Filed Pursuant to Rule 424(b)(3)
Registration No. 333-278829

PROSPECTUS

Up to 1,682,045 Shares of Common Stock

This prospectus relates to the proposed offer and resale or other disposition from time to time by the selling stockholders identified in this prospectus of up to an aggregate of 1,682,045 shares of common stock, par value $0.0001 per share, of Q32 Bio Inc.

We are registering the resale of the shares of common stock pursuant to the selling stockholders' registration rights under a registration rights agreement between us and the selling stockholders. Our registration of the resale of the shares of common stock covered by this prospectus does not mean that the selling stockholders will offer or sell all or any of the shares of common stock. The selling stockholders may offer, sell or distribute all or a portion of their shares of common stock from time to time directly or indirectly through one or more underwriters, broker-dealers or agents, and in one or more public or private transactions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. See the section entitled "*Plan of Distribution*" for more information.

We will not receive any proceeds from any sale of common stock by the selling stockholders pursuant to this prospectus. We have agreed to bear the expenses in connection with the registration of the resale of the shares of common stock to be offered by this prospectus by the selling stockholders other than any underwriting discounts and commissions or transfer taxes relating to the sale of common stock, which will be borne by the selling stockholders.

Our common stock is listed on the Nasdaq Stock Market, or Nasdaq, under the symbol "QTTB." On April 26, 2024, the closing price for our common stock, as reported on Nasdaq, was $28.02 per share.

See the section entitled "Risk Factors" beginning on page 8 of this prospectus to read about factors you should consider before buying our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 29, 2024.

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You should rely only on the information provided in this prospectus, as well as the information incorporated by reference to exhibits to the registration statement of which this prospectus forms a part and any applicable prospectus supplement or amendment. Neither we nor the Selling Securityholders have authorized anyone to provide you with different information. Neither we nor the Selling Securityholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the applicable document. Since the date of this prospectus and the documents filed as exhibits to the registration statement of which this prospectus forms a part, our business, financial condition, results of operations and prospects may have changed.

ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the caption "Selling Stockholders," from time to time, of up to an aggregate of 1,682,045 shares of common stock. We are not selling any shares of common stock under this prospectus, and we will not receive any proceeds from the sale of shares of common stock offered hereby by the Selling Stockholders.

Neither we, nor the selling stockholders, have authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any shares other than the registered shares to which it relates, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy shares in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or shares are sold on a later date. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus incorporates by reference market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included or incorporated by reference in this prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" contained in this prospectus, and under similar headings in other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

A prospectus supplement may add to, update or change the information contained in this prospectus. You should read both this prospectus and any applicable prospectus supplement together with additional information described below under the heading "Where You Can Find Additional Information" or incorporated by reference herein as described under the heading "Incorporation of Certain Information by Reference."

Unless the context otherwise indicates, references in this prospectus to "Company," "we," "our" and "us" refer, collectively to Q32 Bio Inc., a Delaware corporation, and its consolidated subsidiaries (including Legacy Q32).

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains and/or incorporates by reference 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. Our 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 prospectus may include, for example, statements about:

- our strategies, prospects, plans, expectations or objectives of management for our future operations;
- our 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 ADX-097, and our anticipated milestones and timing therefor;
- 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 protect our intellectual property rights;
- our anticipated operations, financial position, ability to raise capital to fund our operations, revenues, costs or expenses; and
- the statements regarding our future economic conditions or performance, statements of belief and any statement of assumptions underlying any of the foregoing.

These forward-looking statements are based on information available to us at the time of this prospectus or the documents incorporated by reference herein 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 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 prospectus in the section entitled "Risk Factors" and in our periodic filings with the Securities and Exchange Commission, or 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. Additional cautionary statements or discussions of risks and uncertainties that could affect our results or the achievement of the expectations described in forward-looking statements may also be contained in any accompanying prospectus supplement. Should one or more of the risks or uncertainties described in this prospectus, or should underlying assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements.

You should read this prospectus and any accompanying prospectus supplement if any, completely and with the understanding that our actual future results, levels of activity and performance as well as other events and circumstances may be materially different from what we expect. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this prospectus. We qualify all of our forward-looking statements by these cautionary statements.

PROSPECTUS SUMMARY

Our Company

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 the 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 the body's first line of defense employing leukocytes 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 it to build a broad and diverse pipeline in the long term. We have multiple product candidates across a variety of autoimmune and inflammatory diseases with clinical readouts for our two lead programs expected in 2024 and 2025.

Bempikibart (ADX-914), our most advanced product candidate, is a fully human anti–interleukin-7 receptor alpha antagonist monoclonal antibody designed to re-regulate adaptive immune function by blocking signaling mediated by interleukin-7 and thymic stromal lymphopoietin. Bempikibart is being studied in two double-blind, placebo-controlled Phase 2 clinical trials designed to establish proof of clinical concept and evaluate our selected Phase 2 dose. One trial is evaluating the use of bempikibart for the treatment of atopic dermatitis and one is evaluating bempikibart for the treatment of alopecia areata. Enrollment in both clinical trials remains ongoing and we remain on track to report topline data from both Phase 2 clinical trials in the second half of 2024.

ADX-097, the lead product candidate from our complement inhibitor platform, is a humanized anti-C3d monoclonal antibody 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. We are developing ADX-097 for the treatment of renal and other complement-mediated diseases of high unmet need, including lupus nephritis, immunoglobulin A nephropathy, complement component 3 glomerulopathy and anti-neutrophil cytoplasmic antibody-associated vasculitis. We have completed a Phase 1 clinical trial of ADX-097 in healthy volunteers. We expect to initiate an open-label Phase 2 renal basket program in the first half of 2024, with initial data expected by year-end 2024, and initiate a Phase 2 clinical trial in AAV, with topline data from both the renal basket and AAV trials anticipated in the second half of 2025.

In addition to ADX-097, we are also engaged in additional pipeline efforts to expand therapeutic opportunities within complement-mediated diseases.

Our development pipeline is shown in the figure below.

Note: AAV = Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis; IgAN = IgA Nephropathy; LN = Lupus Nephritis; C3G = C3 Glomerulopathy.

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 are described more fully in the section entitled "Risk Factors," following this prospectus summary. These risks include the following, among others:

- We have incurred significant losses since inception, expects 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, has 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 has 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 it plans to address with bempikibart, ADX-097 or other product candidates.
- Bempikibart, ADX-097 and 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 candidates, bempikibart and ADX-097, and our clinical trials of such candidates may not be successful.
- Our business relies on certain licensing rights from Bristol Myers Squibb Company, or BMS, that can be terminated in certain circumstances. If we breach the BMS License Agreement, or if we are unable to satisfy our obligations under which we license intellectual property from BMS, we could lose the ability to develop and commercialize bempikibart.
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.
- We and our independent registered public accounting firm have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or 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.
- The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.
- We may incur losses for the foreseeable future and might never achieve profitability.
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.
- We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

Corporate Information

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 https://www.q32bio.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. Our common stock is listed on Nasdaq Global Market under the symbol "QTTB."

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of the common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

The Offering	
Issuer	Q32 Bio Inc.
Common stock Offered by the Selling Stockholders	1,682,045 shares of common stock
Use of Proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus. See the section titled "*Use of Proceeds*" appearing elsewhere in this prospectus for more information.
Nasdaq Symbol	QTTB
Offering Price	The selling stockholders will offer the shares of common stock offered by this prospectus at the prevailing market prices or at privately negotiated prices.
Risk Factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

For additional information concerning the offering, see "Plan of Distribution" beginning on page 208.

RISK FACTORS

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto, and the other financial information concerning us included elsewhere in this prospectus. Additionally, the risks and uncertainties described in this prospectus or any prospectus supplement are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

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, expects 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, has 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 significant net losses in each period since we commenced operations in 2017. Our net losses were $53.7 million and $42.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and December 31, 2022, we had an accumulated deficit of $187.1 million and $133.3 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 our 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 (ADX-914) and ADX-097, initiate additional clinical trials, and continue to research, develop and conduct preclinical studies of our other potential product candidates, and begin to operate as a public company. In addition, if we obtain regulatory approval for any product candidate for commercial sale, including bempikibart or ADX-097, 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 mid-2026. This estimate is based on assumptions that may prove to be materially 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 trials for bempikibart in atopic dermatitis, or AD, and alopecia areata, or AA, our planned

renal basket program in lupus nephritis, or LN, immunoglobulin A, or IgA, nephropathy, or IgAN and complement component 3 glomerulopathy, or C3G, and our planned Phase 2 clinical trial for ADX-097 in anti-neutrophil cytoplasmic antibody, or ANCA, -associated vasculitis, or AAV;

- 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 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 has 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 has 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 it plans to address with bempikibart, ADX-097 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, ADX-097 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, ADX-097 or other product candidates.

Our competitors have developed, are developing or may develop programs and processes competitive with bempikibart, ADX-097 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, ADX-097 and 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, ADX-097 and 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, ADX-097 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, ADX-097 or any other product candidates, including:

- regulators or Institutional Review Board, 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;
- 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, ADX-097 or any other product candidates. We or our current or future collaborators' inability to complete development of, or commercialize, bempikibart, ADX-097 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 candidates, bempikibart and ADX-097, and our clinical trials of such candidates 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 candidates, bempikibart and ADX-097. We are investing a majority of our efforts and financial resources into the research and development of these candidates. 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 2 clinical trials in atopic dermatitis and alopecia areata. Both trials are currently in the dosing phase, and we expect to complete both studies in the second half of 2024. 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 have completed a Phase 1 clinical trial of ADX-097 in healthy volunteers and, pending clearance of any regulatory approvals, we anticipate initiating a renal basket program in LN, IgAN, C3G in the first half of 2024

and a Phase 2 clinical trial in AAV in the first quarter of 2025. The success of ADX-097 may depend on having a comparable safety and efficacy profile and a more convenient dosing schedule (i.e., less frequent dosing) with patient-friendly administration (i.e., SC self-administration) to products currently approved or in development for the indications we plan to pursue.

Bempikibart and ADX-097 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 these product candidates, or any other 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 and ADX-097 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 these candidates, even if approved. If we are not successful in commercializing bempikibart or ADX-097, 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, ADX-097 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 refers 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, ADX-097 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 and ADX-097 leverages the understanding of complement and cytokine 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. ADX-097 is purposefully designed to improve upon currently approved complement inhibiting products by providing inhibition of complement in a tissue-targeted manner. However, the scientific research that forms the basis of efforts to develop bempikibart and ADX-097 is ongoing and has not been successfully proven in clinical trials. The long-term safety and exposure profile of bempikibart and ADX-097 is also unknown.

We may ultimately discover that our technologies for our specific targets and indications and bempikibart, ADX-097 or any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness we currently has only data from our Phase 1 clinical trial and blinded data from our Phase 2 Part A AD clinical trial 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, ADX-097 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. If the products resulting from bempikibart, ADX-097 or any other product candidates prove to be ineffective, unsafe or commercially unviable, our product candidates and pipeline may have little, if any, value, which may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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 contract development and manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; 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 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, ADX-097 or any other product candidates beyond those that we contemplate, if we are unable to successfully complete clinical trials of bempikibart, ADX-097 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, ADX-097 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, ADX-097 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, ADX-097 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, ADX-097 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, including bempikibart or ADX-097. 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, ADX-097 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, ADX-097 or any other product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from bempikibart, ADX-097 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, ADX-097 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, ADX-097 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, ADX-097 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 or ADX-097, 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 are initially focused on our most advanced product candidates, bempikibart and ADX-097. As a result, we may forgo or delay pursuit of opportunities with other potential candidates that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such candidate.

Even if regulatory approval is obtained, any approved products resulting from bempikibart, ADX-097 or any other product candidate 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, ADX-097 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 LN, IgAN, C3G, AAV, AD and 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 or ADX-097 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 is or our existing or future collaborators. Market acceptance of bempikibart, ADX-097 or any other product candidates will depend on many factors, including factors that are not within the control of us.

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, ADX-097 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. Assuming regulatory authorities allow our proposed clinical trials for ADX-097 to proceed after review of our IND or CTA submissions, we intend to initiate a renal basket program in LN, IgAN and C3G and a Phase 2 clinical trial in AAV. However, we may not be able to initiate our planned clinical trials for ADX-097 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.

For example, upon submission of our IND or CTA for our planned clinical trials for ADX-097, 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 our predicted timeline 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 candidates bempikibart and ADX-097. 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, CMOs, 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 the 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 we 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 our. 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 our 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 has 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 EU 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 prevails 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 have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously or concurrently worked for 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 has 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. 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 it 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 candidates, bempikibart and ADX-097, 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, ADX-097 or other product candidates, which would significantly harm our business, results of operations and prospects.

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.

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.

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 and may in the future choose to conduct clinical trials for ADX-097 or other 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. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. 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, ADX-097 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, ADX-097 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 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, ADX-097 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, ADX-097 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 "*Our Business-Government Regulation-Healthcare Reform*" elsewhere in this prospectus 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 "*Our Business-Government Regulation-Other Healthcare Laws and Compliance Requirements*" elsewhere in this prospectus 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, ADX-097 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, ADX-097 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 prospectus 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 EU Member States , 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 EU 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. 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 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 the FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of regulatory approval be submitted to the Agency for review during the pre-approval review period. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. 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. 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.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of employees' or consultants' former employers or their clients. These claims may be costly to defend and if we does not successfully do so, it may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or 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. Litigation may be necessary to defend against these

claims. If we fail in defending 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 these claims, litigation could result in substantial costs and be a distraction to management.

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 expects 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.

