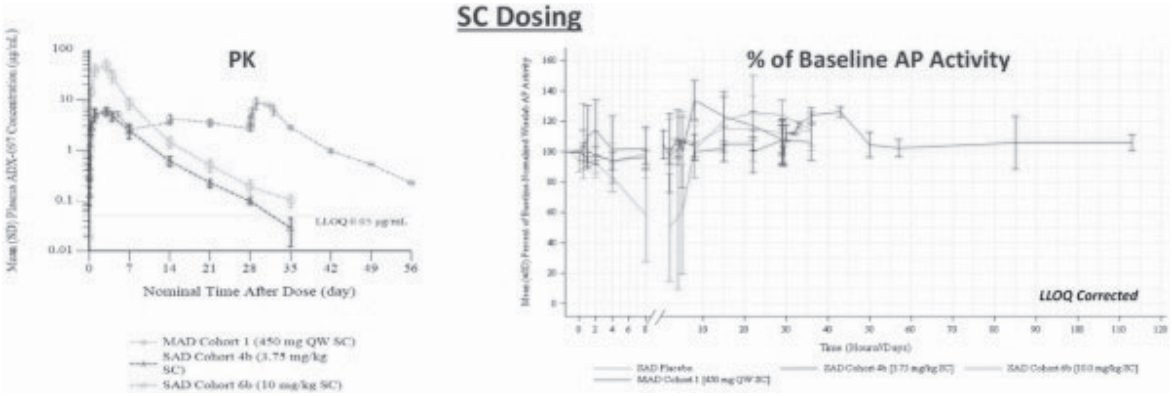


Figure 7: ADX-097-101: Plasma ADX-097 Concentrations and % of Baseline Wieslab AP Activity After Single/Multiple Dose SC of ADX-097



Collaboration and License Agreements

Bempikibart—License Agreement – Bristol-Myers Squibb Company

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

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

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

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

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

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

In October 2023, Amgen Inc., or Amgen, completed the acquisition of Horizon Therapeutics public limited company, or Horizon plc. Following the acquisition of Horizon plc, Legacy Q32 agreed with Amgen to mutually terminate the Horizon Agreements and in November 2023, Legacy Q32 entered into a termination agreement with Horizon, or 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, we entered into an exclusive license agreement, as amended in February 2018, September 2018, and April 2019, or the Colorado License Agreement, with The Regents of the University of Colorado, or 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, or 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.

Competition

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

Manufacturing

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

Intellectual Property

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

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

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

With respect to bempikibart, as of December 31, 2024, we exclusively licensed from Bristol Myers Squibb, or BMS, one patent family relating to antibodies against the IL-7R alpha subunit and uses thereof comprising two issued U.S. patents, two issued patents in Japan, one issued patent in each of China, South Korea, Russia, Saudi Arabia and Singapore, one pending U.S. patent application, and 30 pending patent applications in Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Europe, Hong Kong, India, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, South Africa, Singapore, Taiwan, Thailand, United Arab Emirates, Qatar, Bahrain, Egypt, Kuwait, and Oman. The issued patents are expected to expire in January 2040 and any patents that issue from these pending patent applications are expected to expire in 2040, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

We also own one pending international PCT patent application relating to the use of bempikibart for the treatment of hair-loss disorders such as AA, and another pending international PCT patent application relating to the use of bempikibart for the treatment of AD. Any patents that issue from patent applications derived from or claiming priority to these pending PCT applications are expected to expire in 2044, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

With respect to our ADX-097 program, as of December 31, 2024, we own one patent family relating to ADX-097 and the underlying anti-C3d antibodies, and other fusion constructs of the underlying anti-C3d antibodies and different complement modulators. This family includes three issued U.S. patents, one pending U.S. patent application, one issued patent in each of Australia, Russia and Japan, and 22 pending applications in Australia, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, New Zealand, Philippines, Saudi Arabia, Singapore, South Africa, United Arab Emirates, Qatar, Bahrain, Kuwait, and Oman. The issued patent that covers ADX-097, and any patents that issue from these pending patent applications are expected to expire in December 2039, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

We also own one pending international Patent Cooperation Treaty, or PCT, patent application and one pending patent application in Taiwan, relating to the use of ADX-097 for the treatment of ANCA-associated vasculitis, and another pending international PCT patent application and another pending patent application in Taiwan relating to the use of ADX-097 for the treatment of certain complement-associated renal diseases (such as LN, IgAN, and C3G). Any patents that issue from these Taiwan applications, or patent applications derived from or claiming priority to these pending Taiwan or PCT applications, are expected to expire in 2044, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

We also own one pending PCT patent application relating to targeted treatment of complement-media disease through local complement inhibition based on detection of a urinary biomarker. Any patents that issue from patent applications derived from or claiming priority to this PCT application are expected to expire in 2044, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

We have licensed from various institutions additional patent families that are generally related to C3d targeted complement inhibitors, but that do not specifically cover ADX-097:

- One patent family from the Regents of the University of Colorado, or CU, the MUSC Foundation For Research Development, or MUSC, and the U.S. Department of Veterans Affairs, or USDVA, relating to targeted complement inhibitor constructs based on natural antibodies and uses thereof includes two granted Australian patents and one granted patent in each of Israel and Japan. These patents are expected to expire in 2034, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad;
- Two patent families from CU, the first relating to MAP44 polypeptides and tissue-targeted fusion constructs and uses thereof, and the second relating to modulating the alternative complement pathway;
- The first CU patent family includes one granted patent in each of Australia and Israel and pending patent applications in the U.S., Canada and Australia. The issued patents and any patents that issue from the pending patent applications are expected to expire in 2035, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad. The second CU patent family includes three issued U.S. patents, which are expected to expire in 2029, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad;

- Two patent families from MUSC and USDVA, the first relating to compositions and methods for treating central nervous system injury using a targeted complement inhibitor and another agent or therapy and the second relating to compositions and methods for treating and preventing transplant-associated injury. The first patent family includes two issued U.S. patents, one pending U.S. patent application, and one pending patent application in Europe. The issued patents and any patents that issue from the pending patent applications are expected to expire in 2037, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad. The second patent family includes one pending U.S. patent application and one pending patent application in Europe. Any patents that issue from these pending patent applications are expected to expire in 2037, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad; and
- One patent family from CU and MUSC relating to antibodies against the C3d fragment of complement component 3 includes one reissue patent in the U.S. This reissue U.S. patent is expected to expire in 2031, without accounting for potentially available patent term extensions in the U.S. or abroad.

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

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

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

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

For more information and comprehensive risks related to our proprietary technology, inventions, improvements and product candidates, see the section titled “Risk Factors—Risks Relating to Our Intellectual Property.”

Government Regulation

The U.S. Food and Drug Administration, or the FDA, and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we are currently conducting and in the future may conduct studies or seek approval or licensure of our product candidates. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative

or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business.

U.S. Biologics Regulation

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

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

Preclinical and Clinical Development

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research participants provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries. Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

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

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

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

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

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

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the safety, purity and potency of the final product. Additionally, appropriate packaging must be selected and tested and long-term stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical study investigators. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected suspected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information.

BLA Submission and Review

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

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

Within 60 days following submission of the application, the FDA reviews the BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facilities in which it is manufactured, processed, packed or stored meet standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a complete response letter, or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. The FDA may delay or refuse approval of a BLA

if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

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

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

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies with due diligence to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

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

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits batch data from each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biologics. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies

or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. FDA-approved interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state pharmacy laws, which differ by state. The BPCIA is complex and continues to be interpreted and implemented by the FDA.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the biologic. This six-

month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

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

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute, or AKS; the federal False Claims Act, or FCA; the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar foreign, federal and state fraud, abuse and transparency laws.

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

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

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements or representations relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties,

amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

Data Privacy and Security

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. As our operations and business grow, we may become subject to or affected by U.S. federal and state laws and regulations, including the Health Information Portability and Accountability Act of 1996, and its implementing regulations, as amended, or HIPAA, that govern the collection, use, disclosure, and protection of health-related and other personal information. At the federal level, in addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (the FTCA), 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Regulators and legislators in the U.S. are also increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

In addition, certain state laws govern the privacy and security of personal information. For example, in California the California Consumer Protection Act, or CCPA, which went into effect on January 1, 2020 and was amended effective January 1, 2023 by the California Privacy Rights Act, or CPRA, established a comprehensive privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope. In addition, effective January 1, 2023, the CPRA, imposed additional obligations on companies covered by the CCPA. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information and by establishing the California Privacy Protection Agency to enforce the CCPA.

Other states have passed similar privacy legislation and more states may do so in the future. If enacted, proposed legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington's My Health My Data Act, which became effective on March 31, 2024, regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there are discussions in the U.S. Congress of new comprehensive federal data privacy laws to which we could become subject to, if enacted.

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

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

Coverage and Reimbursement

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

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require it to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

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

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

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

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union, or EU,

provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

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

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

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Also, the U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025; however, legislation has been introduced (but not passed) in the U.S. Congress that would reverse these payment reductions. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may otherwise affect the price we can obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Further, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

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

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

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

Other Government Regulation Outside of the United States

Regulation Outside of the United States

EU Drug Development

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

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

EU Drug Review and Approval

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

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

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

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

EU New Chemical Entity Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be placed on the EU market until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder

obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, however, another company could nevertheless also market another version of the product if such company obtained an MA based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

EU Orphan Designation and Exclusivity

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

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

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

EU Pediatric Investigation Plan

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

PRIME Scheme

In March 2016, the EMA launched an initiative, the PRIority Medicines, or PRIME, scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products

representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact and rapporteur from the CHMP or from the Committee for Advanced Therapies, or CAT, are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's committee level. An initial meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

The aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the EU

The European Commission introduced legislative proposals in April 2023, that if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. The European Parliament and the European Council may propose amendments to the proposals. Once the proposals are approved (with or without amendment), they will be adopted into EU law.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom left the EU on January 31, 2020, and the United Kingdom and the EU have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021.

The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of United Kingdom and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). Except in respect of the new EU Clinical Trials Regulation, the regulatory regime in Great Britain therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of United Kingdom and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new framework mentioned below which will be put in place by the Medicines and Healthcare products Regulatory Agency, or MHRA, the United Kingdom's medicines regulator, from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of MAs from the EMA (and certain other regulators) when considering an application for a Great Britain MA.

On February 27, 2023, the United Kingdom government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA will be responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single United Kingdom-wide MA will be granted by the MHRA for all medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. The Windsor Framework was approved by the EU-United Kingdom Joint Committee on March 24, 2023, so the United Kingdom government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. All existing EU MAs for centrally authorized products were automatically converted (grandfathered) into United Kingdom MAs free of charge on January 1, 2021. For a period of three years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required. On January 24, 2023, the

MHRA announced that a new international recognition framework will be put in place from January 1, 2024, which will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new Great Britain MA. There is now no pre-MA orphan designation in Great Britain. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the Great Britain market, i.e., the prevalence of the condition in Great Britain (rather than the EU) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in Great Britain.

Human Capital

As of December 31, 2024, we had 42 full-time employees, of which 6 have M.D. or Ph.D. degrees. Within our workforce, 31 employees are engaged in research and development and 12 are engaged in general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

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

Facilities

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

Corporate Information

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

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

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at *http://www.sec.gov*. We make available on our website at www.q32bio.com, under “Investors & Media,” free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Research and Development Committee of our Board of Directors are posted on our website, www.q32bio.com, under “Investors & Media”. The information contained in the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. Risk Factors.

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

Risks Related to Our Business

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

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

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

We have incurred recurring operating losses since inception. Our net loss for the years ended December 31, 2024 and 2023 was $47.7 million and $53.7 million, respectively. 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, or 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, or 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, or 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, or CDMOs, and contract research organizations, or 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, or 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, or 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, or 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, or PK, and pharmacodynamic, or 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, or AD, and the Phase 2a SIGNAL-AA trial is evaluating bempikibart for the treatment of alopecia areata, or 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. 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, or 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, or 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. 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, or 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, or 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, or 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, or 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, or BMS, under which we in-license patent rights and know-how that cover bempikibart, or BMS Agreement, and The Regents of the University of Colorado, or 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 "*Business–Collaboration and License Agreements*." 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, or 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, or 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, or 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, or 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, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent, or 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, or BLA, a new drug application, or 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, or 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. With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, 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 March 14, 2025. 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 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, 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 agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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.

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, or 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 it intends to seek approval as biologics may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company

may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

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

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

Any regulatory approvals that we may receive for bempikibart or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such product candidates, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug substances and products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

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

We may face difficulties from healthcare legislative reform measures.

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

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

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;

- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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" elsewhere in this Annual Report on Form 10-K for a more detailed description of the laws that may affect our ability to operate.

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

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

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

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

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

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

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

We may seek one or more designations or expedited programs for our product candidates, but may not receive such designations or be allowed to proceed on expedited program pathways, and even if we do receive such designations and proceed on such expedited program pathways 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.

We may seek fast track designation for some of our 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 fast track designation. 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 if our candidates receive fast track designation, these candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from the clinical development program. Fast track designation 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, or 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*" elsewhere in this Annual Report on Form 10-K 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 December 31, 2024, we had 42 full-time employees, including 3 who hold Ph.D. degrees and 3 who hold M.D. degrees, and one part-time employee; 31 employees are engaged in research and development and 12 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 increase the number of our employees and 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, expand our facilities, and continue to recruit and train additional 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. Moreover, our current physical laboratory space may be insufficient for our near-term research and development hiring plans, and the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. 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, 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. Similarly, the 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, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or 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, or the Federal Reserve, and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, FDIC and Federal Reserve have announced a program to provide up to $25 billion of loans to financial institutions secured by certain government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments and help address liquidity pressures that may arise. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

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

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

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

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

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

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

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

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

If existing securityholders of Homology and Legacy Q32 sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. As of December 31, 2024, 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.

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

As of December 31, 2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 62.2% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

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

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

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

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

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

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

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

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

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

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

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

- establish a classified board of directors such that all members of the board are not elected at one time;
- do not provide for cumulative voting in the election of directors;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- provide that only the board of directors may fill vacancies on the board of directors created by the expansion of the board of directors or the resignation, death or removal of a director;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;

- authorize our board of directors to issue preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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

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

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

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 Annual Report on Form 10-K 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 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 Nasdaq, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. 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 Nasdaq, the SEC or other regulatory authorities.

Legacy Q32 and its independent registered public accounting firm identified a material weakness in our internal control over financial reporting, which has been remediated as of December 31, 2024. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the market price of our common stock.

In preparation of its consolidated financial statements to meet the requirements applicable to the Merger, Legacy Q32 and its independent registered public accounting firm identified a material weakness in its internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified related to deficiencies in Legacy Q32's controls over complex accounting topics. Specifically, Legacy Q32's accounting and internal control infrastructure did not allow for adequate review processes over complex accounting topics due to lack of sufficient personnel. Due to this material weakness, material errors were identified and corrected in Legacy Q32's unaudited condensed consolidated financial statements for the nine months ended September 30, 2023.

We have implemented measures designed to improve internal controls over financial reporting to remediate the control deficiencies that led to the material weakness, including strengthening reviews by our finance team and expanding our accounting and finance team to add additional qualified accounting and finance resources, which includes augmenting our finance team with third party consultants that possess the required expertise to assist management with its review of complex accounting topics.

We implemented and formally documented improved processes and controls, including process narratives and risk and control matrices, to appropriately mitigate risks of material misstatement to the financial statements. We implemented enhanced procedures to make sure all steps are being performed as part of the control procedures to detect any material issues, and that the correct individuals are assigned as control owners to ensure that an appropriate, sufficient, and independent review is taking

place. Our remediated controls have been operating for a sufficient period of time and we have concluded, through testing, that these controls are operating effectively and that the material weakness is remediated as of December 31, 2024.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will prevent or avoid potential future material weaknesses. In addition, our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had Legacy Q32 or its independent registered public accounting firm performed an evaluation of its internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

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

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

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

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

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

Cybersecurity Governance

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

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

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

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

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

Item 2. Properties.

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

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is currently listed on the Nasdaq Global Market under the symbol "QTTB." Prior to the consummation of the Merger, the common stock was listed on the Nasdaq Global Select Market under the symbol "FIXX."

Holders

As of March 1, 2025, we had approximately 12,197,615 shares of common stock issued and outstanding held of record by approximately 29 registered holders. The number of holders of record does not include a substantially greater number of "street name" holders or beneficial holders whose shares of Company common stock are held of record by banks, brokers and other financial institutions.

Dividends

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

Securities Authorized for Issuance under Equity Compensation Plans

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

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

We did not repurchase any of our equity securities or issue any securities that were not registered under the Securities Act during the year ended December 31, 2024.

Use of Proceeds

Not applicable.

Item 6. [Reserved]

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

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

Unless otherwise indicated or the context otherwise requires, references to "Legacy Q32" refers to the business and operations of Q32 Bio Operations (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. To achieve this goal of restoring homeostasis to a dysregulated immune system, we are advancing antibody-based therapeutic candidates designed to target two central pathways of adaptive and innate immunity. The adaptive immune system is largely composed of T- and B-cell mediated cellular and antibody responses; while the innate immune system is a first line of defense employing leukocytes such as monocytes, macrophages, neutrophils, dendritic cells and natural killer cells that are responsible for clearing pathogens and cellular debris, and modulating T- and B-cell function. We believe that targeting these key pathways of immune dysregulation in autoimmune and inflammatory diseases will deliver therapeutics for indications with clear unmet medical need in the near term, while enabling us to build a broad and diverse pipeline in the long term. We have multiple product candidates across a variety of autoimmune and inflammatory diseases.

Bempikibart (ADX-914), our most advanced product candidate, is a fully human anti–interleukin-7 receptor alpha, or IL-7Rα, antagonist monoclonal antibody designed to re-regulate adaptive immune function by blocking signaling mediated by interleukin-7, or IL-7, and thymic stromal lymphopoietin, or TSLP. We have completed two Phase 2a clinical trials evaluating bempikibart; SIGNAL-AA for the treatment of alopecia areata, or AA, and SIGNAL-AD for the treatment of atopic dermatitis, or AD. On December 10, 2024, we announced topline results from both of these trials, as well as our intention to advance bempikibart for the treatment of AA and enroll patients into Part B of the SIGNAL-AA trial in the first half of 2025.

Patients in the SIGNAL Phase 2a clinical trials were dosed with 200mg subcutaneous, or SC, bempikibart every two weeks. In the SIGNAL-AA trial, 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, or RO, and observed favorable pharmacokinetics, or PK, / pharmacodynamic, or PD, properties, consistent with those from the Phase 1 clinical trial. Minimal anti-drug antibodies, or 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 additional AA patients through 36 weeks of treatment in a Part B expansion of the SIGNAL-AA Phase 2a clinical trial and report initial data from SIGNAL-AA Part B in the first half of 2026.

In February 2025, we announced a corporate restructuring to focus on the advancement of bempikibart for the treatment of patients with AA.

ADX-097, a Phase 2 asset and the lead product candidate from our complement inhibitor platform, is a humanized anti-C3d monoclonal antibody, or 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 that we are discontinuing 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 includes 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 expect to incur severance and severance-related charges of approximately $1.1 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., or Amgen, completed the acquisition of Horizon Therapeutics public limited company, or Horizon plc. Following the acquisition, Legacy Q32 agreed with Amgen to mutually terminate the Collaboration and Option Agreement, or the Horizon Collaboration Agreement, and the Asset Purchase Agreement, or the Purchase Agreement, and together with the Horizon Collaboration Agreement, the Horizon Agreements, each between Legacy Q32 and Horizon Therapeutics Ireland DAC, or Horizon. In November 2023, Legacy Q32 entered into a termination agreement with Horizon, or 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, or FASB, Accounting Standards Update, or ASC, Topic 606, *Revenue from Contracts with Customers*, or 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, or the Merger Agreement, with Homology and Kenobi Merger Sub, Inc., a wholly-owned subsidiary of Homology, or 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, or the Merger. Homology changed its name to Q32 Bio Inc., or 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, or Nasdaq, 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, or the Pre-Closing Financing.

On March 25, 2024, or 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, or 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, or 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, or 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, or 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, or the CVR Agreement, representing the contractual right to receive cash payments from the combined company upon the receipt of certain proceeds from a disposition of Homology's pre-merger assets, calculated in accordance with the CVR Agreement.

Financial Overview

As of December 31, 2024, we had cash and cash equivalents of $78.0 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 Annual Report on Form 10-K.

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

Components of Results of Operations

Revenue

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

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

Prior to the 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, or CROs;
- costs related to contract development and manufacturing organizations, or CDMOs, that are primarily engaged to provide drug substance and product for our preclinical studies, clinical trials and research and development programs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;

- costs related to compliance with quality and regulatory requirements;
- employee-related expenses, including salaries, benefits, and stock-based compensation expense, for personnel engaged in research and development functions;
- facilities-related expenses, depreciation, supplies, travel expenses and other allocated expenses; and
- payments made under third-party licensing agreements.

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

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

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

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

General and Administrative Expenses

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

Change in Fair Value of Convertible Notes

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

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

Other Income (Expense), net

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

Income Taxes

Since inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for earned research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2024, we had federal and state net operating loss carryforwards of $121.3 million and $112.1 million, respectively, that expire at various dates through 2040, to the extent subject to expiration. As of December 31, 2024, we also had federal and state research and development tax credit carryforwards of $6.2 million and $2.3 million, respectively, that expire at various dates through 2040.