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 the proposed BIOSECURE Act, 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 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, ADX-097 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, ADX-097 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, ADX-097 or other product candidates will be harmed, and our business will be adversely affected. Moreover, even if we obtain approval of bempikibart, ADX-097 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, CMOs, 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, CMOs, 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 or 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, ADX-097 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 risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

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 "*Our Business-Government Regulation-Data Privacy and Security*" and "*Other Regulatory Matters*" in this prospectus 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 expands operations. Failure to successfully recruit and retain personnel could impact our anticipated development plans and timelines. We are dependent on the continued service of our technical personnel because of the highly technical and novel nature of our product candidates, platform and technologies and the specialized nature of the regulatory approval process. Replacing such personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully execute our business strategy, and we cannot assure you that we will be able to identify or employ qualified personnel for any such position on acceptable terms, if at all. Many of the biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. we do not maintain key person life insurance policies on any of our management team members or key employees. Our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in preclinical and clinical testing, manufacturing, governmental regulation and commercialization. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments may have a negative effect on our operating results. We face increased competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. If we are unable to attract and retain qualified personnel, the rate and success at which we may be able to discover and develop our product candidates and implement our business plan will be limited.

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

As of March 25, 2024, we had 37 full-time employees, including 4 who hold Ph.D. degrees and 3 who hold M.D. degrees, and no part-time employees; 27 employees are engaged in research and development and 10 employees in management or general and administrative activities. In connection with the growth and advancement of our pipeline and becoming 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 such as the COVID-19 pandemic, political crises, geopolitical events, such as 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. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. 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 ongoing 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 our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2023 and December 31, 2022, we had federal and state NOLs of $63.9 million and $91.1 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 our 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 2042. As of December 31, 2023, we had federal research and development tax credit carryforwards of $4.3 million that expire at various dates from 2041 through 2043. In addition, as of December 31, 2023, we had state research and development tax credit carryforwards of $1.8 million that expire at various dates from 2038 through 2043.

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.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

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. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

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 substantially all 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 plan to diversify 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 expect to assess 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 discussed in this proxy statement/prospectus lapse, the trading price of our common stock could decline. Based on shares outstanding as of March 25, 2024, after giving effect to the Pre-Closing Financing (as defined in the Merger Agreement), shares issued upon completion of the Merger and the Reverse Stock Split, we have a total of approximately 11.9 million 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.

Upon the completion of the Merger, and giving effect to the issuance of the Pre-Closing Financing, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 39.16% of our outstanding shares of common stock, subject to certain assumptions, including, but not limited to, Homology's net cash as of closing being equal to $61.3 million and Legacy Q32 issuing approximately $42.0 million of Legacy Q32 common stock in the Pre-Closing Financing. 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.

We have broad discretion in the use of our cash and cash equivalents and the proceeds from the Pre-Closing Financing 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 and the proceeds from the Pre-Closing Financing. You may not agree with our decisions, and our use of the proceeds 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 our cash resources.

Changes in tax laws or in their implementation or interpretation may adversely affect tour business and financial condition.

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. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

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.

Following the Merger, 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

As of the date of this proxy statement / prospectus, there are no pending lawsuits challenging the Merger. However, potential plaintiffs may file lawsuits challenging the Merger. The outcome of any future litigation is uncertain. Such litigation, if not resolved, could prevent or delay consummation of the Merger and result in substantial costs to us or Homology, including any costs associated with the indemnification of directors and officers. One of the closing conditions is the absence of any order or legal requirement that restrains, enjoins, or otherwise prevents the consummation of the Merger. Therefore, if a plaintiff were successful in obtaining an injunction prohibiting the consummation of the Merger on the agreed-upon terms, then such injunction may prevent the Merger from being consummated, or from being consummated within the expected time frame.

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

We will incur significant legal, accounting and other expenses as a public company that Legacy Q32 did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team will consist 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 will be 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 will qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, which allows the 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 proxy statement/prospectus and in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualifies 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 or 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 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 have identified a material weakness in its internal control over financial reporting. If Legacy Q32 is unable to remediate this material weakness, or 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.

Legacy Q32 has plans to implement measures designed to improve internal controls over financial reporting to remediate the control deficiencies that led to the material weakness, including strengthening reviews by its finance team, expanding its accounting and finance team to add additional qualified accounting and finance resources, which may include augmenting its finance team with third party consultants that possess the required expertise to assist management with its review.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has 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 our existing or 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.

USE OF PROCEEDS

This prospectus relates to the potential resale from time to time of some or all of 1,682,045 shares of our common stock. The selling stockholders will receive all of the proceeds from any sale of such shares. We will not receive any proceeds from any sales of shares of our common stock by the selling stockholders.

We have agreed to bear the expenses in connection with the registration of the shares of common stock to be offered by this prospectus by the selling stockholders other than any underwriting discounts and commissions or transfer taxes relating to the sale of common stock, which will be borne by the selling stockholders.

MARKET INFORMATION FOR COMMON STOCK AND DIVIDEND POLICY

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."

As of March 25, 2024, we had approximately 11,929,528 shares of common stock issued and outstanding held of record by approximately 205 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.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Selected Historical Consolidated Financial Data of Homology

The following tables summarize Homology's consolidated financial data. The consolidated statement of operations data for the year ended December 31, 2023 and the consolidated balance sheet data as of December 31, 2023 have been derived from the audited consolidated financial statements of Homology for the year ended December 31, 2023 included or incorporated by reference in this prospectus. You should read the following selected consolidated financial data together with "Homology Management's Discussion and Analysis of Financial Condition and Results of Operations" and Homology's financial statements and the related notes included or incorporated by reference in this prospectus. Homology's historical results are not necessarily indicative of results that should be expected in any future period.

	Year Ended December 31, 2023
	(in thousands, except share and per share data)
Collaboration revenue	$ 1,156
Operating expenses:	
Research and development	62,002
General and administrative	31,256
Restructuring and other charges	9,327
Total operating expenses	102,585
Loss from operations	(101,429)
Gain on lease termination	8,767
Interest income	5,582
Total other income	14,349
Loss before income taxes	(87,080)
Loss from equity method investment	(25,881)
Net loss	$ (112,961)
Net loss per share—basic & diluted	$ (35.16)
Weighted-average common shares outstanding—basic & diluted	3,213,045

	As of December 31, 2023
	(in thousands)
Consolidated Balance Sheet Data:	
Cash and cash equivalents	$ 39,266
Short-term investments	43,387
Assets held for sale	260
Working capital (1)	72,341
Total assets	84,564
Total liabilities	11,573
Accumulated deficit	(542,098)
Stockholders' equity	$ 72,991

(1) Working capital is defined as current assets less current liabilities

Selected Historical Consolidated Financial Data of Legacy Q32

The following tables summarize Legacy Q32's consolidated financial data. The consolidated statement of operations data for the year ended December 31, 2023 and the consolidated balance sheet data as of December 31, 2023 have been derived from Legacy Q32's audited consolidated financial statements included or incorporated by reference elsewhere in this prospectus. You should read the following selected consolidated financial data together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Legacy Q32's consolidated financial statements and the related notes included or incorporated by reference elsewhere in this prospectus. Legacy Q32's historical results are not necessarily indicative of results that should be expected in any future period.

	Year Ended December 31, 2023
	(in thousands, except share and per share data)
Collaboration arrangement revenue	$ (6,651)
Operating expenses:	
Research and development	31,729
General and administrative	9,875
Total operating expenses	41,604
Loss from operations	(48,255)
Change in fair value of convertible notes	(6,193)
Other income (expense), net	1,023
Total other income (expense), net	(5,170)
Loss before provision for income taxes	(53,425)
Provision for income taxes	(318)
Net loss and comprehensive loss	$ (53,743)
Net loss attributable to common stockholders—basic and diluted	$ (7.41)
Weighted-average common shares—basic and diluted	7,253,978

	As of December 31, 2023
	(in thousands)
Consolidated Balance Sheet Data:	
Cash and cash equivalents	$ 25,617
Working capital (1)	14,607
Total assets	47,057
Other non-current liabilities	55,000
Total liabilities	118,533
Convertible preferred stock	111,445
Accumulated deficit	(187,081)
Stockholders' deficit	$ (182,921)

(1) Working capital is defined as current assets less current liabilities

Selected Unaudited Pro Forma Condensed Combined Financial Data of Homology and Q32

The following unaudited pro forma condensed combined financial information was prepared based on the expectation that the Merger will be treated as a reverse recapitalization in accordance with U.S. generally accepted accounting principles, or GAAP. For accounting purposes, Legacy Q32 is considered to be completing an equity financing through the acquisition of Homology in the Merger. This determination is based on the fact that, immediately following the Merger: (i) Legacy Q32's equity holders own a substantial majority of the voting rights in the combined organization, (ii) Legacy Q32 designated a majority (seven of nine) of the initial board of directors of the combined organization, (iii) Legacy Q32's senior management hold all positions in the senior management of the combined organization and no senior employees from Homology will be retained and (iv) Homology primarily holds non-operating assets and the purpose of the transaction was to obtain additional capital to fund the operations of Legacy Q32.

Accordingly, for accounting purposes: (i) the Merger is treated as the equivalent of Legacy Q32 issuing stock to acquire primarily cash and cash equivalents, short-term investments, and other non-operating assets, (ii) the net assets of Homology are recorded based upon the fair value at the time of closing and (iii) the reported historical operating results of the combined company prior to the Merger will be those of Legacy Q32.

The unaudited pro forma condensed combined balance sheet assumes that Legacy Q32's Pre-Closing Financing and the Merger were consummated as of December 31, 2023 and combines the historical balance sheets of Homology and Legacy Q32 as of such date. The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023 assumes that Legacy Q32's Pre-Closing Financing and the Merger were consummated as of January 1, 2023 and combines the historical results of Homology and Legacy Q32 for the respective periods presented.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods. The selected unaudited pro forma condensed combined financial data for the year ended December 31, 2023 are derived from the unaudited pro forma condensed combined financial information and should be read in conjunction with that information. For more information, please see the section entitled "Unaudited Pro Forma Condensed Combined Financial Information" below.

Selected Unaudited Pro Forma Condensed Combined Statements of Operations Data

	Year Ended December 31, 2023 (in thousands, except share and per share data)
Collaboration arrangement revenue	$ (5,495)
Research and development expense	93,731
General and administrative expense	48,431
Restructuring and other charges	9,327
Other income/(expense), net	25,069
Provision for income taxes	(318)
Loss on equity method investment	(25,881)
Loss from operations	(158,114)
Net loss attributable to common stockholders—basis and diluted	$ (158,114)
Net loss per share attributable to common stockholders—basic and diluted	$ (13.23)

Selected Unaudited Pro Forma Condensed Combined Balance Sheet Data

	As of December 31, 2023
Consolidated Balance Sheet Data:	
Cash and cash equivalents	$ 106,883
Short-term investments	43,387
Other non-current liabilities	55,000
Working capital, net (1)	110,901
Total assets	180,128
Total liabilities	116,685
Accumulated deficit	(178,491)
Total stockholders' deficit	$ 63,443

(1) Working capital is defined as current assets less current liabilities

The following unaudited pro forma condensed combined financial statements are based on the Legacy Q32's (as defined below) historical consolidated financial statements and Homology's (as defined below) historical consolidated financial statements as adjusted to give effect to the merger of the companies, accounted for as a reverse recapitalization, and to the issuance of shares in the Q32 Pre-Closing Financing (as defined below). The unaudited pro forma condensed combined financial information gives effect to a one-for-eighteen Reverse Stock Split effected on March 25, 2024. References to Legacy Q32 and Homology in this section refer to Q32 Bio Inc. and Homology Medicines, Inc., in each case prior to the consummation of the Merger (as defined below).

The Merger

On November 16, 2023, Q32 Bio Operations Inc. (previously Q32 Bio Inc.), or Legacy Q32, entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Q32 Bio Inc. (previously Homology Medicines, Inc., or Homology), or the Company, and Kenobi Merger Sub, Inc. a wholly owned subsidiary of Homology, or Merger Sub. Pursuant to the Merger Agreement and subject to the satisfaction or waiver of the conditions therein, Merger Sub merged with and into Legacy Q32, with Legacy Q32 continuing as the surviving company and as a wholly owned subsidiary of the Company, or the Merger. The Merger was completed on March 25, 2024 and the business of Legacy Q32 will continue as the business of the 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.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, or the Effective Time, which was March 25, 2024, each then outstanding share of Legacy Q32 common stock including shares of common stock issued upon conversion of Legacy Q32 preferred stock, conversion of Legacy Q32 convertible notes and shares of Legacy Q32 common stock issued in the Legacy Q32 pre-closing financing (as defined below) was converted into the right to receive a number of shares of Homology's common stock (ignoring rounding of fractional shares) calculated in accordance with the Merger Agreement, or the Exchange Ratio.

At the Effective Time, Homology assumed outstanding and unexercised options to purchase shares of Legacy Q32 common stock, and in connection with the Merger they were converted into options to purchase Homology's common stock based on the Exchange Ratio formula in the Merger Agreement. At the Effective Time, Homology assumed outstanding and unexercised warrants to purchase shares of Legacy Q32 common stock, and in connection with the Merger they were converted into warrants to purchase Homology's common stock based on the Exchange Ratio formula in the Merger Agreement.

Immediately prior to the Effective Time, Legacy Q32 caused the outstanding principal and accrued but unpaid interest on the Legacy Q32 convertible notes to be converted into shares of Legacy Q32 common stock. In addition, the Legacy Q32 preferred stock was converted into Legacy Q32 common stock immediately prior to the Effective Time.