Loss from equity method investment

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

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		
	2024	2023	Change
	(in thousands)		
Collaboration arrangement revenue	$ —	$ (6,651)	$ 6,651
Operating expenses:			
Research and development	48,143	31,729	16,414
General and administrative	17,959	9,875	8,084
Total operating expenses	66,102	41,604	24,498
Loss from operations	(66,102)	(48,255)	(17,847)
Change in fair value of convertible notes	15,890	(6,193)	22,083
Other income (expense), net	4,125	1,023	3,102
Total other income (expense), net	20,015	(5,170)	25,185
Loss before provision for income taxes and loss from equity method investment	(46,087)	(53,425)	7,338
Provision for income taxes	(21)	(318)	297
Loss from equity method investment	(1,625)	—	(1,625)
Net loss	$ (47,733)	$ (53,743)	$ 6,010

Collaboration Arrangement Revenue

We recognized no collaboration arrangement revenue for the year ended December 31, 2024, compared to negative $6.7 million for the year ended December 31, 2023. Upon execution of the Horizon Termination Agreement in November 2023, and pursuant to ASC 606, all previously recognized amounts in 2022 were reversed in 2023. See further discussion under “Revenue” above.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		
	2024	2023	Change
	(in thousands)		
Direct research and development expense by program:			
Bempikibart	$ 28,726	$ 11,722	$ 17,004
ADX-097	5,253	7,185	(1,932)
Discovery and other	856	894	(38)
Unallocated expenses:			
Personnel-related and consulting (including stock-based compensation)	10,435	9,629	806
Indirect research and development expense	2,873	2,299	574
Total research and development expenses	$ 48,143	$ 31,729	$ 16,414

Research and development expenses were $48.1 million for the year ended December 31, 2024, compared to $31.7 million for the year ended December 31, 2023. The increase of $16.4 million was due to increased spend related to our bempikibart program including increased clinical spend of $11.7 million as we completed enrollment and treated patients in our two Phase 2a clinical trials, SIGNAL-AA and SIGNAL-AD, and incurred a development milestone payment of $4.0 million to Bristol-Myers Squibb Company, or BMS, pursuant to the BMS License Agreement. In addition, manufacturing costs related to our bempikibart program increased by approximately $6.2 million related to a cGMP manufacturing run to supply future studies.

Expenses related to our ADX-097 program decreased by $1.9 million primarily due to lower clinical trial costs as the trial was winding down after the completion of the Phase 1 clinical trials in 2023.

The increase in personnel-related and consultant costs was primarily related to higher headcount as compared to the same period in the prior year. Personnel-related and consultant costs for the year ended December 31, 2024 and 2023 included stock-based compensation expense of $1.1 million and $0.5 million, respectively.

General and Administrative Expenses

General and administrative expenses were $18.0 million for the year ended December 31, 2024, compared to $9.9 million for the year ended December 31, 2023. The increase is primarily due to costs associated with the Merger, including severance and retention payments to former employees of Homology, as well as other public company-related costs. General and administrative expenses include stock-based compensation expense of $3.3 million and $0.9 million for the years ended December 31, 2024 and 2023, respectively.

Change in Fair Value of Convertible Notes

Upon closing of the Merger in March 2024, Legacy Q32 converted its outstanding Convertible Notes plus accrued interest into shares of common stock at 90% of the purchase price of the mandatory conversion event. As the Convertible Notes are recorded at fair value, a gain of $15.9 million on the change in fair value prior to the conversion of the Convertible Notes is reflected in the consolidated statement of operation for the year ended December 31, 2024. The change in the fair value of the convertible notes was $6.2 million for the year ended December 31, 2023.

Other Income (Expense), Net

Other income (expense), net was $4.1 million for the year ended December 31, 2024, compared to $1.0 million for the year ended December 31, 2023. Other income (expense), net for the year ended December 31, 2024 includes interest income of $3.9 million, as well as a gain recorded for the change in fair value of the CVR liability of $2.2 million. These increases are partially offset by interest expense of $1.1 million on our venture debt and an other-than-temporary impairment charge of approximately $0.7 million we recorded because it was determined that the fair value of our equity investment in OXB (US) LLC was less than its carrying value. The increase in other income (expense), net is primarily 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 year ended December 31, 2024.

Provision for Income Taxes

Provision for income taxes was less than $0.1 million for the year ended December 31, 2024, compared to $0.3 million for the year ended December 31, 2023.

Since inception, Legacy Q32 has not recorded any U.S. federal or state income tax benefits for the net losses it has incurred in each year or for its earned research and development tax credits, due to its uncertainty of realizing a benefit from those items. As of December 31, 2023, Legacy Q32 had no gross unrecognized tax benefits.

Loss from equity method investment

Prior to May 22, 2024, we accounted for our investment in OXB (US) LLC using the equity method of accounting and recorded our share of gains or losses from OXB (US) LLC on a quarterly basis. For the year ended December 31, 2024, we recorded a loss from equity method investment of $1.6 million, representing our share of OXB (US) LLC's net loss. See Notes 2 and 6 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information regarding the equity method of accounting.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have funded our operations primarily 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 December 31, 2024, 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 December 31, 2024, we had cash and cash equivalents of $78.0 million.

Going Concern

We have incurred significant operating losses since inception and, as of December 31, 2024, had an accumulated deficit of $234.8 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 December 31, 2024, we had cash and cash equivalents of $78.0 million. We expect that our cash and cash equivalents as of December 31, 2024, 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:

	Years Ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (67,715)	$ (18,677)
Net cash provided by (used in) investing activities	19,925	(5)
Net cash provided by financing activities	95,138	406
Increase/(decrease) in cash, cash equivalents and restricted cash	$ 47,348	$ (18,276)

Operating Activities

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

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

For the year ended December 31, 2023, net cash used in operating activities of $18.7 million was primarily due to a net loss of $53.7 million partially offset by a change in net operating assets and liabilities of $26.3 million and net non-cash operating expenses of $8.7 million. The change in net operating assets and liabilities was primary attributable to an increase in a

contingent liability, accounts payables, accrued expenses and other current liabilities, prepaid expenses and other current assets and other non-current assets of $52.6 million, partially offset by a decrease in deferred revenue and operating lease liability of $26.3 million. The non-cash operating expenses consisted of a $6.2 million change in fair value of convertible notes, stock-based compensation expense of $1.4 million, non-cash lease expenses of $0.5 million, and depreciation and amortization of $0.6 million.

Investing Activities

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

For the year ended December 31, 2023, net cash used in investing activities consisted of purchases of property and equipment.

Financing Activities

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

For the year ended December 31, 2023, net cash provided by financing activities consisted of $5.5 million of proceeds from the borrowings under a new loan and security agreement, partially offset by payments of $5.2 million associated with the repayment of Legacy Q32's initial loan and security agreement.

Pre-Closing Financing

In connection with the Merger Agreement, certain third parties entered into the Pre-Closing Financing as described above under "—Recent Developments—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 December 31, 2024 (in thousands):

	Payments Due by Period			
	Total	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligation	$ 8,121	$ 3,276	$ 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, or the BMS License Agreement, with Bristol-Myers Squibb Company, or 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, or 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, or the Colorado License Agreement, with The Regents of the University of Colorado, or 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, or 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

Management's discussion and analysis of its financial condition and results of operations is based on its consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Actual results could materially differ from those estimates.

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

Revenue Recognition

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

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

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

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

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

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

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

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

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

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

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

Research and Development Expenses and Related Accrued and Prepaid Expenses

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

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

As part of the process of preparing our consolidated financial statements, management is required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. Management makes estimates of its prepaid and accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to us at that time. Management periodically confirms the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include fees paid to:

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

Management bases the expense recorded related to contract research and manufacturing on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CDMOs and CROs that supply materials and conduct services. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, management estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, management adjusts the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Convertible Notes

We account for all convertible notes issued under the fair value option election of ASC 825. The financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized within other income (expense), net in the accompanying consolidated statements of operations and the portion of the fair value adjustment attributed to a change in the instrument-specific credit risk is recognized as a component of other comprehensive loss, if any. The fair value is based on significant inputs not observable in the market, namely potential financing scenarios, the likelihood of such scenarios, the expected time for each scenario to occur, and the required market rates of return utilized in modeling these scenarios.

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 fair value prior to the conversion of the Convertible Notes is reflected in the consolidated statement of operations for the year ended December 31, 2024. We recorded a loss of $6.2 million related to the change in fair value of the Convertible Notes for the year ended December 31, 2023.

Stock-Based Compensation Expense

We account for stock-based awards in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation,* or ASC 718. ASC 718 requires all stock-based awards issued to employees and members of our board of directors, or the Board, for their services to be recognized as expense in the statements of operations based on their grant date fair values. We use the value of our common stock to determine the fair value of its stock-based awards. For stock options and time-based restricted stock awards, we expense the fair value of the awards on a straight-line basis over each award's service period, which is generally the period in which the related services are received. For performance-based stock awards, we use the accelerated attribution method to expense the awards over the implicit service period based on the probability of achieving the performance conditions. We account for stock-based awards to non-employees consistently with the accounting for awards to employees and measure stock-based awards granted to non-employees based on their grant date fair value and recognize the resulting value as stock-based compensation expense during the period the related services are rendered. We account for forfeitures as they occur.

Determination of the Fair Value of Common Stock

Prior to the Merger, given the absence of an active market for our common stock, the fair values of the shares of common stock underlying Legacy Q32's stock-based awards were determined on each grant date by the Board with input from management, considering its most recently available third-party valuations of our common stock and the Board's assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the grant date. Historically, these independent third-party valuations of our equity instruments were performed contemporaneously with identified value inflection points. The third-party valuations were prepared in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, or the Practice Aid. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In addition to considering the results of these third-party valuations, the Board considered various objective and subjective factors to determine the fair value of our equity instruments as of each grant date, which may be later than the most recently available third-party valuation date, including:

- the lack of liquidity of our equity as a private company;
- the prices of our convertible preferred stock sold to outside investors in arm's length transactions and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preferences of our convertible preferred stock;
- the progress of our research and development efforts, including the status of preclinical studies and clinical trials for our product candidates;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into strategic collaborative and license agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;

- any external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company, given prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The hybrid method is a probability-weighted expected return method, or PWERM, by which the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and stock-based compensation expense could be materially different.

Now that a public trading market for our common stock has been established in connection with the completion of the Merger, it will no longer be necessary for the Board to estimate the fair value of our common stock in connection with our accounting for granted stock options and restricted stock awards, as the fair value of our common stock will be determined based on the trading price of our common stock on Nasdaq.