At the Effective Time, each person who, as of immediately prior to the Effective Time, was a stockholder of record of Homology or had the right to receive Homology's common stock was entitled to receive 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, the holder's representative and the rights agent, or the CVR Agreement, representing the contractual right to receive consideration from the post-closing 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 unaudited pro forma condensed combined balance sheet includes $7.6 million of contingent consideration with respect to the CVRs.

The Merger was treated as a reverse recapitalization in accordance with GAAP because on the effective date of the Merger, the pre-combination assets of Homology were primarily cash and cash equivalents, short-term investments and other non-operating assets. Any in-process research and development assets that remained as of the combination were de minimis value when compared to the cash, cash equivalents and short-term investments obtained through the Merger.

Immediately after the consummation of the Merger, based on the final Exchange Ratio of 0.0480, Legacy Q32 securityholders owned approximately 74.4% of Homology's common stock, and Homology's securityholders owned approximately 25.6% of Homology's common stock, after giving effect to the Legacy Q32 pre-closing financing. Under certain circumstances further described in the Merger Agreement, the ownership percentages were adjusted for Homology's actual net cash as of the closing, as defined in the Merger Agreement, or Net Cash, if net cash was less than $59.5 million or greater than $60.5 million and to the extent there are any changes to the amount of the Legacy Q32 Pre-Closing Financing (as defined below). Actual net cash was $61.3 million at closing and there were no changes to the amount of the Legacy Q32 Pre-Closing Financing.

The percentage ownership of the combined company was derived using a stipulated value for Legacy Q32 of approximately $237.0 million, inclusive of the Legacy Q32 Pre-Closing Financing, and a stipulated value for Homology of approximately $81.3 million. The valuation of Homology was determined based on actual net cash, as defined in the Merger Agreement, of $61.3 million at a determination date prior to the closing of the Merger plus an additional $20.0 million of equity value. The value from any future monetization of Homology operating assets, including fixed assets, intellectual property, and the equity method investment, will be delivered to legacy Homology equity holders via a cash dividend as stipulated in the CVR. The fair value of consideration transferred is not indicative of the combined entities' enterprise value upon consummation of the Merger.

The Q32 Pre-Closing Financing

In connection with the Merger Agreement, certain investors have entered into a subscription agreement with Legacy Q32 to purchase shares of Legacy Q32 common stock for an aggregate purchase price of approximately $42.0 million, or the Legacy Q32 Pre-Closing Financing. The Legacy Q32 Pre-Closing Financing occurred prior to the closing of the Merger. Shares of the Legacy Q32 common stock issued pursuant to the Legacy Q32 Pre Closing Financing were converted into shares of Homology's common stock in accordance with the Exchange Ratio at the Effective Time.

The unaudited pro forma condensed combined balance sheet assumes that the Legacy Q32 Pre-Closing Financing, and the Merger were consummated as of December 31, 2023 and combines the historical balance sheets of Homology and Legacy Q32 as of such date. The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023 assumes that the Legacy Q32 Pre-Closing Financing and the Merger were consummated as of January 1, 2023 and combines the historical results of Homology and Legacy Q32 for the respective periods presented.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Homology and Legacy Q32 been a combined organization during the specified periods. The actual results reported in periods following the merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this pro forma financial information.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in combination with the separate historical financial statements of Homology and Legacy Q32, and each company's respective Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. The accounting policies of Homology may materially vary from those of Legacy Q32. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the closing, management will conduct a final review of Homology's accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Homology's results of operations or reclassification of assets or liabilities to conform to Legacy Q32's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on these unaudited pro forma condensed combined financial statements.

Unaudited Pro Forma Condensed Combined Balance Sheet
December 31, 2023
(in thousands)

	Legacy Q32	Homology	Legacy Q32 Pre-closing Financing Adjustments	Pro Forma Merger Adjustments	Notes (See Note 4)	Pro Forma Combined
Assets						
Current assets:						
Cash and cash equivalents	$ 25,617	$ 39,266	$ 42,000	$ —	**A**	$ 106,883
Short-term investments	—	43,387	—	—		43,387
Assets held for sale	—	260	—	—		260
Prepaid expenses and other current assets	3,099	1,001	—	(432)	**G**	3,668
Total current assets	28,716	83,914	42,000	(432)		154,198
Restricted cash	5,647	—	—	—		5,647
Equity method investment	—	—	—	6,939	**H**	6,939
Property and equipment, net	1,782	—	—	—		1,782
Right-of-use asset, operating leases	6,301	650	—	—		6,951
Other non-current assets	4,611	—	—	—		4,611
Total assets	$ 47,057	$ 84,564	$ 42,000	$ 6,507		$ 180,128
Liabilities, Convertible Preferred Stock and Stockholders' Deficit						
Current liabilities:						
Accounts payable	$ 3,468	$ 3,234	$ —	$ —		$ 6,702
Accrued expenses and other current liabilities	9,763	7,021	—	17,615	**D, E, F,G**	34,399
Venture debt, current portion	878	—	—	—		878
Convertible notes	—	—	—	—		—
Operating lease liabilities, current portion	—	1,318	—	—		1,318
Deferred revenue, current portion	—	—	—	—		—
Total current liabilities	14,109	11,573	—	17,615		43,297
Deferred revenue, net of current portion	—	—	—	—		—
Operating lease liabilities, net of current portion	6,248	—	—	—		6,248
CVR liability	—	—	—	7,559	**H**	7,559
Venture debt	4,581	—	—	—		4,581
Convertible notes	38,595	—	—	(38,595)	**B**	—
Other non-current liabilities	55,000	—	—	—		55,000
Total liabilities	118,533	11,573	—	(13,421)		116,685
Series A convertible preferred stock	47,458	—	—	(47,458)	**C**	—
Series A-1 convertible preferred stock	4,132	—	—	(4,132)	**C**	—
Series B convertible preferred stock	59,855	—	—	(59,855)	**C**	—
Total convertible preferred stock	111,445	—	—	(111,445)		—
Stockholders' deficit:						
Preferred stock	—	—	—	—		—
Common stock	1	6	4	12	**K**	23
Additional paid-in-capital	4,159	615,088	41,996	(419,332)	**B**	241,911
Accumulated other comprehensive loss	—	(5)	—	5	**K**	—
Accumulated deficit	(187,081)	(542,098)	—	550,688	**K**	178,491
Total stockholders' deficit	(182,921)	72,991	42,000	131,373		63,443
Total liabilities, convertible preferred stock and stockholders' deficit	$ 47,057	$ 84,564	$ 42,000	$ 6,507		$ 180,128

The accompanying notes are an integral part of this pro forma condensed financial information.

Unaudited Pro Forma Condensed Combined Statement of Operations
For the Year Ended December 31, 2023
(in thousands, except share and per share amounts)

	Legacy Q32	Homology	Legacy Q32 Pre-closing Financing Adjustments	Pro Forma Merger Adjustments	Notes	Pro Forma Combined
Collaboration arrangement revenue	$ (6,651)	$ 1,156	$ —	$ —		$ (5,495)
Operating expense:						
Research and development	31,729	62,002	—	—		93,731
General and administrative	9,875	31,256	—	7,300	F, G	48,431
Restructuring and other charges	—	9,327	—	—		9,327
Total operating expense	41,604	102,585	—	7,300		151,489
Loss from operations	(48,255)	(101,429)	—	(7,300)		(156,984)
Change in fair value of convertible notes	(6,193)	—	—	6,193	J	—
Gain on conversion of convertible notes	—	—	—	9,697	B	9,697
Gain on lease termination	—	8,767	—	—		8,767
Other income (expense), net	1,023	5,582	—	—		6,605
Total other income (expense), net	(5,170)	14,349	—	15,890		25,069
Loss before provision for income taxes	(53,425)	(87,080)	—	8,590		(131,915)
Provision for income taxes	(318)	—	—	—		(318)
Loss from equity method investment	—	(25,881)	—	—		(25,881)
Net loss and comprehensive loss	$ (53,743)	$ (112,961)	$ —	$ 8,590		$ (158,114)
Net loss attributable to common stockholders'—basic and diluted	$ (7.41)	$ (35.16)			L	$ (13.23)
Weighted-average common shares—basic and diluted	7,253,978	3,213,046			L	11,953,619

The accompanying notes are an integral part of this pro forma condensed financial information.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

All amounts below are in thousands, unless specifically noted otherwise, except share and per share amounts.

1. Description of Transaction

Upon the Effective Time, all shares of Legacy Q32 common stock outstanding immediately prior to the Effective Time, after giving effect to the preferred stock conversion, convertible notes conversion, and the Legacy Q32 Pre-Closing Financing, were converted into the right to receive 8,699,887 shares of Homology's common stock in the aggregate, based on an assumed Exchange Ratio of 0.0480, which has been adjusted to reflect the one-for-eighteen Reverse Stock Split. This Exchange Ratio was determined pursuant to a formula described in more detail in the Merger Agreement.

The aggregate value of the consideration to be paid in the Merger was $59.2 million. The fair value of consideration transferred is based on the number of common shares Homology stockholders will own of the combined company upon consummation of the merger, multiplied by the closing price or fair value of Homology common stock on March 21, 2024, as well as the fair value of outstanding options to purchase Homology common stock and the fair value of the CVR. The fair value of consideration transferred is not indicative of the combined entities enterprise value upon consummation of the Merger. As the Merger will be accounted for as a reverse recapitalization, any difference between the consideration to be transferred in the merger and the fair value of the net assets acquired will be recorded as an adjustment to additional paid-in capital.

Final stockholders approval was received on March 15, 2024. Consummation of the Merger was subject to certain closing conditions and was closed on March 25, 2024.

2. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information gives effect to a Reverse Stock Split of one-for-eighteen for stockholders of record on March 25, 2024.

The unaudited pro forma condensed combined financial information has been prepared in accordance with SEC Regulation S-X Article 11. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2023 give effect to the Legacy Q32 Pre-Closing Financing and Merger as if they had been consummated on January 1, 2023. The unaudited pro forma condensed combined balance sheet as of December 31, 2023 gives effect to the Legacy Q32 Pre-Closing Financing and the Merger as if they had been consummated on December 31, 2023.

For accounting purposes, Legacy Q32 is considered to be the acquiring company and the Merger will be accounted for as a reverse recapitalization of Legacy Q32 because on the Merger date, the pre-combination assets of Homology were primarily cash, cash equivalents, short-term investments and other non-operating assets. For purposes of these pro forma financial statements, the total estimated purchase price is summarized as follows (in thousands, except share and per share amounts):

Estimated number of shares of the combined company to be owned by Homology stockholders (i)	3,223,190
Multiplied by the assumed price per share of Homology stock (ii)	$ 15.84
Total	51,055
Estimated fair value of assumed Homology equity awards based on pre-combination service (iii)	562
Estimated fair value of the contingent value right (iv)	7,559
Total estimated purchase price	$ 59,176

i. Reflects the number of shares of common stock of the combined company that Homology equity holders would own as of the closing pursuant to the Merger Agreement. This amount is calculated, for purposes of this unaudited pro forma condensed combined financial information, based on shares of Homology common stock outstanding as of March 25, 2024.

ii. Reflects the price per share of Homology common stock, which is the closing trading price of Homology common stock outstanding as of March 21, 2024.

iii. The estimated purchase price includes the estimated acquisition-date fair value of the assumed Homology equity awards attributable to pre-combination service (which amount is determined based on the closing trading price of Homology common stock on March 21, 2024, the number of Homology equity awards outstanding on March 25, 2024, and the period of service provided by the holders of the awards prior to the merger closing date). The following table presents on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the estimated acquisition date fair value of the assumed Homology equity awards:

Expected term (in years)	1
Volatility	64.52%
Risk free interest rate	5.23%
Dividend yield	—

iv. The estimated fair value of the CVR is $7.6 million, which is based on the estimated fair value of Homology's equity method investment in OXB Solutions as of February 21, 2024 and in-process research and development assets subject to the CVR. Refer to Note 6 to financial statements included in Homology's Annual Report on Form 10-K for the year ended December 31, 2023 for a description of the method used to estimate the fair value of the investment in OXB Solutions. The fair value of the of the in-process research and development assets was determined to be $0.6 million. Since the IPR&D has no future alternative use, it is not reflected on the unaudited pro forma condensed combined balance sheet.

The actual purchase consideration for the net assets of Homology will vary based on the actual fair value of the investment in OXB Solutions and in-process research and development assets and the resulting effect on the fair value of the CVR; however, any difference between the consideration transferred and the fair value of the net assets of Homology following determination of the actual purchase consideration for Homology will be reflected as an adjustment to additional paid-in capital. The estimated purchase consideration reflected in these unaudited pro forma condensed combined financial information does not purport to represent what the actual purchase consideration as the accounting is still preliminary.

Under reverse recapitalization accounting, the subsequent financial statements of Legacy Q32 will reflect the operations of the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer. The accompanying unaudited pro forma condensed combined financial information is derived from the historical financial statements of Homology and Legacy Q32, and include adjustments to give pro forma effect to reflect the accounting for the transaction in accordance with U.S. GAAP. The historical financial statements of Legacy Q32 will become the historical financial statements of the combined company.

Legacy Q32 and Homology may incur significant costs associated with integrating the operations of Legacy Q32 and Homology after the Merger is completed. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies which may result from the Merger.