Recently Issued and Adopted Accounting Pronouncements

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

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

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024 and, based on this evaluation, concluded that our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) was effective as of December 31, 2024. We previously identified a material weakness in our internal control over financial reporting related to Legacy Q32's controls over complex accounting topics. Specifically, Legacy Q32's accounting and internal control infrastructure did not allow for adequate review processes over complex accounting topics due to lack of sufficient personnel. We have concluded that this material weakness in our internal control over financial reporting was due to the fact that we had limited resources and did not have the necessary business processes and related internal controls formally designed and implemented coupled with the appropriate resources to oversee our business processes and controls and has been remediated as of December 31, 2024. A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Remediation Efforts to Address Material Weakness

During 2024, we have taken a number of actions to improve the Company's internal control over financial reporting in an effort to remediate the material weakness, We have implemented measures designed to improve our internal control over financial reporting, including strengthening reviews by our finance team as well as expanding our accounting and finance team to add additional qualified accounting and finance resources which includes augmenting our finance team with third party consultants that possess the required expertise to assist management with its review of complex accounting topics.

We implemented and formally documented improved processes and controls, including process narratives and risk and control matrices, to appropriately mitigate risks of material misstatement to the financial statements. We implemented enhanced procedures to make sure all steps are being performed as part of the control procedures to detect any material issues, and that the correct individuals are assigned as control owners to ensure that an appropriate, sufficient, and independent review is taking place. Our remediated controls have been operating for a sufficient period of time and we have concluded, through testing, that these controls are operating effectively and that the material weakness is remediated as of December 31, 2024.

Changes in Internal Control over Financial Reporting

Except with respect to the changes in connection with our implementation of the remediation plan discussed above, there have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a)

None.

(b)

Rule 10b5-1 Trading Arrangements

No Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements, as defined in Item 408(c) of Regulation S-K, were adopted, modified, or terminated by officers or directors of the Company, nor were there any material changes to the procedures by which security holders may recommend nominees to the Company's board of directors, during the three months ended December 31, 2024.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

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

(2) Financial Statement Schedules.

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

(3) Exhibits.

Exhibit Number	Description
2.1+	Agreement and Plan of Merger, dated as of November 16, 2023, by and among Homology Medicines, Inc., Kenobi Merger Sub, Inc. and Q32 Bio Inc (incorporated by reference to Exhibit 2.1 of the Registrant's Registration Statement on form S-4 filed December 18, 2023 (File No. 333-276093)).
3.1	Restated Certificate of Incorporation, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed April 3, 2018 (File No. 001-38433)).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company-reverse stock split and authorized share increase, dated March 25, 2024 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company-name change, dated March 25, 2024 (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
3.4	Amended and Restated Bylaws, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed December 18, 2020 (File No. 001-38433)).
4.1	Description of Registrant's Securities (incorporated by reference to Exhibit 4.1 of the Registrant's Form 10-K/A filed April 12, 2024 (File No. 001-38433)).
10.1+	Subscription Agreement, dated November 16, 2023, by and among Q32 Bio Operations Inc. (formerly Q32 Bio Inc.) and certain parties thereto (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.2+	Registration Rights Agreement, dated March 25, 2024, by and among Q32 Bio Operations Inc. (formerly Q32 Bio Inc.) and certain parties thereto (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.3	Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.4	Contingent Value Rights Agreement dated March 23, 2024, by and between Homology Medicines Inc. and Equiniti Trust Company, LLC (incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.5#	Form of Indemnification Agreement for Officers of Q32 Bio Inc. (incorporated by reference to Exhibit 10.6 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.6#	Form of Indemnification Agreement for Directors of Q32 Bio Inc. (incorporated by reference to Exhibit 10.7 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.7#	Q32 Bio Inc. 2017 Stock Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.8 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.8#	Q32 Bio Inc. 2024 Stock Option and Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.9 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.9#	Q32 Bio Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.10#	Q32 Bio Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.11 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.11#	Q32 Bio Inc. Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.12 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).

10.12	Q32 Bio Inc. Warrant to Purchase Common Stock dated December 11, 2020 (incorporated by reference to Exhibit 10.13 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.13	Q32 Bio Inc. Warrant to Purchase Common Stock dated July 12, 2023 (incorporated by reference to Exhibit 10.14 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.14#	Employment Agreement between Q32 Bio Inc. and Jodie Morrison, dated March 25, 2024 (incorporated by reference to Exhibit 10.15 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.15#	Employment Agreement between Q32 Bio Inc. and Lee Kalowski, dated March 25, 2024 (incorporated by reference to Exhibit 10.16 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.16#	Employment Agreement between Q32 Bio Inc. and Jason Campagna, dated March 25, 2024 (incorporated by reference to Exhibit 10.17 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.17#	Employment Agreement between Q32 Bio Inc. and Shelia Violette, dated March 25, 2024 (incorporated by reference to Exhibit 10.18 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
10.18+†	Asset Purchase Agreement, dated August 12, 2022, by and between Q32 Bio Inc. and Horizon Therapeutics Ireland DAC (incorporated by reference to Exhibit 10.36 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.19+†	Collaboration and Option Agreement, dated August 12, 2022, by and between Q32 Bio Inc. and Horizon Therapeutics Ireland DAC (incorporated by reference to Exhibit 10.37 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.20†	Termination Agreement, dated November 10, 2023, between Q32 Bio Inc. and Horizon Therapeutics DAC (incorporated by reference to Exhibit 10.38 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.21+†	Exclusive License Agreement, dated August 9, 2017, between Q32 Bio Inc. and The Regents of the University of Colorado (incorporated by reference to Exhibit 10.39 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.22†	First Amendment to the Exclusive License Agreement, dated February 8, 2017, between Q32 Bio Inc. and The Regents of the University of Colorado (incorporated by reference to Exhibit 10.40 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.23†	Second Amendment to the Exclusive License Agreement, dated September 27, 2018, between Q32 Bio Inc. and The Regents of the University of Colorado (incorporated by reference to Exhibit 10.41 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.24†	Third Amendment to the Exclusive License Agreement, dated April 9, 2019, between Q32 Bio Inc. and The Regents of the University of Colorado (incorporated by reference to Exhibit 10.42 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.25+†	License Agreement, dated as of September 14, 2019, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.43 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.26†	First Amendment to License Agreement, dated as of August 13, 2021, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.44 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.27	Second Amendment to License Agreement, dated as of July 26, 2022, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.45 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.28†	Third Amendment to License Agreement, dated as of July 26, 2022, between Q32 Bio Inc. and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.46 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.29+	Lease Agreement, dated March 20, 2021, by and between Q32 Bio Inc. and PPF OFF 828-830 WINTER STREET LLC (incorporated by reference to Exhibit 10.47 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.30+	Loan and Security Agreement, dated as of December 11, 2020, by and between Q32 Bio Inc. and Silicon Valley Bank, as amended (incorporated by reference to Exhibit 10.50 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.31	First Amendment to Loan and Security Agreement, dated December 30, 2021, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.51 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.32	Second Amendment to Loan and Security Agreement, dated June 30, 2022, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.52 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).

10.33+	Third Amendment to Loan and Security Agreement, dated August 10, 2022, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.53 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.34+	Fourth Amendment to Loan and Security Agreement, dated December 21, 2022, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.54 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.35+	Fifth Amendment to Loan and Security Agreement, dated April 26, 2023, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.55 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.36+	Sixth Amendment to Loan and Security Agreement, dated July 12, 2023, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.56 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.37	Seventh Amendment to Loan and Security Agreement, dated November 2, 2023, by and between Q32 Bio Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.57 of the Registrant's Form S-4 filed on December 18, 2023 (File No. 333-276093)).
10.38+	Consent and Eighth Amendment to Loan and Security Agreement, by and between Q32 Bio, Inc. and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, dated March 22, 2024 (incorporated by reference to Exhibit 10.5 of the Registrant's Form 8-K filed March 27, 2024 (File No. 001-38433)).
19.1*	Insider Trading Policy.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Form 10-K/A filed April 12, 2024 (File No. 001-38433)).
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm of the Registrant.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 of the Registrant's Form 10-K/A filed April 12, 2024 (File No. 001-38433)).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

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

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

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

Item 16. Form 10-K Summary

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Q32 BIO INC.

Date: March 11, 2025 /s/ Jodie Morrison

Name: Jodie Morrison
Title: Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jodie Morrison Jodie Morrison	Chief Executive Officer and Director *Principal Executive Officer*	March 11, 2025
/s/ Lee Kalowski Lee Kalowski	Chief Financial Officer and President *Principal Financial Officer and Principal Accounting Officer*	March 11, 2025
/s/ David Grayzel David Grayzel	Director	March 11, 2025
/s/ Diyong Xu Diyong Xu	Director	March 11, 2025
/s/ Isaac Manke Isaac Manke	Director	March 11, 2025
/s/ Arthur Tzianabos Arthur Tzianabos	Director	March 11, 2025
/s/ Kathleen LaPorte Kathleen LaPorte	Director	March 11, 2025
/s/ Mary Thistle Mary Thistle	Director	March 11, 2025
/s/ Mark Iwicki Mark Iwicki	Director	March 11, 2025
/s/ Bill Lundberg Bill Lundberg	Director	March 11, 2025

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Q32 Bio Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Accrued and Prepaid Research and Development Expenses

Description of the Matter

The Company's accrued external research and development expenses totaled $2.6 million at December 31, 2024. In addition, the Company's current and noncurrent prepaid external research and development expenses were $2.1 million and $0.1 million, respectively, at December 31, 2024. As discussed in Note 2 to the consolidated financial statements, the Company analyzes the progress of the research activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued and prepaid balances at the end of any reporting period for the Company's clinical trials costs, and costs to manufacture its product candidates. The Company is required to estimate such accruals and prepaids using judgment based on certain information, including actual costs incurred or level of effort expended, as reported to the Company by its vendors. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred.

Auditing the Company's accrued and prepaid research and development expenses was complex, as accounting for the costs associated with the clinical trials, and costs to manufacture its product candidates, requires subjective estimates of the level of services performed and the associated costs incurred by multiple service providers that perform service on the Company's behalf. In addition, while the Company's estimates of accrued and prepaid research and development expenses are primarily based on information received related to each contract from its vendors, the Company may need to make an estimate based on its evaluation of the status of the related services since the actual amounts incurred are not typically known at the time the consolidated financial statements are issued.

How We Addressed the Matter in Our Audit

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

Accounting for Reverse Merger Acquisition of Homology Medicines, Inc.

Description of the Matter

As further described in Notes 1 and 3 to the consolidated financial statements, on March 25, 2024, the Company completed a reverse merger with Homology Medicines, Inc. ("Homology"), with Legacy Q32 continuing as the surviving entity as a wholly-owned subsidiary of Homology. The reverse merger was accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles with Legacy Q32 as the accounting acquirer of Homology. Accordingly, the reverse merger was treated as the equivalent of Legacy Q32 issuing stock to acquire the net assets of Homology.

We identified the evaluation of the reverse merger with Homology as a critical audit matter. Evaluating the Company's accounting treatment of the reverse merger required a high degree of auditor judgment to evaluate the Company's (i) determination of the accounting acquirer, and (ii) assessment of the transaction as a reverse recapitalization.