3. Shares of Homology Common Stock Issued to Legacy Q32 Stockholders upon Closing of the Merger

Prior to the Merger, all Convertible Notes and outstanding shares of Legacy Q32 convertible preferred stock were converted into Legacy Q32 common stock, which were exchanged for shares of Homology common stock based on the Exchange Ratio determined in accordance with the Merger Agreement. The Exchange Ratio for purposes of the unaudited pro forma condensed combined financial information was derived using a stipulated value for Legacy Q32 of approximately $237 million (including the Legacy Q32 pre-closing financing disclosed above) and for Homology of approximately $81.3 million. The estimated number of shares of common stock that Homology has issued to Legacy Q32's common stockholders, preferred stockholders and convertible note holders as of March 25, 2024 (ignoring rounding of fractional shares) is determined as follows:

Shares of Legacy Q32 common stock outstanding	7,472,835
Estimated shares of Legacy Q32's common stock to be issued upon consummation of the Legacy Q32 Concurrent Financing	35,032,111
Shares of Legacy Q32 common stock to be issued upon conversion of Legacy Q32 preferred stock	108,818,415
Shares of Legacy Q32 common stock to be issued upon conversion of Legacy Q32 convertible notes	29,853,711
Total	181,177,072
Exchange ratio	0.0480
Estimated shares of Homology common stock to be issued to Legacy Q32 shareholders upon closing of the Merger	8,699,887

The Exchange Ratio and shares of Homology common stock issued to Legacy Q32's securityholders has been adjusted to give effect to the Reverse Stock Split.

4. Pro Forma Adjustments

Adjustments included in the column under the heading "Legacy Q32 Pre-Closing Financing Adjustments" are primarily based on information contained within the subscription agreement for the Legacy Q32 Pre-Closing Financing and adjustments included in the column under the heading "Pro Forma Merger Adjustments" are primarily based on information contained within the Merger Agreement. Further analysis will be performed after the completion of the Merger to confirm these estimates.

Both Legacy Q32 and Homology have a history of generating net operating losses and maintain a full valuation allowance against their net deferred tax assets. For the year ended December 31, 2023, Homology did not record an income tax provision. Legacy Q32 has recorded a tax provision of $0.3 million for the year ended December 31, 2023. Management of both entities have not identified any changes to the income tax positions due to the merger that would result in an incremental tax expense or benefit. Accordingly, no tax related adjustments have been reflected for the pro forma adjustments.

The pro forma adjustments, based on preliminary estimates that could change materially as additional information is obtained, are as follows:

A. The Legacy Q32 Pre-Closing Financing which closed immediately prior to the consummation of the Merger. The adjustment reflects cash proceeds of $42.0 million from the sale and issuance of 35,032,111 shares of Legacy Q32 common stock at a purchase price of $1.20 per share pursuant to the subscription agreement entered into in connection with the Legacy Q32 Pre-Closing Financing. The issuance of common stock related to this Pre-Closing Financing results in an increase of $4 thousand to common stock and an increase of $42.0 million to

additional paid-in-capital in the unaudited pro forma condensed combined balance sheet. The potential use of proceeds from the Legacy Q32 pre-closing financing has not yet been finalized, and as a result, for the purposes of the unaudited pro forma condensed combined statement of operations, no adjustments were made to reflect interest income from the potential investment of the proceeds or any other use of proceeds from the Legacy Q32 pre-closing financing.

B. Upon closing, 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. For the purposes of the unaudited pro forma condensed combined statements of operations, Legacy Q32's conversion of its convertible notes is reflected as if it occurred on January 1, 2023, resulting in the issuance of 29,853,711 shares of Legacy Q32 common stock. As the convertible notes are recorded at fair value, a gain of $9.7 million on conversion of convertible stock is reflected in the unaudited pro forma condensed combined statement of operation for the year ended December 31, 2023. Since the conversion of the convertible notes are reflected as if it occurred on January 1, 2023, an adjustment to remove $6.2 million of change in fair value of convertible notes recorded in 2023 was recorded (refer to Letter J). The conversion of the Legacy Q32 convertible notes into shares of Legacy Q32 common stock results in an increase of $2 thousand to common stock and an increase of $22.7 million to additional paid-in-capital in the unaudited pro forma condensed combined balance sheet.

C. Immediately prior to completing the Merger, all classes of convertible preferred stock of Legacy Q32 were converted to Legacy Q32 common stock. The Series A convertible preferred stock converted to 47,628,788 shares of Legacy Q32 common stock, the Series A-1 convertible preferred stock converted to 6,500,000 shares of Legacy Q32 common stock and the Series B convertible preferred stock converted to 54,689,627 shares of Legacy Q32 common stock. The conversion of the Legacy Q32 preferred stock into shares of Legacy Q32 common stock results in an increase of $11 thousand to common stock and an increase of $111.4 million to additional paid-in-capital in the unaudited pro forma condensed combined balance sheet.

D. To reflect Homology's estimated transaction costs of $2.8 million that were not accrued as of December 31, 2023, consisting of legal and accounting related fees of approximately $1.0 million, and investment banking fees of approximately $1.8 million as an increase to accrued expenses and an increase to accumulated deficit of $2.8 million in the unaudited pro forma condensed combined balance sheet.

E. To reflect Legacy Q32's estimated transaction costs of $7.5 million that were not accrued as of December 31, 2023, consisting of legal and accounting related fees of approximately $4.7 million and investment banking fees of approximately $2.8 million as an increase to accrued expenses and a reduction to additional paid-in capital of $7.5 million in the unaudited pro forma condensed combined balance sheet. As the merger will be accounted for as a reverse recapitalization equivalent to the issuance of equity for the primarily cash and cash equivalents, short-term investments, and other non-operating assets of Homology, these direct and incremental costs are treated as a reduction of the net proceeds received within additional paid-in capital. The adjustments for transaction costs exclude costs related to Legacy Q32's ongoing operations as a public company, which will be charged to expense as incurred.

F. Estimated compensation expense of $5.4 million related to change-in-control cash payments, retention and severance payments resulting from pre-existing employment agreements that will be payable in cash in connection with the Merger but were not incurred as of December 31, 2023 is reflected as an increase to accrued expenses and accumulated deficit in the unaudited pro forma condensed combined balance sheet. Homology's compensation costs of $5.4 million are reflected as general and administrative expense in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023.

G. To remove Homology's prepaid D&O Insurance policy of $0.4 million as a reduction to prepaid expenses and other current assets and accumulated deficit of $0.4 million in the unaudited pro forma condensed combined balance sheet, and replace it with a $1.9 million D&O tail policy as an increase to accrued expenses and accumulated deficit of $1.9 million in the unaudited pro forma condensed combined balance sheet. Homology's

D&O tail policy expense of $1.9 million is reflected as general and administrative expense in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023.

H. The estimated fair value of the CVR is $7.6 million, of which $7.0 million was related to the estimated fair value of the CVR related to Homology's equity method investment in OXB Solutions as of February 21, 2024. Refer to Note 6 to financial statements included in Homology's Annual Report on Form 10-K for the year ended December 31, 2023 for a description of the method used to estimate the fair value of the investment. The estimated fair value of the CVR also includes $0.6 million attributed to the in-process research and development assets subject to the CVR. Since the IPR&D has no future alternative use it is not reflected on the unaudited pro forma condensed combined balance sheet.

I. Homology's historical financial statements were adjusted to give pro forma effect to events in connection with the Merger that include the elimination of Homology's historical common stock, additional paid-in capital and accumulated deficit balances and the capitalization of the fair value of the estimated number of common shares of the combined company to be owned by Homology stockholders.

J. To remove $6.2 million of change in fair value of convertible notes for the year ended December 31, 2023, since the notes are assumed to convert on January 1, 2023. Refer to letter B above.

K. The impacts of the adjustments from the Merger for the Pre-Closing Financing and pro forma adjustments on the equity accounts are included in the table below.

The amounts of the elimination of Homology's historical equity carrying values within the table above include the impacts of the pro forma adjustments related to pre-merger expenses of Homology. A reconciliation from the amounts of Homology's historical equity carrying values contained within the unaudited pro forma condensed combined balance sheet as of December 31, 2023 is as follows:

(amounts in thousands, except share amounts)	Common Legacy Q32 Shares	Common Legacy Q32 Amount	Common Homology Shares	Common Homology Amount	Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Deficit	Notes
Legacy Q32 historical equity carrying values as of December 31, 2023	7,472,835	1	—	—	4,159	(187,081)	—	(182,921)	
Homology historical equity carrying values as of December 31, 2023 (i), (iii)	—	—	3,223,190	6	615,088	(542,098)	(5)	72,991	
Combined historical equity carrying values as of December 31, 2023	7,472,835	1	3,223,190	6	619,247	(729,179)	(5)	(109,930)	
Effect of Consummation of Legacy Q32 pre-closing financing	35,032,111	4	—	—	41,996	—	—	42,000	A
Total Legacy Q32 Pre-closing Financing Adjustments	35,032,111	4	—	—	41,996	—	—	42,000	

(amounts in thousands, except share amounts)	Common Legacy Q32 Shares	Common Legacy Q32 Amount	Common Homology Shares	Common Homology Amount	Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Deficit	Notes
To remove $6.2 million of change in fair value of Legacy Q32's convertible notes for the year ended December 31, 2023 since the notes are assumed to convert on January 1, 2023	—	—	—	—	—	6,193	—	6,193	
Conversion of Legacy Q32 convertible notes into Legacy Q32 common stock	29,853,711	2	—	—	22,703	9,697	—	32,402	B
Conversion of outstanding Legacy Q32 convertible preferred stock into Legacy Q32 common stock	108,818,415	11	—	—	111,435	—	—	111,446	C
Stock-based compensation costs recognized by Homology related to acceleration of vesting of equity awards upon closing (ii), (iii)	—	—	51,865	1	561	(562)	—	—	
Derecognition of Homology prepaid item being written off (ii)	—	—	—	—	—	(432)	—	(432)	G
Homology transaction costs associated with the transaction	—	—	—	—	—	(2,815)	—	(2,815)	D
Elimination of Homology's historical equity carrying values, after pro forma adjustments	—	—	—	—	(545,912)	545,907	5	—	I
Elimination of IPR&D	—	—	—	—	(620)	—	—	(620)	
Exchange of outstanding Legacy Q32's common stock based on the assumed Exchange Ratio for purposes of these pro forma condensed combined financial statements (iii)	(181,177,072)	(18)	8,699,887	16	2	—	—	—	

(amounts in thousands, except share amounts)	Common Legacy Q32 Shares	Common Legacy Q32 Amount	Common Homology Shares	Common Homology Amount	Additional Paid-In-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Deficit	Notes
Payment of transaction costs associated with the merger	—	—	—	—	(7,501)	—	—	(7,501)	E
Payment of transaction related insurance costs	—	—	—	—	—	(1,900)	—	(1,900)	G
Payment of change-in-control, retention and severance in connection with the merger	—	—	—	—	—	(5,400)	—	(5,400)	F
Total Pro Forma Merger Adjustments	(42,504,946)	(5)	8,751,752	17	(419,332)	550,688	5	131,373	
Pro Forma Combined	—	—	11,974,942	23	241,911	(178,491)	—	63,443	

(i) Homology shares are as of March 25, 2024.

(ii) Homology shares are as of March 25 2024. This adjustment reflects the acceleration of Homology share-based compensation and is treated as a pre-combination expense.

(iii) Homology shares have been adjusted for a one-for-eighteen Reverse Stock Split.

L. The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net loss for the year ended December 31, 2023. In addition, the number of shares used in calculating the pro forma combined basic and diluted net loss per share has been adjusted to give effect to the issuance of Homology's common stock in connection with the Legacy Q32 pre-closing financing and the Merger. As the combined organization is in a net loss position for both periods presented, any adjustment for potentially dilutive shares would be anti-dilutive, and as such basic and diluted loss per share are the same for the period. The following table presents the calculation of the pro forma weighted average number of common stock outstanding. The estimated number of shares reflects the impact of the Reverse Stock Split that was effected prior to consummation of the merger:

	Year Ended December 31, 2023
Weighted-average Legacy Q32 common shares outstanding—basic and diluted	7,253,978
Impact of Legacy Q32 pre-closing financing assuming consummation as of January 1, 2023	35,032,111
Impact of Legacy Q32 convertible notes assuming conversion as of January 1, 2023	29,853,711
Impact of Legacy Q32 convertible preferred stock assuming conversion as of January 1, 2023	108,818,415
Total	180,958,215
Application of exchange ratio to historical Legacy Q32 weighted-average shares outstanding	0.05
Adjusted Legacy Q32 weighted-average shares outstanding	8,688,709
Impact of Homology common stock related to stock units that accelerated vesting as of January 1, 2023	18,963
Impact of common shares issued upon vesting of equity awards for the combined company as of January 1, 2023	32,902
Weighted-average Homology common shares outstanding—basic and diluted	3,213,046
Pro forma combined weighted-average number of shares of common stock—basic and diluted	11,953,619

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 Legacy Q32's consolidated financial statements and the related notes appearing elsewhere or incorporated by reference in this prospectus. This discussion and other parts of this prospectus 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 prospectus.

Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Legacy Q32" refers to the business and operations of Q32 Bio Operations (previously Q32 Bio Inc.) and its consolidated subsidiaries prior to the Merger, and references to "the Company" "we," "us," "our" and other similar terms refer to the business and operations of Q32 Bio Inc. (previously Homology Medicines, Inc., or Homology) and its consolidated subsidiary following the Merger. Unless otherwise indicated, the information in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section does not reflect the effects of the Reverse Stock Split.

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 with clinical readouts for our two lead programs expected in 2024 and 2025.

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. Bempikibart is being studied in two double-blind, placebo-controlled Phase 2 clinical trials designed to establish proof of clinical concept and evaluate our selected Phase 2 dose. One trial is evaluating the use of bempikibart for the treatment of atopic dermatitis, or AD, and one is evaluating bempikibart for the treatment of alopecia areata, or AA. Enrollment in both clinical trials remains ongoing and we remain on track to report topline data from both Phase 2 clinical trials in the second half of 2024.

ADX-097, 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. We are developing ADX-097 for the treatment of renal and other complement-mediated diseases of high unmet need,

including lupus nephritis, or LN, immunoglobulin A, or IgA, nephropathy, or IgAN, complement component 3 glomerulopathy, or C3G, and anti-neutrophil cytoplasmic antibody, or ANCA-associated vasculitis, or AAV. We have completed a Phase 1 clinical trial of ADX-097 in healthy volunteers. We expect to initiate an open-label Phase 2 renal basket program in the first half of 2024, with initial data expected by year-end 2024, and initiate a Phase 2 clinical trial in AAV, with topline data from both the renal basket and AAV trials anticipated in the second half of 2025.

In addition to bempikibart and ADX-097, we are also engaged in additional pipeline efforts to expand therapeutic opportunities within complement mediated diseases.

Recent Developments

Rights to Bempikibart

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 between Legacy Q32 and Horizon Therapeutics Ireland DAC, or 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.

In October 2023, Amgen, Inc., or Amgen, completed the acquisition of Horizon Therapeutics public limited company, or Horizon plc. Following its acquisition of Horizon plc, Legacy Q32 agreed with Amgen to mutually terminate the Horizon Agreements and on November 2023, Legacy Q32 and Horizon entered into a termination agreement, 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 all 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.

These potential payments to Horizon are not in exchange for a distinct good or service and, therefore; Legacy Q32 accounts for consideration payable to a customer 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 the customer, 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 collaboration arrangement. 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, the Company entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Legacy Q32 and Kenobi Merger Sub, Inc., a wholly owned subsidiary of the Company, 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 the Company, or the Merger. In connection with the consummation of the Merger, we changed our name from Homology Medicines, Inc. to Q32 Bio Inc., and Legacy Q32, which remains as a wholly-owned subsidiary of the Company, changed its name from Q32 Bio Inc. to Q32 Bio Operations Inc. On March 26, 2024, our common stock began trading on the Nasdaq Global Market under the ticker symbol "QTTB". The business of Legacy Q32 will continue as the business of the 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 Legacy Q32 to purchase shares of Legacy Q32's common stock for an aggregate purchase price of $42.0 million, or the Pre-Closing Financing.

On March 25, 2024 (the Closing Date), following approval by the stockholders of the Company and Legacy Q32, 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 our 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, we effected a one-for-eighteen reverse stock split of its then outstanding common stock, or the Reverse Stock Split. Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, or the Effective Time, which was March 25, 2024, 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 7,017,842 shares of our common stock calculated in accordance with the Exchange Ratio at the Effective Time. Lastly, each option to purchase Legacy Q32's shares that was outstanding and unexercised immediately prior to the Effective Time was converted into an option to purchase shares of our common stock based on the final Exchange Ratio of 0.0480, or the Exchange Ratio. Immediately following the Merger, stockholders of Legacy Q32 owned approximately 74.4% of the outstanding common stock of the combined company.

The Merger will be 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 the accounting acquirer and Homology is the acquired company 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 Company; (iii) Legacy Q32's executive management team became the management of the Company; (iv) the pre-combination assets of Homology were primarily cash and cash equivalents, short-term investments, and other non-operating assets (the in-process research and development assets potentially remaining as of the combination are de minimis value); and (v) the Company was named Q32 Bio Inc. and is headquartered in Legacy Q32's office in Waltham, Massachusetts. 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 will be recorded at their acquisition-date fair value in the financial statements of the Company and the reported operating results prior to the Merger will be those of Legacy Q32.

At the Effective Time, each person who as of immediately prior to the Effective Time was a stockholder of record of Homology or had the right to receive Homology's common stock was entitled to receive 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.

The Company currently expects to use the approximately $130.0 million in cash, cash equivalents and marketable securities, which includes the approximately $42.0 million from the Pre-Closing Financing, immediately after completion of the Merger and after deducting estimated transaction expenses as follows:

- approximately $27.2 million for continued clinical development of bempikibart including approximately $19.0 million in remaining clinical development expenses to fund the program through Phase 2 completion of its ongoing clinical trials and $8.2 million in CMC costs to support advancing the program through its ongoing clinical trials and to enable of advancing clinical development beyond the current Phase 2 trials;

- approximately $20.2 million for continued development of ADX-097 including approximately $12.2 million to support its planned Phase 2 clinical trials, $3.7 million in CMC related costs to support the ongoing development and $4.4 million in research and other non-clinical ADX-097 related activities;
- approximately $0.9 million for discovery and other platform-related activities; and
- the remainder for other general corporate purposes.

The specific allocation of the expected cash, cash equivalents and marketable securities immediately after completion of the Merger towards specific programs will depend on, among other things, results from the combined company's research and development efforts for each program and the timing and success of its clinical trials. Based on the combined company's current planned use of the cash, cash equivalents and marketable securities immediately after completion of the Merger and after deducting estimated transaction expenses, such funds are estimated to be sufficient to enable the combined company to fund its operating expenses and capital expenditure requirements to mid-2026. This estimate is based on assumptions that may prove to be wrong, and the combined company could use its expected capital resources sooner than currently anticipated.

The Company does not expect the proceeds from the completion of the Merger, including the approximately $42.0 million from the Pre-Closing Financing, and Legacy Q32's existing cash, cash equivalents, and marketable securities, will be sufficient for it to advance any of its programs through regulatory approval, and the combined company will need to raise additional capital to complete the development and potential commercialization of any of its programs. The Company may also use a portion of its cash, cash equivalents, and marketable securities, to acquire, in-license or invest in products, technologies or businesses that are complementary to its 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 prospectus.

The expected use of proceeds represents current intentions based upon present plans and business condition. As of the date of this prospectus, the Company cannot predict with complete certainty all of the particular uses for the expected cash available upon the closing of the Merger or the actual amounts that it will spend on the uses set forth above.

Financial Operations Overview

Revenue

Since its inception, we have not generated any revenue from product sales, and management does not expect the 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 is within the scope of Topic 606. Specifically, Legacy Q32 concluded that the research services required to be performed as part of the Horizon Collaboration Agreement represent an output of Legacy Q32's ordinary activities, and this represents 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 Topic 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 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. As of December 31, 2022, Legacy Q32 had received $32.5 million of the $55.0 million transaction price from Horizon. Legacy Q32 recognized $6.7 million of collaboration agreement revenue for the year ended December 31, 2022. As of December 31, 2023, Legacy Q32 had received the full $55.0 million, which Legacy Q32 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, Legacy Q32 accounts 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 is not probable that the respective milestones will be achieved at this time.

Research and Development

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 its 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; and
- facilities-related expenses, depreciation, supplies, travel expenses and other allocated expenses.

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 its 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 it 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 decided 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 its 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 a public company.

Change in Fair Value of Convertible Notes

During 2022, Legacy Q32 recognized a liability as a result of the issuance of convertible promissory notes, or the Convertible Notes. Legacy Q32 accounts for all Convertible Notes issued under the fair value option election of ASC 825, *Financial Instruments* (ASC 825). The financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized within other income (expense) 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 change in fair value of the Convertible Notes is expected to vary period over period, based on changes in the estimated fair value of the equity into which the Convertible Notes will be issued, the pending Merger with Homology, or other future financing, and other factors.

Other income (expense), net

Other income (expense), net consists of interest income primarily earned on money market fund accounts and other short-term investments and interest expense related to Legacy Q32's debt obligations.

Results of Operations

Comparison of the years ended December 31, 2023 and 2022

The following table summarizes Legacy Q32's results of operations for the years ended December 31, 2023 and 2022:

	Years Ended December 31,		
	2023	2022	Change
	(in thousands)		
Collaboration arrangement revenue	$ (6,651)	$ 6,651	$(13,302)
Operating expenses:			
Research and development	31,729	35,814	(4,085)
General and administrative	9,875	10,062	(187)
Total operating expense	41,604	45,876	(4,272)
Loss from operations	(48,255)	(39,225)	(9,030)
Change in fair value of convertible notes	(6,193)	(2,402)	(3,791)
Other income (expense), net	1,023	(1,120)	2,143
Loss before provision for income taxes	(53,425)	(42,747)	(10,678)
Provision for income taxes	(318)	(62)	(256)
Net loss	$(53,743)	$(42,809)	$(10,934)

Collaboration Arrangement Revenue

Legacy Q32 recognized negative $6.7 million of collaboration arrangement revenue for the year ended December 31, 2023 compared to $6.7 million for the year ended December 31, 2022. Upon initiation of the Horizon Termination Agreement 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 Legacy Q32's research and development expenses for the years ended December 31, 2023 and 2022:

	Years Ended December 31,		
	2023	2022	Change
	(in thousands)		
Direct research and development expense by program:			
ADX-097	$ 7,185	$10,109	$(2,924)
Bempikibart	11,722	11,892	(170)
Discovery and other	894	1,270	(376)
Unallocated expenses:			
Personnel-related and consulting (including stock-based compensation)	9,629	9,990	(361)
Indirect research and development expense	2,299	2,553	(254)
Total research and development expenses	$31,729	$35,814	$(4,085)

Research and development expenses were $31.7 million for the year December 31, 2023, compared to $35.8 million for the year ended December 31, 2022. Expenses related to Legacy Q32's ADX-097 program decreased as the program was winding down, specifically CMC redevelopment costs decreased by $1.3 million, toxicology and other activities by $0.8 million, and Phase 1 clinical study costs by $0.8 million when compared to the previous year. Expenses related to Legacy Q32's bempikibart program decreased due to a reduction in toxicology cost of $2.2 million as the program substantially completed its six-month toxicology study in fiscal year 2022 and a reduction in regulatory costs of $0.3 million offset by an increase of $2.3 million in clinical spend. Legacy Q32 completed its Phase 1 clinical trial in the first half of 2022 and subsequently incurred start-up costs related to two planned Phase 2 trials, the first of which was initiated in October 2022, and the second in September 2023, which expenses increased as the Phase 2 trial advanced throughout 2023. Discovery and Other decreased $0.4 million due to the company focusing resources on moving the programs into the clinic.

The decrease in personnel-related and consultant costs were primarily related to a decrease in headcount and use of consultants. Personnel-related and consultant costs for the years ended December 31, 2023 and 2022 included stock-based compensation expense of $0.5 million and $0.4 million, respectively. The decrease in indirect research and development costs related to facility and other costs primarily associated with Legacy Q32 incurring additional facility and start-up costs associated with moving into a new office and lab facility during 2022.

General and Administrative Expenses

General and administrative expenses were $9.9 million for the year ended December 31, 2023, compared to $10.1 million for the year ended December 31, 2022. The decrease is due to lower recruiting costs and market research studies.

Change in Fair Value of Convertible Notes

Change in the fair value of the convertible notes was $6.2 million for the year ended December 31, 2023, compared to $2.4 million for the year ended December 31, 2022.

Other Income (Expense), Net

Other income (expense), net was $1.0 million for the year ended December 31, 2023, compared to an expense of $(1.1 million) for the year ended December 31, 2022. Other income (expense), net for the year ended December 31, 2023 is made up primarily of interest expense on Legacy Q32's venture debt of $0.5 million offset by interest income of $1.2 million. The increase in other income (expense), net is due to a higher average cash balance resulting in higher interest income in addition to higher yields for the year ended December 31, 2023.

Income taxes

Provision for income taxes was $0.3 million for the year ended December 31, 2023 compared to $62 thousand for the year ended December 31, 2022.

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. During 2022, it amended its prior year tax filings and settled an unrecognized tax benefit recorded in the prior year and primarily driven by transfer pricing reimbursement from the U.S. to Australia including interest and penalties which explains the year-over-year decrease in income tax expenses.

Liquidity and Capital Resources

Sources of Liquidity

Since its inception, Legacy Q32 has incurred significant operating losses and negative cash flows from operations. Legacy Q32 has not yet commercialized any of its product candidates, which are in various phases of preclinical and clinical development, and it does not expect to generate revenue from sales of any products for several years, if at all. To date, Legacy Q32 has funded its operations primarily from proceeds from the sales of its convertible preferred stock, convertible notes, venture debt, and proceeds from the Horizon Collaboration Agreement. From inception through December 31, 2023, Legacy Q32 raised $111.4 million in aggregate cash proceeds, net of issuance costs, from the sales of its Series A convertible preferred stock, Series A1 convertible preferred stock and Series B convertible preferred stock and received payments of $55.0 million in connection with its collaboration agreement with Horizon. Legacy Q32 also received $30.0 million from the sales of convertible notes and $5.5 million from its venture debt. As of December 31, 2023, Legacy Q32 had cash and cash equivalents of $25.6 million.

Going Concern

Legacy Q32 has incurred significant operating losses since inception and, as of December 31, 2023, had an accumulated deficit of $187.1 million. Legacy Q32 expects negative cash flows from operations and net losses for the foreseeable future as it continues to invest significantly in research and development of its product candidates and platform. Legacy Q32 has not yet commercialized any product and does not expect to generate revenue from sales of any products for several years, if at all.