How We Addressed the Matter in Our Audit

To evaluate the accounting for the reverse merger acquisition of Homology, our audit procedures included, among others, evaluating (i) management's technical accounting analysis

performed to determine the accounting acquirer in the transaction, and (ii) the assessment of the transaction as a reverse recapitalization, supported by our subject matter resources. We inspected minutes of board of directors' meetings, executed transaction agreements, and other information to assess the nature and structure of the reverse merger in evaluating management's conclusions with the assistance of professionals in our firm with expertise in accounting for business combinations.

/s/ Ernst & Young LLP

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

Boston, Massachusetts

March 11, 2025

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 77,965	$ 25,617
Prepaid expenses and other current assets	3,912	3,099
Total current assets	81,877	28,716
Equity investment	2,600	—
Property and equipment, net	1,370	1,782
Right-of-use asset, operating leases	5,722	6,301
Restricted cash and restricted cash equivalents	647	5,647
Other noncurrent assets	116	4,611
Total assets	$ 92,332	$ 47,057
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,989	$ 3,468
Accrued expenses and other current liabilities	7,479	9,763
CVR liability	2,900	—
Venture debt, current portion	3,097	878
Total current liabilities	16,465	14,109
Lease liability, net of current portion	5,636	6,248
Venture debt, net of current portion	9,556	4,581
Convertible notes	—	38,595
Other noncurrent liabilities	55,000	55,000
Total liabilities	86,657	118,533
Commitments and contingencies (Note 10)		
Series A convertible preferred stock, $0.0001 par value, no shares and 2,286,873 shares authorized, issued and outstanding as of December 31, 2024 and 2023, respectively (liquidation preference of $47,629 at December 31, 2023)	—	47,458
Series A-1 convertible preferred stock, $0.0001 par value, no shares and 312,094 shares authorized, issued and outstanding at December 31, 2024 and 2023, respectively (liquidation preference of $5,753 as of December 31, 2023)	—	4,132
Series B convertible preferred stock, $0.0001 par value, no shares and 2,625,896 shares authorized, issued and outstanding at December 31, 2024 and 2023, respectively (liquidation preference of $60,000 as of December 31, 2023)	—	59,855
Total convertible preferred stock	—	111,445
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 400,000,000 shares authorized, 12,197,615 and 359,569 shares issued and outstanding at December 31, 2024 2023, respectively	2	1
Additional paid-in capital	240,487	4,159
Accumulated other comprehensive loss	—	—
Accumulated deficit	(234,814)	(187,081)
Total stockholders' equity (deficit)	5,675	(182,921)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 92,332	$ 47,057

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

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

	Years Ended December 31,	
	2024	2023
Collaboration arrangement revenue	$ —	$ (6,651)
Operating expenses:		
Research and development	48,143	31,729
General and administrative	17,959	9,875
Total operating expenses	66,102	41,604
Loss from operations	(66,102)	(48,255)
Change in fair value of convertible notes	15,890	(6,193)
Other income (expense), net	4,125	1,023
Total other income (expense), net	20,015	(5,170)
Loss before provision for income taxes and loss from equity method investment	(46,087)	(53,425)
Provision for income taxes	(21)	(318)
Loss from equity method investment	(1,625)	—
Net loss	$ (47,733)	$ (53,743)
Net loss per share—basic	$ (5.12)	$ (153.96)
Net loss per share—diluted	$ (6.58)	$ (153.96)
Weighted-average common shares—basic	9,320,884	349,060
Weighted-average common shares—diluted	9,657,696	349,060

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

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

	Years Ended December 31,	
	2024	2023
Net loss	$ (47,733)	$ (53,743)
Other comprehensive income (loss):		
Change in unrealized gain (loss) on available for sale securities, net	—	—
Total other comprehensive gain (loss)	—	—
Comprehensive loss	$ (47,733)	$ (53,743)

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

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

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	2,286,873	$ 47,458	312,094	$ 4,132	2,625,896	$ 59,855	343,550	$ 1	$ 2,625	$ —	$ (133,338)	$ (130,712)
Issuance of common stock from option exercises	—	—	—	—	—	—	16,019	—	106	—	—	106
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,428	—	—	1,428
Net loss	—	—	—	—	—	—	—	—	—	—	(53,743)	(53,743)
Balance as of December 31, 2023	2,286,873	$ 47,458	312,094	$ 4,132	2,625,896	$ 59,855	359,569	$ 1	$ 4,159	$ —	$ (187,081)	$ (182,921)
Conversion of convertible preferred stock to common stock in connection with the Merger	(2,286,873)	(47,458)	(312,094)	(4,132)	(2,625,896)	(59,855)	5,224,863	1	111,444	—	—	111,445
Issuance of common stock in the pre-closing financing	—	—	—	—	—	—	1,682,045	—	42,000	—	—	42,000
Issuance of common stock for conversion of convertible notes	—	—	—	—	—	—	1,433,410	—	22,705	—	—	22,705
Issuance of common stock to Homology shareholders in reverse recapitalization	—	—	—	—	—	—	3,229,633	—	64,292	—	—	64,292
Issuance of common stock from option exercises	—	—	—	—	—	—	255,486	—	1,694	—	—	1,694
Issuance of common stock from RSU vesting	—	—	—	—	—	—	12,609	—	—	—	—	—
Reverse recapitalization transaction costs	—	—	—	—	—	—	—	—	(10,013)	—	—	(10,013)
Issuance of CVR at fair value	—	—	—	—	—	—	—	—	(180)	—	—	(180)
Stock-based compensation expense	—	—	—	—	—	—	—	—	4,386	—	—	4,386
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(47,733)	(47,733)
Balance as of December 31, 2024	—	$ —	—	$ —	—	$ —	12,197,615	$ 2	$ 240,487	$ —	$ (234,814)	$ 5,675

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

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

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (47,733)	$ (53,743)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and issuance costs	194	87
Amortization of premium on short-term investments	(221)	—
Depreciation expense	487	499
Stock-based compensation expense	4,386	1,428
Non-cash lease expense	579	544
Loss from equity method investment	1,625	—
Loss on impairment of equity investment	675	—
Change in fair value of CVR liability	(2,180)	—
Change in fair value of convertible notes	(15,890)	6,193
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	276	(94)
Other noncurrent assets	386	(4,503)
Accounts payable	(1,043)	2,033
Operating lease liability	(1,542)	(471)
Accrued expenses and other current liabilities	(7,714)	199
Contingent liability	—	55,000
Deferred revenue	—	(25,849)
Net cash used in operating activities	(67,715)	(18,677)
Cash flows from investing activities:		
Purchases of property and equipment	(75)	(5)
Maturities of short-term investments	20,000	—
Net cash provided by (used in) investing activities	19,925	(5)
Cash flows from financing activities:		
Proceeds from borrowings under loan and security agreement	7,000	5,500
Payments on borrowings under loan and security agreement	—	(5,200)
Proceeds from issuance of common stock in pre-closing financing	42,000	—
Cash acquired in connection with reverse recapitalization	53,158	—
Payment of reverse recapitalization transaction costs	(8,714)	—
Proceeds from exercise of common stock options	1,694	106
Net cash provided by financing activities	95,138	406
Net increase (decrease) in cash, cash equivalents, restricted cash and restricted cash equivalents	47,348	(18,276)
Cash, cash equivalents, restricted cash and restricted cash equivalents at beginning of period	31,264	49,540
Cash, cash equivalents, restricted cash and restricted cash equivalents at end of period	$ 78,612	$ 31,264
Supplemental disclosure of non-cash operating, investing and financing activities:		
Interest payments on venture debt	$ 856	$ 422
Short-term investments acquired in connection with reverse recapitalization	$ 19,905	$ —
Issuance of CVR at fair value	$ 180	$ —

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

Q32 BIO INC.
NOTES TO 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 consolidated financial statements are issued.

As of December 31, 2024, the Company had an accumulated deficit of $234.8 million and cash and cash equivalents of $78.0 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 consolidated financial statements.

The Company has incurred recurring operating losses since its inception. During the year ended December 31, 2024, the Company incurred a net loss of $47.7 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 consolidated financial statements have been prepared in conformity with GAAP and have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

Principles of Consolidation

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

Use of Estimates

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

Segment Information

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

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

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

Foreign Currency Translations

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

Concentrations of Credit Risk and Significant Suppliers

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

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

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

Off Balance Sheet Risk

As of December 31, 2024 and 2023, the Company had no off balance sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Comprehensive Income (Loss)

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

Cash, Cash Equivalents, Restricted Cash and Restricted Cash Equivalents

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

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

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

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

	December 31,	
	2024	2023
Cash and cash equivalents	$ 77,965	$ 25,617
Restricted cash and cash equivalents	647	5,647
Total cash, cash equivalents, restricted cash and restricted cash equivalents	$ 78,612	$ 31,264

Short-Term Investments

Short-term investments represent holdings of available-for-sale marketable securities in accordance with the Company's investment policy and cash management strategy. Short-term investments have maturities of greater than 90 days at the time of purchase and mature within one year from the balance sheet date. Investments in marketable securities are recorded at fair value, with any unrealized gains and losses reported within accumulated other comprehensive income as a separate component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the underlying security. Such amortization and accretion, together with interest on securities, are included in interest income in the Company's consolidated statements of operations. The cost of marketable securities sold is determined based on the specific identification method and any realized gains or losses on the sale of investments are reflected as a component of other income.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

Deferred Transaction Costs

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

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Investments in Equity Securities

The Company uses the equity method of accounting to account for an investment in an entity that it does not control, but in which it has the ability to exercise significant influence over operating and financial policies. The Company's proportionate share of the net income or loss of the entity is included in consolidated net income (loss). Judgments regarding the level of influence over the equity method investment include consideration of key factors such as the Company's ownership interest, representation on the board of directors or other management body and participation in policy-making decisions.

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

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

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

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

At December 31, 2024, the Company accounted for its investment in Oxford Biomedica (US) LLC ("OXB (US) LLC") using the cost method (see Note 6).

Property and Equipment

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

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

Leases

The Company evaluates whether an arrangement is or contains a lease at contract inception. If a contract is or contains a lease, lease classification is determined at lease commencement, which represents the date at which the underlying asset is made available for use by the Company. The Company's lease terms are generally measured at the respective lease's noncancelable term and exclude any optional extension terms as the Company is not reasonably certain to exercise such options. The Company elected the short-term lease exemption and therefore does not recognize lease liabilities and right of use assets for lease arrangements with original lease terms of twelve months or less.

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

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

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

Impairment of Long-Lived Assets

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

Debt and Warrant Issuance Costs

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

Research and Development Expenses

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

The Company has entered into various research and development related contracts with external parties. The payments under these agreements are recorded as research and development expenses as the underlying services are performed or the goods are received. The Company records accrued liabilities for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research activities, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued and prepaid balances at

the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

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

Revenue Recognition

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

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

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

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

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

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

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

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

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

Stock-Based Compensation

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

The fair value of options on the date of grant is calculated using the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on the trading price of the Company's stock, historical data, peer company data and judgment regarding future trends and factors. The Company accounts for forfeitures as they occur.