As of December 31, 2023, Legacy Q32 had cash and cash equivalents of $25.6 million. Legacy Q32 expects that its cash and cash equivalents as of December 31, 2023, together with the proceeds from the issuance of additional shares of common stock in the Pre-Closing Financing for aggregate proceeds of $42.0 million and Homology's net cash and cash equivalents of $61.3 million on the closing date should be sufficient to fund its operations through mid-2026. Management based its projections of operating capital requirements on Legacy Q32's current operating plan, which includes several assumptions that may prove to be incorrect, and Legacy Q32 may use all

of its available capital resources sooner than management expects. Legacy Q32 expects 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 Legacy Q32 will be able to raise additional capital from these sources on favorable terms, or at all.

Cash Flows

The following table summarizes the Legacy Q32's cash flows for the periods indicated:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (18,677)	$ (10,957)
Net cash used in investing activities	(5)	(2,466)
Net cash flows provided by financing activities	406	30,069
Increase/(decrease) in cash, cash equivalents and restricted cash	$ (18,276)	$ 16,646

Operating Activities

Legacy Q32's cash flows from operating activities are greatly influenced by Legacy Q32's use of cash for operating expenses and working capital requirements to support Legacy Q32's business. Legacy Q32 has historically experienced negative cash flows from operating activities as Legacy Q32 invested in developing clinical programs, drug discovery efforts and related infrastructure.

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.

During the year ended December 31, 2022, net cash used in operating activities of $11.0 million consisted of a net loss of $42.8 million, partially offset by a change in net operating assets and liabilities of $26.9 million and net non-cash operating expenses of $4.9 million. The change in net operating assets and liabilities was primarily attributable to an increase in prepaid expenses, accrued expenses and deferred revenue of $ 28.4 million, partially offset by a decrease in other current assets, accounts payable and operating lease liability of $1.5 million. The non-cash operating expenses consisted mainly of a $2.4 million change in fair value of convertible notes, stock-based compensation expense of $1.2 million, non-cash lease expenses of $0.8 million and depreciation and amortization expense of $0.5 million.

Investing Activities

For the years ended December 31, 2023 and 2022, net cash used in investing activities consisted of purchases for property and equipment.

Financing Activities

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 and $106 thousand of proceeds from the exercise of common stock options offset by payments of $5.2 million associated with the repayment of Legacy Q32's initial loan and security agreement.

For the year ended December 31, 2022, net cash provided by financing activities consisted of $30.0 million of proceeds from the issuance of Legacy Q32's convertible notes and $69 thousand of proceeds from the exercise of common stock options.

Pre-Closing Financing

In connection with the Merger Agreement, certain third parties have entered into the Legacy Q32 Pre-Closing Financing as described above under "—Recent Developments—Merger with Homology and the Pre-Closing Financing." On March 25, 2024, or 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.

Future Funding Requirements

Management expects our expenses to increase substantially in connection with its ongoing research and development activities, particularly as it advances the preclinical activities and clinical trials of its product candidates. In addition, upon the completion of the Merger, we expect 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 its 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 ADX-097, 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 it receives 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 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;

- the extent to which we acquire or in-license other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

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, the net proceeds of the Legacy Q32 Pre-Closing Financing, together with our cash and cash equivalents will enable us to fund its operating expenses and capital expenditure requirements into mid-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 its available capital resources sooner than management expects.

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 product candidates, if approved, we will require substantial additional capital. Accordingly, until such time that we can generate a 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 themselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from recent bank failures. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Management cannot provide assurance that we will ever generate positive cash flow from operating activities.

Contractual Obligations and Commitments

Lease Obligations

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

The following table summarizes our contractual obligations and commitments as of December 31, 2023 (in thousands):

	Payments Due by Period			
	Total	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligation	$9,150	$ 3,181	$ 3,475	$ 2,494

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

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 Legacy Q32 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 Legacy Q32 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 Legacy Q32 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. Legacy Q32 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, Legacy Q32 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. Legacy Q32'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 (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. Legacy Q32 may terminate the Colorado License Agreement

for convenience upon providing prior written notice to Colorado. Colorado may terminate the Colorado License Agreement or convert Legacy Q32's exclusive license to a non-exclusive license if Legacy Q32 breaches certain obligations under the Colorado License Agreement and fails to cure such breach. The Colorado License Agreement will terminate automatically upon Legacy Q32's dissolution, insolvency, or bankruptcy. Legacy Q32 has the right to terminate the agreement for any reason upon written notice, and therefore, this agreement has not been included in the discussion above.

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 Legacy Q32 obtained sublicensable licenses from BMS to research, develop and commercialize licensed products, including bempikibart, for any and all uses worldwide. The licenses granted to Legacy Q32 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, Legacy Q32 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 Legacy Q32's obligation to pay BMS royalties or September 2029.

In consideration for the license, Legacy Q32 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, Legacy Q32 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.

Legacy Q32'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, or the Royalty Term. If Legacy Q32 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 Legacy Q32 fails to meet its diligence obligations under the BMS License Agreement, for Legacy Q32's insolvency, or if Legacy Q32 or its affiliates challenges the validity, scope, enforceability, or patentability of any of the licensed patents. Legacy Q32 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 Legacy Q32's material breach, BMS will regain rights to bempikibart and Legacy Q32 must grant BMS an exclusive license under Legacy Q32's patent rights covering bempikibart, subject to a low single digit percentage royalty on net sales of bempikibart payable to Legacy Q32 by BMS. Legacy Q32 has the right to terminate the agreement for any reason upon written notice, and therefore, this agreement has not been included in the discussion above.

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, 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 a termination agreement, 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.

Critical Accounting Policies and Significant Judgments and Estimates

Legacy Q32 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. Legacy Q32 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. Legacy Q32 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 Legacy Q32's significant accounting policies are described in more detail in the notes to its consolidated financial statements appearing elsewhere or incorporated by reference into this prospectus, management believes that the following accounting policies are those most critical to the judgments and estimates used in the preparation of Legacy Q32's consolidated financial statements.

Revenue Recognition

Under ASC Topic 606, Revenue from Contracts with Customers (Topic 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 Topic 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. Legacy Q32 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 Topic 606, Legacy Q32 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. Legacy Q32 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.

Legacy Q32 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, Legacy Q32 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. Legacy Q32 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, Legacy Q32 considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. Legacy Q32 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, Legacy Q32 estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. Legacy Q32 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, Legacy Q32 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, Legacy Q32 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 Legacy Q32'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, Legacy Q32 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, Legacy Q32 adjusts consideration for the effects of the time value of money if the timing of payments provides Legacy Q32 with a significant benefit of financing. Legacy Q32 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.

Legacy Q32 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.

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 Legacy Q32's consolidated financial statements, management is required to estimate its accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with its personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when Legacy Q32 has not yet been invoiced or otherwise notified of the actual costs. The majority of its service providers invoice Legacy Q32 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 Legacy Q32 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 its 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 Legacy Q32 does not expect its estimates to be materially different from amounts actually incurred, its 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

Legacy Q32 accounts for all Convertible Notes issued under the fair value option election of ASC 825, *Financial Instruments* (ASC 825). The financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized within other income (expense) 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. Legacy Q32 recorded $6.2 million and $2.4 million loss related to the change in fair value of the Convertible Notes for the years ended December 31, 2023 and 2022, respectively.

Stock-Based Compensation Expense

Legacy Q32 accounts for stock-based awards in accordance with ASC Topic 718, Compensation – Stock Compensation (ASC 718). ASC 718 requires all stock-based awards issued to employees and members of Legacy Q32's board of directors (the "Board") for their services to be recognized as expense in the statements of operations based on their grant date fair values. Legacy Q32 uses the value of its common stock to determine the fair value of its stock-based awards. For stock options and time-based restricted stock awards, Legacy Q32 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, Legacy Q32 uses the accelerated attribution method to expense the awards over the implicit service period based on the probability of achieving the performance conditions. Legacy Q32 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. Legacy Q32 accounts for forfeitures as they occur.

Fair Value of Stock-Based Awards

Legacy Q32 determines the fair value of restricted stock awards in reference to the fair value of its common stock less any applicable purchase price. Management estimates the fair value of Legacy Q32's stock options granted with service-based conditions using the Black-Scholes option pricing model, which requires inputs of subjective assumptions, including: (i) the expected volatility of our common stock, (ii) the expected term of the award, (iii) the risk-free interest rate, (iv) expected dividends and (v) the fair value of its common stock. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, management bases the estimate of expected volatility on the historical volatilities of a representative group of publicly traded guideline companies. For these analyses, it selects companies with comparable characteristics and with historical share price information that approximates the expected term of the stock-based awards. Management computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period that approximates the calculated expected term of its stock options. Management will continue to apply this method until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. Legacy Q32 estimates the expected term of its stock options granted to employees and directors using the simplified method, whereby the expected term equals the average of the vesting term and the original contractual term of the option. It utilizes this method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected dividend yield is assumed to be zero as Legacy Q32 has no current plans to pay any

dividends on common stock. Legacy Q32 has elected to use the expected term for stock options granted to non-employees, using the simplified method, as the basis for the expected term assumption. However, Legacy Q32 may elect to use either the contractual term or the expected term for stock options granted to non-employees on an award-by-award basis.

Determination of the Fair Value of Common Stock

Given the absence of an active market for its common stock prior to the Merger, 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 its 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 its 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 Legacy Q32's 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 its equity as a private company;
- the prices of its convertible preferred stock sold to outside investors in arm's length transactions and the rights, preferences and privileges of its convertible preferred stock as compared to those of its common stock, including the liquidation preferences of its convertible preferred stock;
- the progress of its research and development efforts, including the status of preclinical studies and clinical trials for its product candidates;
- its stage of development and business strategy and the material risks related to its 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 Legacy Q32, given prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

For financial statement purposes, management performed common stock valuations at various dates, which resulted in valuation of its common stock of $0.90 per share as of December 31, 2023, $0.82 per share as of October 27, 2023, $0.81 per share as of September 15, 2023, $0.36 per share as of September 30, 2022, and $0.35 per share as of December 27, 2021. There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding its future operating performance, the stage of development of our product candidates, the timing and probability of a potential initial public offering or

other liquidity event and the determination of the appropriate valuation methodology at each valuation date. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and management uses significantly different assumptions or estimates, its stock-based compensation expense could be materially different.

Once a public trading market for its 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 its common stock in connection with its accounting for granted stock options and restricted stock awards, as the fair value of its common stock will be determined based on the trading price of its common stock on Nasdaq.

Valuation Methodologies

Legacy Q32 used a hybrid of the probability-weighted expected returns method, or PWERM, and the Option Pricing Method, or OPM, when allocating enterprise value to classes of securities.

Under the PWERM, the value of an enterprise, and its underlying common stock are estimated based on an analysis of future values for the enterprise, assuming various outcomes. The value of the common stock is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes and the rights of each class of equity. The future values of the common stock under the various outcomes are discounted back to the valuation date at an appropriate risk-adjusted discount rate and then probability weighted to determine the value for the common stock.

The OPM treats common stock and preferred stock as call options on the enterprise's equity value, with exercise prices based on the liquidation preferences of the preferred stock. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preferences at the time of a liquidity event. The Black-Scholes option pricing model is used to price the call option, and the model includes assumptions for the time to liquidity and the volatility of equity value.

The hybrid method is a blend of the PWERM and OPM, estimating the probability-weighted value across multiple scenarios and then using the OPM to estimate the allocation of value within one or more of those scenarios. When using the hybrid method, Legacy Q32 assumed three scenarios: an early initial public offering, or IPO, scenario, a late IPO scenario and a remain-private scenario. The IPO scenarios reflect an exit or liquidity event by means of a sale of common stock to the public where the estimated IPO price is based, in part, on a review of recent IPO information of comparable public companies at a similar stage to us at the time of their IPO. The comparable IPO companies considered for these scenarios consisted of biopharmaceutical companies at various stages of development ranging from discovery stage to completion of early-stage clinical trials. Additional comparable IPO companies at similar product development stages in the broader biopharmaceutical industry were also considered. We converted the estimated future value in an IPO to present value using a risk-adjusted discount rate. The equity value for the remain-private scenario was estimated using the discounted cash flow method or by back-solving to the price of recently issued preferred stock. In the remain-private scenario, value is allocated to our equity securities using the OPM. In the OPM, volatility is estimated based on the trading histories of selected guideline public companies. The relative probability of each scenario was determined based on an assessment of then-current market conditions and our expectations as to timing and prospects of an IPO.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and certain recently adopted accounting pronouncements that have or may potentially impact Legacy Q32's financial position and results of operations is included in Note 2 to Legacy Q32's audited consolidated financial statements appearing elsewhere or incorporated by reference in this prospectus.

Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2023 and 2022, Legacy Q32 had cash, cash equivalents, restricted cash, and restricted cash equivalents of $31.3 million, $49.5 million, respectively, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of Legacy Q32's cash or cash equivalents.

All of Legacy Q32's employees and operations are currently located in the United States. Legacy Q32 has, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, Legacy Q32 has had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, Legacy Q32 believes it does not have a material exposure to foreign currency risk.

Inflation generally affects Legacy Q32 by increasing its cost of labor. Legacy Q32 does not believe that inflation had a material effect on its business, financial condition or results of operations during the years ended December 31, 2023 or 2022.

HOMOLOGY MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of Homology Medicines, Inc.'s, or Homology, financial condition and results of operations should be read in conjunction with its "Selected Consolidated Financial Data" and its consolidated financial statements, related notes and other financial information included or incorporated by reference elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties such as Homology's plans, objectives, expectations and intentions.

Unless otherwise indicated or the context otherwise requires, references in this "Homology Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Homology Medicines, Inc." or "Homology" refers to the business and operations of Homology Medicines, Inc. (now Q32 Bio Inc.) and its consolidated subsidiaries prior to the Merger, references to "Q32 Bio Inc." or "Q32" refer to the business and operations of Q32 Bio Operations Inc. (previously Q32 Bio Inc.) and its consolidated subsidiaries prior to the Merger, and references to "the Company,", "us," "we," or other similar words refer to the business and operations of Q32 Bio Inc. and its consolidated subsidiaries after the Merger. Unless otherwise indicated, the information in this "Homology Management's Discussion and Analysis of Financial Condition and Results of Operations" section is as of December 31, 2023 and does not reflect the effects of the Merger or the Reverse Stock Split.

Overview

Homology was a clinical-stage genetic medicines company focused on transforming the lives of patients suffering from rare genetic diseases with significant unmet medical needs by addressing the underlying cause of the disease. Homology's proprietary platform is designed to utilize its human hematopoietic stem cell-derived adeno-associated virus vectors, or AAVHSCs, to precisely and efficiently deliver single administration genetic medicines *in vivo* through a nuclease-free gene editing modality, gene therapy, or gene therapy to express antibodies platform, or GTx-mAb, which is designed to produce antibodies throughout the body.

In July 2023, Homology completed a review of its business and its Board of Directors approved a plan to explore, review and evaluate a range of potential strategic options available to it, including, without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. Based on the financing environment and the anticipated clinical development timeline for its lead program, HMI-103, Homology stopped further development of its programs and reduced its workforce by 86% to significantly reduce its ongoing operating costs as Homology evaluated strategic alternatives.

Agreement and Plan of Merger

After a comprehensive review of strategic alternatives, on November 16, 2023, Homology entered into an Agreement and Plan of Merger, or the Merger Agreement, with Q32 Bio Operations Inc. (previously Q32 Bio Inc.), a Delaware corporation, or Legacy Q32, and Kenobi Merger Sub, Inc., a Delaware corporation, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Legacy Q32, with Legacy Q32 continuing as Homology's wholly owned subsidiary and the surviving corporation of the merger, or the Merger.

Merger Consideration

Subject to the terms and conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger, or the Effective Time, all Legacy Q32 preferred stock was converted into Legacy Q32 common stock pursuant to the organizational documents of Legacy Q32, or the Legacy Q32 Preferred Stock Conversion, and (ii) at the Effective Time, (a) each outstanding share of Legacy Q32 common stock (excluding Legacy Q32 common stock issued in the Concurrent Financing, as described below) was converted into the right to receive a

number of shares of Homology's common stock, calculated in accordance with the Merger Agreement, (b) each outstanding Legacy Q32 stock option and warrant that has not previously been exercised prior to the closing of the Merger was assumed by Homology and become an option or warrant, as applicable, to purchase a number of shares of Homology common stock and (c) the Legacy Q32 common stock issued in the Concurrent Financing was converted into the right to receive a number of shares of Homology common stock calculated in accordance with the Merger Agreement. The shares of Homology common stock issued to stockholders of Legacy Q32 was calculated using a formula in the Merger Agreement based on the equity value of each of Legacy Q32 and Homology. At the closing of the Merger, Legacy Q32 was ascribed an aggregate equity value of $195 million and Homology's equity value was approximately $80 million .

Concurrent Financing

Pursuant to the Merger Agreement, immediately prior to the Effective Time, Legacy Q32 consummated a financing through the sale of its common stock for aggregate gross proceeds of $42 million based on the same aggregate equity value of Q32 used in the Merger, or the Concurrent Financing. On November 16, 2023, Legacy Q32 entered into subscription agreements with certain accredited investors, or the Investors, for the Concurrent Financing with gross proceeds to Legacy Q32 of $42 million. In connection with the Concurrent Financing, at the closing of the Merger, Legacy Q32 entered into a registration rights agreement with the Investors providing for the registration under the Securities Act of 1933, as amended, or the Securities Act, of the shares of common stock sold in the Concurrent Financing. The consummation of the transactions contemplated by the subscription agreements was conditioned on the satisfaction or waiver of the conditions set forth in the Merger Agreement and in the subscription agreements. Shares of Legacy Q32 common stock issued pursuant to the Concurrent Financing were converted into shares of Homology common stock in connection with the Merger in accordance with the Merger Agreement.

Contingent Value Rights Agreement

On March 23, 2024, the Company entered into a Contingent Value Rights Agreement, or the CVR Agreement, with Equiniti Trust Company, LLC, or the Rights Agent, pursuant to which Homology's common stockholders of record as of March 21, 2024 received one contingent value right, each a CVR, for each outstanding share of Homology common stock held by such stockholder on such date.

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 its HMI-103, HMI-204, Capsids and AAVHSC Platform, including any equity interests held directly or indirectly by the Company in Oxford Biomedica (US) LLC (f/k/a Oxford Biomedica Solutions LLC and Roadrunner Solutions LLC), or OXB (US) LLC, pursuant to that certain Equity Securities Purchase Agreement, dated as of January 28, 2022, by and between Homology and OXB Solutions, or the Legacy Assets, and such disposition, or a Legacy Asset Disposition, net of certain tax, transaction costs and certain other expenses.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the holders of the CVRs. There can be no assurance that any holders of CVRs will receive payments with respect thereto. The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or any other instrument and will not be registered with the Securities and Exchange Commission, or SEC. The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in the Company or any of its affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

Former Clinical Programs

Homology's former clinical programs include: HMI-103, an investigational gene editing candidate for the treatment of patients with phenylketonuria, or PKU; HMI-203, an investigational gene therapy candidate for the treatment of patients with mucopolysaccharidosis type II (MPS II), or Hunter syndrome; and HMI-102, an investigational gene therapy candidate for the treatment of adult patients with PKU. Homology's former preclinical programs include: HMI-104, a GTx-mAb gene therapy candidate for the treatment of patients with paroxysmal nocturnal hemoglobinuria, or PNH, and HMI-204, a gene therapy candidate for metachromatic leukodystrophy, or MLD. The Company is currently exploring strategic alternatives for HMI-103 (Adult/Pediatric PKU), HMI-204 (MLD) and its capsids and AAVHSC platform, including the sale of these programs.

In August 2023, Homology withdrew its Clinical Trial Application, or CTA, for HMI-203 in Canada. In September 2023, Homology withdrew its IND for HMI-102, which the FDA formally acknowledged in November 2023. In December 2023, Homology withdrew its IND for HMI-203 and in March 2024, Homology withdrew its IND for HMI-103. All clinical trial sites have been notified that all studies Homology was conducting for its programs were terminated; sites have been duly notified of their responsibilities. Homology has also withdrawn all orphan drug designations for its programs in both the United States and the EU.

In September 2023, Homology inactivated the pheEDIT Phase 1 gene editing clinical trial evaluating HMI-103 in adults with classical PKU (NCT05222178). In October 2023, Homology reported clinical data from the first dose cohort in the pheEDIT trial. As of the data cut-off date of September 14, 2023, HMI-103 was generally well-tolerated in all three participants with no serious adverse events, and the majority of treatment-related adverse events were mild and transient. All liver function tests remained in the normal range during the prophylactic immunosuppression regimen incorporating the T-cell inhibitor tacrolimus in combination with corticosteroid. Participant 1 experienced a reduction in plasma phenylalanine, or Phe, levels to below the U.S. American College of Medical Genetics and Genomics PKU treatment guideline threshold of <360 µmol/L, and the majority of Phe levels were below 360 mmol/L through 39 weeks post-dose, including after the initiation of dietary protein supplementation. Participant 2 experienced a meaningful plasma Phe reduction of 50% at 23 weeks post-dose. Participant 3 experienced a meaningful plasma Phe reduction of 60% at 14 weeks post-dose.

In August 2023, Homology terminated both the pheNIX Phase 1/2 gene therapy clinical trial evaluating HMI-102 in adults with classical PKU and the juMPStart Phase 1 gene therapy clinical trial evaluating HMI-203 in adults with Hunter Syndrome. INDs for both the pheNIX Phase 1/2 and juMPStart Phase 1 clinical trials have been withdrawn.

Oxford Biomedica (US) LLC Transaction

On March 10, 2022, Homology closed a transaction with Oxford Biomedica (US) LLC (f/k/a Roadrunner Solutions LLC and Oxford (US) LLC), or OXB (US) LLC, Oxford Biomedica (US), Inc., or OXB, and Oxford Biomedica plc, or OXB Parent, and collectively with OXB, Oxford, pursuant to the Equity Securities Purchase Agreement, or the Purchase Agreement, dated as of January 28, 2022, by and among Homology, OXB (US) LLC and Oxford, whereby, among other things, Homology and Oxford agreed to collaborate to operate OXB (US) LLC, which provides AAV vector process development and manufacturing services to biotechnology companies, which Homology refers to as the Oxford Biomedica (US) LLC Transaction, or the OXB (US) LLC Transaction. OXB (US) LLC incorporates Homology's proven 'plug and play' process development and manufacturing platform, as well as Homology's experienced team and high-quality GMP vector production capabilities that Homology built and operated since 2019.

Pursuant to the terms of the Purchase Agreement and a contribution agreement, or the Contribution Agreement, entered into between Homology and OXB (US) LLC prior to the closing of the OXB (US) LLC Transaction, or the Closing, Homology agreed to assign and transfer to OXB (US) LLC all of its assets that are primarily used in the manufacturing of AAV vectors for use in gene therapy or gene editing products, but excluding certain assets related to manufacturing or testing of its proprietary AAV vectors, or collectively, the Transferred Assets, in

exchange for 175,000 common equity units in OXB (US) LLC, or Units, and OXB (US) LLC assumed from Homology, and agreed to pay, perform and discharge when due, all of Homology's duties, obligations, liabilities, interests and commitments of any kind under, arising out of or relating to the Transferred Assets.

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

Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB (US) LLC, or the OXB (US) LLC Operating Agreement, which was executed in connection with the Closing, at any time following the three-year anniversary of the Closing, (i) OXB will have an option to cause us to sell and transfer to OXB, and (ii) Homology will have an option to cause OXB to purchase from Homology, in each case all of its equity ownership interest in OXB (US) LLC at a price equal to 5.5 times the revenue for the immediately preceding 12-month period, subject to a maximum amount of $74.1 million. Pursuant to the terms of the OXB (US) LLC Operating Agreement, Homology is entitled to designate one director on the board of directors of OXB (US) LLC, currently Paul Alloway, Ph.D., Homology's President and Chief Operating Officer.

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

License Agreements

In April 2016, Homology entered into an exclusive license agreement with City of Hope, or COH, pursuant to which COH granted Homology an exclusive, sublicensable, worldwide license, or the COH License, to certain AAV vector-related patents and know-how owned by COH to develop, manufacture, use and commercialize products and services covered by such patents and know-how in any and all fields. On August 6, 2021, Homology received notice from COH that Homology did not accomplish at least one of the partnering milestones by the applicable deadline, as set forth in the COH License. This notice does not affect Homology's exclusive license in the field of mammalian therapeutics, including all human therapeutics, associated diagnostics, and target validation, or the Mammalian Therapeutic Field, where Homology retains exclusive rights. Instead, the notice served as written notice that the exclusive license granted pursuant to the COH License in all fields except the Mammalian Therapeutic Field converted from exclusive to non-exclusive effective as of September 20, 2021, which was forty-five days from the receipt of notice. In connection with the conversion, any royalty obligations and sublicensee fees relating to fields outside of the Mammalian Therapeutic Field shall be reduced by a certain percentage. This change to Homology's exclusive worldwide license with COH did not impact any of its therapeutic product development candidates, including HMI-102, HMI-103, HMI-104, HMI-203 and HMI-204.

Corporate Headquarters Lease

In November 2021, Homology entered into an amendment of its December 2017 lease agreement, or the Lease Amendment, for its corporate headquarters in Bedford, Massachusetts. The Lease Amendment increased the space under the lease by approximately 23,011 square feet, or the Expansion Premises, and extended the expiration date of the existing premises under the lease from February 2027 to June 2030. The term with respect to the Expansion Premises commenced May 1, 2022 and will continue for a period of ten years and five months. The term of the Expansion Premises and the existing premises are not coterminous. Annual base rent for the

existing premises under the Lease Amendment is approximately $4.7 million beginning on March 1, 2027, and increases by three percent annually; annual base rent for the Expansion Premises is approximately $1.4 million per year and increases by three percent annually. The Lease Amendment allows for tenant improvement allowances not to exceed $6.3 million in the aggregate. Under the terms of the agreement with Oxford, Homology's lease for its corporate headquarters, including the Expansion Premises, has been assigned to OXB (US) LLC with Homology subleasing a portion of lab and office space back from OXB (US) LLC. Effective October 1, 2023, Homology was released from being primary obligor under such lease. See Note 10 to Homology's consolidated financial statements included elsewhere in this prospectus for additional information regarding this lease agreement.

Financial Overview

Since Homology's inception in 2015 through December 31, 2023, Homology has raised approximately $721 million in aggregate net proceeds through its initial public offering, or IPO, in April 2018, follow-on public offerings of common stock in April 2019 and April 2021, proceeds from the sale of common stock under an "at-the-market" sales agreement, equity investments from pharmaceutical companies, preferred stock financings and Homology's agreement with Oxford. Included in Homology's net proceeds is a $130.0 million up-front cash payment from its agreement with Oxford, $50.0 million from a former collaboration partner, comprised of an up-front payment of $35.0 million and a $15.0 million equity investment, and a $60.0 million equity investment from Pfizer Inc., or Pfizer, through a private placement transaction.