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

Income Taxes

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

Income taxes are accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying

amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

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

Subsequent Event Considerations

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

Recent Accounting Pronouncements

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

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

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 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 consolidated statement of operations for the year ended December 31, 2024. The Company also incurred transaction costs of $10.0 million and this amount is recorded in additional paid-in capital in the accompanying consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2024.

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

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

For the portion of the CVR agreement that is related to Homology's equity interest in OXB (US) LLC, the Company recorded a CVR liability of $4.9 million representing its estimated fair value as of the date of the Merger. Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB (US) LLC, at any time following the three-year anniversary of the closing of the transaction between OXB (US) LLC, Oxford Biomedica (US), Inc. and the Company (formerly known as Homology Medicines, Inc.) on March 10, 2022, (i) Oxford Biomedica (US), Inc. 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. caused the Company to sell and transfer to Oxford Biomedica (US), Inc., all of the Company's equity interest in OXB (US) LLC. See Note 21.

4. Short-Term Investments

The Company may invest its excess cash in fixed income instruments denominated and payable in U.S. dollars, including U.S. treasury securities, commercial paper, corporate debt securities and asset-backed securities in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The Company did not have any short-term investments as of December 31, 2024 and December 31, 2023.

5. Fair Value Measurements

The carrying values of the Company's prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair value due to their short-term nature. The carrying value of the Company's term loan as of December 31, 2024 (see Note 11) approximated fair value based on interest rates currently available to the Company.

The tables below present information about the Company's assets and liabilities that are regularly measured and carried at fair value on a recurring basis at December 31, 2024 and December 31, 2023 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 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

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2023 are summarized as follows (in thousands):

Description	Balance as of December 31, 2023	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	$ 24,100	$ 24,100	$ —	$ —
Total cash equivalents	$ 24,100	$ 24,100	$ —	$ —
Restricted cash equivalents:				
Money market funds	$ 5,000	$ 5,000	$ —	$ —
Total restricted cash equivalents	$ 5,000	$ 5,000	$ —	$ —
Total financial assets	$ 29,100	$ 29,100	$ —	$ —
Liabilities				
Convertible notes	$ 38,595	$ —	$ —	$ 38,595
Total financial liabilities	$ 38,595	$ —	$ —	$ 38,595

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.

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. This model requires the use of estimates and assumptions including estimated future revenues and discount rates. 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 $2.9 million as of December 31, 2024. The Company recorded in other income (expense), net, $1.5 million for the change in estimated fair value during the year ended December 31, 2024.

During the years ended December 31, 2024 and 2023, there were no transfers between Level 1, Level 2 and Level 3 measurements. There have been no impairments of the Company's assets measured and carried at fair value during the years ended December 31, 2024 and 2023.

Legacy Q32 issued convertible notes (the "Convertible Notes") totaling $30.0 million during the year ended December 31, 2022. Legacy Q32 concluded that the Convertible Notes and its related features are within the scope of FASB ASC Topic 825, *Financial Instruments* (ASC 825), as a combined financial instrument, and Legacy Q32 elected the fair value option where changes in fair value of the Convertible Notes are measured through the accompanying consolidated statement of operations until settlement. The Convertible Notes liability represents a Level 3 measurement within the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include the underlying fair value of the equity instrument into which the Convertible Notes are convertible. The fair value is based on significant inputs not observable in the market, namely potential financing scenarios, the likelihood of such scenarios, the expected time for each scenario to occur, and the required market rates of return utilized in modeling these scenarios.

Year Ended December 31, 2023	Scenario 1	Scenario 2	Scenario 3
Probability of each scenario	80%	15%	5%
Expected Term (years)	0.25	0.25	0.42
Required market rates of return	15.0%	15.0%	15.0%

The Convertible Notes had an estimated fair value of $38.6 million as of December 31, 2023. The Company recorded in other income (expense), net, an interest expense of $1.5 million and a charge of $4.7 million on the change in estimated fair value during the year ended December 31, 2023. There was no change in fair value attributable to the instrument-specific credit risk for the year ended December 31, 2023.

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

6. Investment in Equity Securities

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

The Company recorded its equity method investment in OXB (US) LLC at fair value upon the effective date of the Merger. The fair value of the equity method investment was determined based on the market approach. This approach estimated the fair value of OXB (US) LLC based on the implied value for the entity, including the Options (as defined in Note 3 above), for a controlling interest in OXB (US) LLC at the entity's formation. As part of its fair value analysis, the Company determined that the Options 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. As of September 30, 2024, the Company performed an assessment to evaluate whether the investment was impaired and determined that the fair value of its investment in OXB (US) LLC was negatively impacted due to a change in OXB (US) LLC's forecasted performance. The Company utilized a monte carlo simulation model, also known as a probability simulation, to estimate the fair value of its investment. This model requires the use of estimates and assumptions including estimated future revenues and discount rates which are significant unobservable inputs representing Level 3 measurements within the fair value hierarchy. The Company determined that the decline in value was deemed to be other than temporary and recorded an impairment charge of approximately $0.7 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. As of December 31, 2024, the carrying value of the equity investment was $2.6 million and the Company determined that the investment was not impaired.

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.

7. Property and Equipment, Net

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

	December 31,	
	2024	2023
Lab equipment	$ 1,382	$ 1,382
Furniture and fixtures	351	341
Computer equipment	89	85
Leasehold improvements	1,001	940
Total property and equipment	2,823	2,748
Less accumulated depreciation	(1,453)	(966)
Property and equipment, net	$ 1,370	$ 1,782

Depreciation expense for the years ended December 31, 2024 and 2023 was approximately $0.5 million in each period. No impairment losses occurred in 2024 and 2023. The Company had no losses on disposal of fixed assets in 2024 and 2023.

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

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

	December 31,	
	2024	2023
Prepaid external research and development	$ 2,076	$ 1,834
Payroll tax credit	555	755
Prepaid expenses	885	427
Other	396	83
Total prepaid expenses and other current assets	$ 3,912	$ 3,099

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

	December 31,	
	2024	2023
Deferred transaction costs	$ —	$ 3,912
Prepaid external research and development - long term	116	676
Other	—	23
Total other noncurrent assets	$ 116	$ 4,611

9. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2024	2023
Accrued compensation and related expenses	$ 2,782	$ 3,003
Accrued external research and development	2,611	3,578
Accrued professional services and other	1,474	2,328
Operating lease liability, current	612	538
Accrued taxes payable	—	316
Total accrued expenses and other current liabilities	$ 7,479	$ 9,763

10. Commitments and Contingencies

As of December 31, 2024, the Company had several 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 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 consolidated balance sheet. The Company received $0.4 million in a tenant improvement allowance that was applied against the right-of-use asset.

As of December 31, 2024, the Company's headquarters lease had a weighted-average remaining lease term of 7.0 years and weighted average incremental borrowing rate of 7.5%.

Amounts reported in the consolidated balance sheet for leases where the Company is the lessee as of December 31, 2024 and December 31, 2023 were as follows (in thousands):

	December 31,	
	2024	2023
Assets:		
Operating lease right-of-use assets	$ 5,722	$ 6,301
Total operating lease right-of-use assets	$ 5,722	$ 6,301
Liabilities:		
Current:		
Operating lease liabilities	$ 612	$ 538
Noncurrent:		
Operating lease liabilities, net of current portion	5,636	6,248
Total operating lease liabilities	$ 6,248	$ 6,786

The following table summarizes operating lease costs for the years ended December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Fixed lease costs	$ 1,029	$ 999
Variable lease costs	43	73
Total lease costs	$ 1,072	$ 1,072

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 consolidated statements of operations. Future minimum lease payments under non-cancelable lease agreement as of December 31, 2024 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	$ 1,060
2026	1,092
2027	1,124
2028	1,158
2029	1,193
Thereafter	2,494
Total minimum lease payments	8,121
Less imputed interest	(1,873)
Total lease liability	$ 6,248
Lease liability, current portion	612
Lease liability, net of current portion	5,636
Total	$ 6,248

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. During the first quarter of 2024, prior to the Merger, Homology had fully abandoned the space and accordingly, had shortened the remaining useful of its right-of-use asset to equal the time remaining until the planned abandonment date. At the effective time of the Merger, the Company recorded a liability of approximately $1.0 million representing the present value of the future minimum lease payments due under

this sublease. As of December 31, 2024, there are no future lease payments due under the Homology sublease and therefore no liability on the Company's consolidated balance sheet.

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 years ended December 31, 2024 and 2023, the Company had zero research and development expense for any milestone related to the Colorado License Agreement. The financial statements as of December 31, 2024 and 2023 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 6,628,788 Series A preferred shares to BMS and agreed to use commercially reasonable efforts to develop and commercialize at least one licensed product in key geographic markets. In addition, the Company agreed to pay BMS (i) development and regulatory milestone payments in aggregate amounts ranging from $32 million to $49 million per indication for the first three indications and commercial milestone payments in an aggregate amount of up to $215 million on net sales of licensed products, (ii) tiered royalties ranging from rates in the mid-single digit percentages to up to 10% of net sales, with increasing rates depending on the cumulative net sales, (iii) up to 60% of sublicense income, which percentage decreases based on the development stage of

bempikibart at the time of the sublicensing event, and (iv) ongoing fees associated with the prosecution, maintenance, or filing of the licensed patents.

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

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

In July 2024, the Company made a $4.0 million development milestone payment to BMS and recorded it as research and development expenses. As of December 31, 2024, 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

On December 11, 2020, the Company entered into a Loan and Security Agreement with Silicon Valley Bank, a California corporation ("Loan Agreement") for a lending facility of up to $25 million. The Company received $5.0 million upon execution of the Agreement ("2020 Term A Loan Advance") and had the ability to draw up to $20.0 million in three separate term loan advances if certain performance milestones are met. The term loan bears interest at an annual rate equal to the greater of the prime rate or 3.25%. The Loan Agreement provides for interest-only payments until April 30, 2022, and repayment of the aggregate outstanding principal balance of the term loan in monthly installments starting on July 1, 2022 through December 1, 2023. The commencement of principal payments and the maturity date will be deferred by one year upon the occurrence of a contingent event. In addition, the Company paid a fee of $0.1 million upon closing and is required to pay a fee of 2.0% of the aggregate

amount of advances under the Loan Agreement at maturity. At its option, the Company may elect to prepay all or a portion of the outstanding advances by paying the principal balance, and all accrued and unpaid interest, and a prepayment premium. In connection with the Loan Agreement, the Company granted the lender a security interest in all of its personal property now owned or hereafter acquired, excluding intellectual property (but including the rights to payment and proceeds from the sale, licensing or disposition of intellectual property), and a negative pledge on intellectual property. The Loan Agreement also contains certain events of default, representations, warranties and non-financial covenants of the Company. If the Company fails to make payments when due or breaches any operational covenant or has any event of default, this could have a material adverse effect on its business and financial condition. The Company was in compliance with all covenants at December 31, 2024.

On June 30, 2022, a second amendment to the Loan Agreement was entered into with the lender that extended the interest-only payment until December 31, 2022 followed by 24 equal monthly payments of principal plus interest, with a loan maturity date of December 31, 2024. The amendment increased the final payment from 2.0% to 4.0% of the advanced payment and modified the prepayment premium.

On August 10, 2022, a third amendment to the Loan Agreement was entered into with the lender. Per the terms of the amendment and in conjunction with the Collaboration Agreement (as defined below), the Company transferred $5.0 million into a restricted cash collateral money market account which is included as Restricted cash and restricted cash equivalents on the balance sheet. This restricted cash equivalent covers the amount of the debt outstanding as of the third amendment effective date.

On December 21, 2022, a fourth amendment to the Loan Agreement was entered into with the lender that extended the interest-only payment until July 1, 2023 followed by 18 equal monthly payments of principal plus interest, with a loan maturity date of December 1, 2024.

On April 26, 2023, a fifth amendment to the Loan Agreement was entered into with the lender. The amendment provides that the Company must maintain at least 50% of its consolidated cash with the lender. In addition, the Company shall at all times have on deposit in operating and depository accounts maintained with the lender, unrestricted and unencumbered cash in an amount equal to the lesser of (i) 100% of the dollar value of the Company's consolidated cash and (ii) 110% of the then-outstanding obligations of the Company to the bank. So long as the Company is in compliance with those terms, the Company shall be permitted to maintain accounts with other banks or financial institutions.

On July 12, 2023, a sixth amendment to the Loan Agreement was entered into with the lender. The amendment provides for one term loan advance (the "2023 Term A Loan Advance") in an original principal amount of $5.5 million and required the Company to repay the outstanding 2020 Term A Loan Advance of $5.0 million, including the final payment of $0.2 million. Upon the occurrence of a contingent event, the lender shall make up to three additional term loan advances at the Company's request in original principal amounts of $7.0 million, $7.5 million and $5.0 million. The amounts must be drawn by the Company before March 31, 2024, March 31, 2025 and July 1, 2025, respectively. The interest-only period was extended through June 30, 2024 followed by 36 equal monthly payments of principal plus interest. The term loan bears interest at an annual rate equal to the greater of the prime rate minus 0.25% or 8.00%.

On November 2, 2023, a seventh amendment to the Loan Agreement was entered into with the lender. The additional loan advance of $7.0 million, the first advance stated in the sixth amendment to the Loan Agreement, could be drawn down once the company received net cash proceeds of at least $75.0 million from (a) the issuance and sale of its equity securities to investors satisfactory to the lender and/or (b) a business development transaction satisfactory to the lender; provided that, at least, $37.5 million of such net cash proceeds must be received from the issuance and sale of equity securities to investors satisfactory to the lender. The seventh amendment extended the time the Company has to receive the net proceeds to March 31, 2024.

On March 21, 2024, an eighth amendment to the Loan Agreement was entered into with the lender. The eighth amendment extended the time the Company had to receive the net proceeds to May 31, 2024 and also extended the time the Company could draw down on the first advanced payment of $7.0 million from March 31, 2024 to May 31, 2024. The date changes were adjusted to align the milestone in the Loan Agreement with the closing of the Merger. On March 26, 2024, the Company received the first advance payment of $7.0 million per the terms of the Loan Agreement.

On July 19, 2024, a ninth amendment to the Loan Agreement was entered into with the lender that extends the interest-only period through July 1, 2025 followed by 24 equal monthly payments of principal plus interest. The loan matures on July 1, 2027.

In conjunction with the Loan Agreement, 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. The warrants had a total relative fair value of $39 thousand upon issuance and were recorded as a debt discount.

In conjunction with the sixth amendment, the Company issued 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 were issued in two separate tranches of 5,078 based upon certain milestone events. 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 $1.1 million and $0.5 million for the years ended December 31, 2024 and 2023, respectively. The effective rate on the Loan Agreement, including the amortization of the debt discount and issuance costs was 9.55% and 10.42%, respectively, at each of December 31, 2024 and 2023. The components of the long-term debt balance are as follows (in thousands):

	December 31,	
	2024	2023
Principal amount of term loans	$ 12,500	$ 5,500
Unamortized debt discount and issuance costs	153	(41)
Carrying amount	12,653	5,459
Less current portion	(3,097)	(878)
Long-term debt, net	$ 9,556	$ 4,581

Convertible Notes

On May 20, 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 bear 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 $0.3 million and $1.5 million for the years ended December 31, 2024 and 2023, respectively. 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 contain mandatory conversion features whereby the total outstanding amount of principal and accrued and unpaid interest of the Convertible Notes shall automatically convert 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. If the mandatory conversion events do not occur the holders of the Convertible Notes may request the Convertible Notes plus accrued interest be converted into Series B preferred stock at the Series B convertible price of $1.0971.

The Company elected to account for the Convertible Notes at fair value where changes in fair value of the notes are measured through the consolidated statements of operations until settlement. Subsequent to December 31, 2023 and per the Merger further discussed in Note 1, the Convertibles Notes converted into 1,433,410 shares of common stock. The Company recorded a gain on the change in fair value prior to the conversion of the Convertible Notes of $15.9 million in other income (expense), net during the year ended December 31, 2024.

As the Convertible Notes were settled with equity securities subsequent to December 31, 2023 but prior to the issuance of the financial statements, per FASB ASC Topic 470, *Debt*, the Company recorded the Convertible Notes at the fair value totaling $38.6 million as a long-term liability on its consolidated balance sheet as of December 31, 2023. The Company recorded in other income (expense), net interest expense of $1.5 million and a charge of $4.7 million related to the change in estimated fair value during the year ended December 31, 2023.

12. Convertible Preferred Stock

On March 25, 2024, immediately prior to completing the Merger, all classes of convertible preferred stock of Legacy Q32 were converted to Legacy Q32 common stock, and then exchanged in the Merger for shares of the Company's common stock using the Exchange Ratio. The Series A convertible preferred stock converted into an aggregate of 2,286,873 shares of Legacy Q32 common stock, the Series A-1 convertible preferred stock converted into an aggregate of 312,094 shares of Legacy Q32

common stock and the Series B convertible preferred stock converted into an aggregate of 2,625,896 shares of Legacy Q32 common stock. The conversion of the Legacy Q32 preferred stock into shares of Legacy Q32 common stock resulted in an increase of less than $0.1 million to common stock and an increase of $111.4 million to additional paid-in-capital immediately prior to completing the Merger.

13. Common Stock

As of December 31, 2024, the Company's Certificate of Incorporation, as amended, authorized the Company to issue 400,000,000 shares of common stock, $0.0001 par value per share.

The Company has reserved the following shares of common stock for future issuance:

	December 31,	
	2024	2023
Shares reserved upon the conversion of authorized Series A preferred stock	—	2,286,873
Shares reserved upon the conversion of authorized Series A-1 preferred stock	—	312,094
Shares reserved upon the conversion of authorized Series B preferred stock	—	2,625,896
Shares reserved for future issuance under the 2017 Stock Incentive Plan	—	56,065
Shares reserved for future issuance under the 2024 Stock Incentive Plan	1,760,657	—
Shares reserved for future issuance under the 2024 Employee Stock Purchase Plan	120,836	—
Shares reserved upon the conversion of the convertible notes	—	1,433,411
Shares reserved for stock option exercises	1,942,920	1,112,275
Shares reserved for warrants	18,144	18,144
	3,842,557	7,844,758

14. Stock-Based Compensation

2017 Stock Option and Grant Plan

Legacy Q32 adopted the 2017 Stock Option and Grant Plan and subsequent amendments (the "2017 Plan") with 1,246,290 shares of common stock reserved for issuance to employees, directors, and consultants. The 2017 Plan allowed for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock awards. As of December 31, 2024, there were no additional shares available for future grant under the 2017 Plan.

2024 Stock Option and Incentive Plan

On March 15, 2024, Homology's board of directors adopted and subsequently, Homology's stockholders approved the Q32 Inc. 2024 Stock Option and Incentive Plan (the "2024 Plan"), which became effective upon the closing of the Merger. The 2024 Plan replaced the 2017 Plan, as well as the Homology 2015 Stock Incentive Plan (the "Homology 2015 Plan"), and the Homology 2018 Plan (together with the Homology 2015 Plan, the "Homology Incentive Plans.") Upon effectiveness of the 2024 Plan, the Company ceased granting new awards under the 2017 Plan and the Homology Incentive Plans.

The 2024 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock or cash-based awards to officers, employees, directors and consultants of the Company. The number of shares of common stock initially available for issuance under the 2024 Plan was 2,839,888 shares of common stock. The 2024 Plan provides that the number of shares reserved and available for issuance under the 2024 Plan will automatically increase each January 1, beginning on January 1, 2025, by 5% of the outstanding number of shares on the immediately preceding December 31, or such lesser amount as determined by the plan administrator. As of December 31, 2024, there were 1,760,657 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.

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 year ended December 31, 2024.

Stock Options

Stock options granted by the Company typically vest over a four-year period and have a ten-year contractual term. The following table summarizes the Company's stock option activity during the year ended December 31, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	1,112,275	$ 7.50	6.87	$ 10,712
Assumed in reverse recapitalization	32,685	$ 7.56		
Granted	1,071,073	$ 17.27		
Exercised	(255,486)	$ 6.81		
Cancelled	(17,627)	$ 17.63		
Outstanding at December 31, 2024	1,942,920	$ 12.93	8.33	$ 12,380
Vested and expected to vest at December 31, 2024	1,942,920	$ 12.93	8.33	$ 12,380
Exercisable at December 31, 2024	673,356	$ 8.43	7.04	$ 12,380

The per share weighted-average grant date fair value per share of options granted in the year ended December 31, 2024 was $12.42. The total fair value of options vested during the year ended December 31, 2024 was $2.4 million. As of December 31, 2024, total unrecognized compensation costs to the unvested stock options were approximately $12.6 million, which is expected to be recognized over a weighted-average period of 2.7 years. The total intrinsic value of options exercised during the year ended December 31, 2024 was $7.0 million.

Stock-Based Compensation Expense

For the purpose of calculating stock-based compensation, the Company estimates the fair value of stock options using the Black-Scholes option-pricing model. This model incorporates various assumptions, including the expected volatility, expected term, and interest rates.

The underlying assumptions used to value stock options granted using the Black-Scholes option-pricing model during the years ended December 31, 2024 and 2023 were as follows:

	Years Ended December 31,	
	2024	2023
Risk-free interest rate range	3.48% - 4.34%	3.59% - 4.67%
Expected dividend rate	—	—
Expected term (years) range	5.17 - 6.11	5.08 - 6.12
Expected stock price volatility range	92.0% - 94.1%	88.9% - 94.0%

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.

The Company recorded stock-based compensation expense in the following expense categories of its statements of operations (in thousands):

	Years Ended December 31,	
	2024	2023
Research and development	$ 1,105	$ 500
General and administrative	3,281	928
Total stock-based compensation expense	$ 4,386	$ 1,428

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 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, 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 years ended December 31, 2024 and 2023 related to services provided by these investors and board members.

No amounts were due to related parties at December 31, 2024 or December 31, 2023.

17. Defined Contribution Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code (the 401(k) Plan). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants the option to elect to defer a portion of their annual compensation on a pretax basis, as well as Roth post tax deferrals. As currently designed, the Company is not required to make and has not made any contributions to the 401(k) Plan.

18. Income Taxes

For the years ended December 31, 2024 and 2023, the Company recorded current and deferred income tax expense of less than $0.1 million and $0.3 million, respectively. The Company’s effective tax rate of 0% differs from the U.S. statutory tax rate of 21% primarily as a result of the valuation allowance maintained against the Company’s net deferred tax assets.

For financial reporting purposes, loss from operations before income taxes includes the following components (in thousands):

	Years Ended December 31,	
	2024	2023
Pretax loss:		
United States	$ (47,716)	$ (53,430)
Foreign	4	5
Loss before provision for income taxes	$ (47,712)	$ (53,425)

The components of the Company's provision for income taxes are as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Current:		
Federal	$ —	$ 316
State	20	1
Foreign	1	1
Total current	21	318
Total income tax provision	$ 21	$ 318

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	Years Ended December 31,	
	2024	2023
Federal income tax expense at statutory rate	21.0 %	21.0 %
State income taxes, net of federal benefit	9.1	5.9
Permanent differences	(0.8)	(1.0)
Stock-based compensation expense	1.3	(0.2)
Gain/loss on convertible note conversion	7.1	—
Convertible note revaluation	0.7	(1.8)
Research and development tax credits	3.8	3.1
Change in valuation allowance	(42.2)	(27.6)
Effective income tax rate	— %	(0.6)%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities consisted of the following (in thousands):

	2024	2023
Deferred tax assets:		
Federal net operating loss carryforwards	$ 25,468	$ 13,412
State net operating loss carryforwards	7,086	3,500
Contingent liability	14,801	14,876
Accruals and reserves	743	818
Capitalized intangible assets	3,591	2,828
Tax credit carryforwards	7,978	5,762
Capitalized R&D expenditures	46,552	13,546
Lease liability	1,682	1,835
Stock compensation and other	733	544
Total gross deferred tax assets before valuation allowance	108,634	57,121
Less: Valuation allowance	(106,876)	(55,078)
Net deferred tax assets	1,758	2,043
Deferred tax liabilities:		
Fixed assets	(218)	(339)
Right of use asset	(1,540)	(1,704)
Net deferred tax assets	$ —	$ —

The Company had gross deferred tax assets before valuation allowances of $108.6 million and $57.1 million as of December 31, 2024 and 2023, respectively, principally attributable to net operating losses, the contingent liability and capitalized R&D expenditures. The Company has provided a valuation allowance for the full amount of the deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. The Company recorded an increase to the valuation allowance of $51.8 million during the year ended December 31, 2024 as a result of the 2024 book losses and the Merger with Homology.

As of December 31, 2024, the Company has $121.3 million of federal net operating loss carryforwards which can be carried forward indefinitely, and $112.1 million of state net operating loss carryforwards that expire at various dates beginning in 2040.

Subject to the limitations described below, as of December 31, 2024, the Company had federal and state research and development tax credit carryforwards of $6.2 million and $2.3 million, respectively available to reduce future tax liabilities which start to expire in 2038. The Company has generated federal and state research and development credits but has not conducted a study to document the qualified activity. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 of the Internal Revenue Code, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382 of the Internal Revenue Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term-tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitations may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company files income tax returns in the United States, Australia and Massachusetts. The statute of limitations for assessment by the IRS and state tax authorities is closed prior to 2021, although carryforward attributes that were generated prior to tax year 2021 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. The Company is currently not under examination by the IRS or any other jurisdictions for any tax years. The statute of limitations for assessment by the Australian Taxation Office is four years from the date of return filing. The Company is not currently under examination by the Australian Taxation Office for any tax years.

The Company's current intention is to permanently reinvest the total amount of its unremitted earnings in the local international jurisdiction. As such, the Company has not provided for taxes on the unremitted earnings of its international subsidiary. As of December 31, 2024, the Company's foreign subsidiary does not have any unremitted foreign earnings.

The Company establishes reserves for uncertain tax positions based on management's assessment of exposures associated with tax positions taken on tax return filings. The tax reserves are analyzed periodically, and adjustments are made as events occur to warrant adjustments to the reserve.

As of December 31, 2024, the Company had no gross unrecognized tax benefits. The Company does not expect the unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes both interest and penalties associated with uncertain tax positions as a component of income tax expense. As of December 31, 2024, the Company has no accrued penalties and provisions for interest.

19. Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the applicable period. In computing diluted net income (loss) per share, only potential shares of common stock that are dilutive are included. The Company considered each issue or series of issues of potential shares of common stock separately when determining whether potential shares of common stock are dilutive or antidilutive. The Company made such determination in sequence from the most dilutive to the least dilutive and concluded that its Convertible Notes are dilutive to net income per share for the year ended December 31, 2024. Pursuant to FASB ASC Topic 260, *Earnings Per Share*, the Company applied the if-converted method to determine the effect of its Convertible Notes on the diluted earnings per share calculations. Pursuant to such method, the Company adjusted the numerator for the gains or losses recognized during the period

in net income from the Convertible Notes and the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the Convertible Notes were converted as of the beginning the period.

(in thousands, except per share amounts)	Years Ended December 31, 2024	2023
Numerator:		
Net income (loss)-basic	$ (47,733)	$ (53,743)
Net income (loss)-diluted	$ (63,533)	$ (53,743)
Denominator:		
Weighted-average common shares outstanding-basic	9,320,884	349,060
Dilutive securities	336,812	—
Weighted-average common shares outstanding-diluted	9,657,696	349,060
Net income (loss) per share-basic	$ (5.12)	$ (153.96)
Net income (loss) per share-diluted	$ (6.58)	$ (153.96)

As of December 31, 2024, the Company's potentially dilutive securities, which include stock options and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. As of December 31, 2023, the Company's potentially dilutive securities, which include convertible preferred stock, convertible notes, stock options and warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Years Ended December 31, 2024	2023
Series A convertible preferred stock	—	2,286,874
Series A-1 convertible preferred stock	—	312,094
Series B convertible preferred stock	—	2,625,897
Options to purchase common stock	1,942,920	1,120,014
Warrants to purchase common stock	18,145	18,145

In addition, during the year ended December 31, 2022, Legacy Q32 issued the Convertible Notes with a principal balance of $30.0 million. As described in Note 11, the Convertible Notes contained conversion features whereby the Convertible Notes and any accrued interest may have converted into either a variable number of shares of common stock or into shares of Series B preferred stock based on a fixed exchange ratio. Any shares of Series B preferred stock issued to settle the Convertible Notes would then be convertible into shares of common stock. The Convertible Notes were excluded from the computation of diluted net loss per share attributable to common stockholders for the year ended December 31, 2023, because including them would have had an anti-dilutive effect. Per the Merger further discussed in Note 1, the Convertible Notes converted into 1,433,410 shares of common stock at the effective date of the Merger.

20. Segment Reporting

The Company operates as one operating segment, focused on research, development, and discovering, developing and delivering therapies for its novel biologics. The Company's CEO, as the chief operating decision maker ("CODM"), manages and allocates resources to the operations of the Company on a consolidated basis. Managing and allocating resources on a total-company basis enables the CODM to assess the overall level of resources available and how to best deploy those resources across research and development projects that are in line with our long-term company-wide strategic goals. Consistent with this decision-making process, the Company's 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 years ended December 31, 2024 and 2023:

	Years Ended December 31,	
	2024	2023
	(in thousands)	
Direct research and development expense by program:		
Bempikibart	$ 28,726	$ 11,722
ADX-097	5,253	7,185
Discovery and other	856	894
Personnel-related costs (excluding stock-based compensation)	16,122	13,166
Other G&A expenses	9,586	5,824
Interest (income) expense, net	(2,832)	(693)
Other segment items (1)	(9,978)	15,645
Total segment net loss	$ 47,733	$ 53,743

(1) Other segment items are included in order to reconcile to total segment net 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. In 2023, other segment items also includes the reversal of collaboration arrangement revenue related to the termination of the Horizon Agreement (see Note 15).

21. Subsequent Events

Strategic Restructuring

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 is discontinuing 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 includes 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 expects to incur severance and severance-related charges of approximately $1.1 million. The Company 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.

Option Repricing

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 1,904,998.

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.

Pursuant to the Plans, the Company's board of directors, as the administrator of the Plans, has discretionary authority, exercisable on such terms and conditions that it deems appropriate under the circumstances, to reduce the exercise price in effect for or effect repricing through cancellation and re-grants of outstanding options under the Plans. In approving the Option Repricing, the board of directors considered the impact of the Original Price of outstanding stock options on the incentives provided to employees and directors, the lack of retention value provided by the outstanding stock options to employees and directors, and the impact of such options on the capital structure of the Company.

The Company expects that the Option Repricing will result in additional share-based compensation expense that will be recognized in the Company's statements of operations in future periods; however, the amount of additional share-based compensation expense and the periods over which it will be recognized have not yet been determined.

Exercise of Call Option by OXB (US) LLC

As discussed in Notes 1 and 3, at the effective time of the merger with Homology, 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 representing the contractual right to receive cash payments, if any, from the combined company upon the receipt of certain proceeds, net of permitted deductions for expenses incurred in connection with pre-merger Homology assets, from a disposition of Homology's pre-merger assets, including any equity interests held directly or indirectly by the Company in 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.

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Chief Executive Officer

Lee Kalowski
Chief Financial Officer and President

Jason Campagna, M.D., Ph.D.
Chief Medical Officer

Shelia Violette, Ph.D.
Chief Scientific Officer

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STOCK EXCHANGE INFORMATION
Q32 Bio Inc., or Q32, stock is publicly traded on the Nasdaq Capital Market under the trading symbol: QTTB

ANNUAL MEETING
Q32's annual meeting of stockholders will be held virtually via the internet, at:
9:00 a.m., Eastern Time
June 13, 2025
www.virtualshareholdermeeting.com/QTTB2025

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Kathleen LaPorte
Pharmaceutical Executive (Former)

Bill Lundberg, M.D.
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Arthur Tzianabos, Ph.D.
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Lifordi Immunotherapeutics, Inc.
Venture Partner
5AM Ventures