Homology was incorporated and commenced operations in 2015. Since Homology's incorporation and until December 31, 2023, Homology devoted substantially all of its resources to organizing and staffing its business, business planning, raising capital, developing its technology platform, advancing HMI-102, HMI-103 and HMI-203 through IND-enabling studies and into clinical trials, advancing HMI-202 and HMI-104 into IND-enabling studies, researching and identifying additional product candidates, developing and implementing manufacturing processes and manufacturing capabilities, building out its manufacturing and research and development space, enhancing its intellectual property portfolio and providing general and administrative support for these operations. Until December 31, 2023, Homology had financed its operations primarily through the sale of common stock, through the sale of preferred stock, through funding from Homology's collaboration partner and through proceeds received as a result of its transaction with OXB (US) LLC.

Through December 31, 2023, Homology had not generated any revenue from product sales. Homology recognized $1.2 million and $3.2 million in collaboration revenue for the years ended December 31, 2023 and 2022, respectively.

Since inception, Homology has incurred significant operating losses. Homology's net losses for the years ended December 31, 2023 and 2022 were $113.0 million and $5.0 million, respectively. On March 10, 2022, Homology closed its transaction with OXB (US) LLC and recorded a gain of $131.2 million on the sale of its manufacturing business (see Note 6 to Homology's consolidated financial statements included elsewhere in this prospectus for additional information regarding the OXB (US) LLC Transaction). As of December 31, 2023 and 2022, Homology had an accumulated deficit of $542.1 million and $429.1 million, respectively.

Homology's total operating expenses were $102.6 million and $136.5 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, Homology had cash, cash equivalents, and short-term investments of $82.7 million. Due to the discontinuation of all of Homology's clinical trials and research activities, as well as its reduction in force of all but a few custodial employees, Homology's management concluded that there is a substantial doubt regarding its ability to continue as a going concern for more than twelve months after the date of the consolidated financial statements incorporated by reference to this Registration Statement. See "Liquidity and Capital Resources."

Components of Homology's Results of Operations

Revenue

Through December 31, 2023, Homology had not generated any revenue from product sales. Homology recorded $1.2 million in collaboration revenue for the year ended December 31, 2023, related to the Stock Purchase Agreement with Pfizer (see Note 17 to Homology's consolidated financial statements incorporated by reference to this Registration Statement for additional information regarding revenue recognition discussions).

Operating Expenses

Homology's operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and Development Expenses

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

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, and other third parties that conduct research, preclinical activities and clinical trials on Homology's behalf as well as CMOs, including OXB (US) LLC, that manufacture Homology's product candidates for use in its preclinical testing and clinical trials;
- costs of outside consultants, including their fees and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials; and
- allocated expenses for rent and other operating costs.

Homology expensed research and development costs as incurred and research and development activities had historically been central to Homology's business model.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in Homology's executive, finance, human resources, legal, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs, rent expense, maintenance of facilities and other operating costs including expenses associated with being a public company.

Other Income

Other income consists of a gain on the termination of Homology's lease and interest income earned on its cash, cash equivalents, and short-term investments. Homology's interest income has increased due to significantly higher yields on invested funds during the year ended December 31, 2023 as compared to the prior year period.

Income Taxes

Since Homology's inception in 2015, it has not recorded any U.S. federal or state income tax benefits for the net losses it has incurred in any year or for its earned research and development tax credits, due to Homology's

uncertainty of realizing a benefit from those items. As of December 31, 2023, Homology had federal and state net operating loss carryforwards of $326.2 million and $317.3 million, respectively, that expire at various dates through 2043, to the extent subject to expiration. As of December 31, 2023, Homology also had federal and state research and development tax credit carryforwards of $65.5 million and $17.2 million, respectively, that expire at various dates through 2043. Included in the $65.5 million of federal research and development credit carryforwards is $50.7 million of orphan drug credit carryforwards.

Critical Accounting Policies and Use of Estimates

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

While Homology's significant accounting policies are described in more detail in the notes to its consolidated financial statements included elsewhere in this prospectus, Homology believes that the following accounting policy is the most critical to the judgments and estimates used in the preparation of Homology's consolidated financial statements.

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

Homology bases its accrued expenses related to preclinical and clinical studies on its estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct and manage preclinical studies and clinical trials and CMOs, including OXB (US) LLC, that manufacture product for Homology's research and development activities. The financial terms of these agreements are sometimes subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to Homology's vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical milestones. In accruing fees, Homology 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 Homology's estimate, Homology adjusts the accrual or amount of prepaid expense accordingly.

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

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

The following table summarizes Homology's results of operations for the years ended December 31, 2023 and 2022:

	For the Year ended December 31,		
(in thousands)	**2023**	**2022**	**Change**
Collaboration revenue	$ 1,156	$ 3,208	$ (2,052)
Operating expenses:			
Research and development	62,002	98,351	(36,349)
General and administrative	31,256	38,138	(6,882)
Restructuring and other charges	9,327	—	9,327
Total operating expenses	102,585	136,489	(33,904)
Loss from operations	(101,429)	(133,281)	31,852
Other income:			
Gain on sale of business	—	131,249	(131,249)
Gain on lease termination	8,767	—	8,767
Interest income	5,582	3,230	2,352
Total other income	14,349	134,479	(120,130)
Income (loss) before income taxes	(87,080)	1,198	(88,278)
Provision for income taxes	—	(715)	715
Loss from equity method investment	(25,881)	(5,488)	(20,393)
Net loss	$(112,961)	$ (5,005)	$(107,956)

Collaboration Revenue

Collaboration revenue for the year ended December 31, 2023 was $1.2 million, compared to $3.2 million for the year ended December 31, 2022. Collaboration revenue in both periods was due to the recognition of deferred revenue related to the Stock Purchase Agreement with Pfizer. Homology previously recognized deferred revenue from Pfizer over Pfizer's right of first refusal, or ROFR, period of 30 months during which Pfizer could have negotiated a potential collaboration on the development and commercialization of HMI-102 and HMI-103. The ROFR period expired in May 2023.

Research and Development Expenses

(in thousands)	For the Year ended December 31, 2023	2022	Change
External development costs for clinical programs:			
HMI-102	$ 4,514	$16,245	$(11,731)
HMI-103	18,525	19,358	(833)
HMI-203	9,643	15,839	(6,196)
Other development-stage programs' external development costs	13,526	9,794	3,732
Employee-related costs	11,820	29,654	(17,834)
Other research and development costs	3,974	7,461	(3,487)
Total research and development expenses	$62,002	$98,351	$(36,349)

Research and development expenses for the year ended December 31, 2023 were $62.0 million, compared to $98.4 million for the year ended December 31, 2022. The decrease of $36.3 million was primarily associated with Homology's decision to stop further development of its programs and reduce its workforce by 86% in July 2023 in an effort to decrease Homology's ongoing operating costs. As of December 31, 2023, Homology had no remaining obligations with its CRO or any other vendors associated with its former clinical trials and has recognized expense for any remaining contractual obligations owed under its Supply Agreement with OXB (US) LLC; there are no minimum purchase commitments under the Supply Agreement in 2024. All contracts with vendors previously performing research and development activities for Homology have been terminated and all expenses have been recorded.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2023 were $31.3 million, compared to $38.1 million for the year ended December 31, 2022. The decrease of $6.9 million was primarily due to a $4.6 million decrease in employee-related costs as a result of the reduction in workforce Homology instituted in the third and fourth quarters of 2023. In addition, consulting expenses decreased by $2.8 million as the prior year included a fee of $2.5 million paid to a strategic advisory firm that assisted Homology with the OXB (US) LLC transaction. There were also decreased market research costs, travel and insurance costs, all associated with Homology's decision to reduce in the second half of 2023 its workforce in an effort to decrease ongoing operating costs.

Restructuring and Other Charges

In connection with the corporate restructuring that reduced Homology's workforce by approximately 80 employees, or 86%, in the third quarter of 2023 and an additional 6 employees in the fourth quarter of 2023, Homology recorded a restructuring charge for severance and related costs of $10.3 million during the year ended December 31, 2023. Homology also modified certain stock options and restricted stock units granted to the terminated employees in a prior period. These equity modifications resulted in a net reduction to stock-based compensation expense of $1.0 million reflected within restructuring and other charges during the year ended December 31, 2023. See Notes 9 and 14 to Homology's consolidated financial statements included elsewhere in this prospectus for additional information regarding restructuring and other charges. Homology did not record restructuring and other charges for the year ended December 31, 2022.

Gain on Sale of Business

Gain on sale of business for the year ended December 31, 2022 was $131.2 million. On March 10, 2022, Homology closed its transaction with OXB (US) LLC and recorded a gain of $131.2 million on the sale of its manufacturing business. See Note 6 to Homology's consolidated financial statements included elsewhere in this prospectus for details surrounding the sale.

Gain on Termination of Lease

Gain on lease termination for the year ended December 31, 2023 was $8.8 million. Effective October 1, 2023, Homology was released from being primary obligor under its corporate headquarters lease and therefore derecognized the right-of-use asset and operating lease liability, recording the difference as a gain within other income on the consolidated statements of operations. See Note 10 to Homology's consolidated financial statements included elsewhere in this prospectus for details surrounding the transaction.

Interest Income

Interest income for the year ended December 31, 2023 was $5.6 million, compared to $3.2 million for the year ended December 31, 2022. The increase of $2.4 million was primarily the result of interest income generated at higher yields on invested funds for the year ended December 31, 2023, compared to the year ended December 31, 2022.

Provision for Income Taxes

Homology recorded an income tax provision of $0.7 million for the year ended December 31, 2022. The tax provision predominately resulted from the gain associated with the sale of Homology's manufacturing business due to the transaction with Oxford. Though Homology had taxable income for the year ended December 31, 2022, Homology had federal and state net operating loss carryforwards and research and development tax credits available to offset most of that taxable income for the period. Homology did not record an income tax provision (benefit) for the year ended December 31, 2023, as Homology was in a taxable loss position for the year.

Loss from Equity Method Investment

Homology records its share of gains or losses from OXB (US) LLC on a quarterly basis. For the year ended December 31, 2023 and 2022, Homology recorded a loss from equity method investment of $25.9 million and $5.5 million, respectively, representing its share of OXB (US) LLC's net loss during the year ended December 31, 2023 and the period from March 11, 2022 through December 31, 2022, respectively. For the year ended December 31, 2023, OXB (US) LLC recorded an impairment charge of $119.1 million which significantly increased OXB (US) LLC's net loss for the period. In addition, the loss from equity method investment for the year ended December 31, 2023 includes an other-than-temporary impairment charge of approximately $3.8 million Homology recorded because it was determined that the fair value of its equity method investment in OXB (US) LLC was less than its carrying value. After recording Homology's share of OXB (US) LLC's net loss, the carrying value of Homology's equity method investment was reduced to $0.0 million. See Notes 2 and 6 to Homology's consolidated financial statements included elsewhere in this prospectus for more information regarding the equity method of accounting.

Net Loss

Net loss for the year ended December 31, 2023 was $113.0 million, compared to $5.0 million for the year ended December 31, 2022. The increase in Homology's net loss was primarily due to a gain of $131.2 million in the prior year on the sale of its manufacturing business, offset by Homology's operating expenses as described above.

Liquidity and Capital Resources

Since Homology's inception, Homology has incurred significant operating losses. Homology does not have any approved products and Homology has never generated any revenue from product sales. To date, Homology has financed its operations primarily through the sale of common stock, the sale of preferred stock, through an up-front payment and funding of research candidates from a collaboration partner and through the gross proceeds

from its transaction with OXB (US) LLC. Since Homology's inception in 2015, it has raised approximately $721 million in aggregate net proceeds through its IPO in April 2018, follow-on public offerings of common stock in April 2019 and April 2021, proceeds from the sale of common stock under an "at-the-market" sales agreement, equity investments from pharmaceutical companies, preferred stock financings and its agreement with Oxford. Included in Homology's net proceeds is a $130.0 million up-front cash payment from its agreement with Oxford, $50.0 million from a former collaboration partner, comprised of an up-front payment of $35.0 million and a $15.0 million equity investment and a $60.0 million equity investment from Pfizer through a private placement transaction.

ATM Program

On March 9, 2023, Homology filed a Registration Statement on Form S-3 (File No. 333-270414) (the "Shelf") with the SEC in relation to the registration of up to an aggregate of $250.0 million of its common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for a period up to three years from the date of the filing. The Shelf became effective on March 17, 2023. Homology also simultaneously entered into a sales agreement with Cowen and Company, LLC, or Cowen, as sales agent, providing for the offering, issuance and sale by the Company of up to an aggregate of $75.0 million of Homology common stock from time to time in "at-the-market" offerings under the Shelf, or the ATM. Homology did not sell any shares of common stock under the ATM during the year ended December 31, 2023. As of December 31, 2023, there remained $75.0 million of common stock available for sale under the ATM.

Oxford Biomedica (US) LLC Transaction

On March 10, 2022, Homology closed a transaction with OXB (US) LLC pursuant to the Purchase Agreement, dated as of January 28, 2022, by and among Homology, OXB (US) LLC and Oxford, whereby, among other things, Homology and Oxford agreed to collaborate to operate OXB (US) LLC, which provides AAV vector process development services and manufacturing services to pharmaceutical and biotechnology companies. Pursuant to the terms of the agreements entered into as part of the OXB (US) LLC Transaction, Homology assigned and transferred to OXB (US) LLC all of its assets that were primarily used in the manufacturing of AAV vectors for use in gene therapy and gene editing products. Oxford paid Homology $130.0 million upfront and invested $50.0 million to fund the new company in exchange for an 80 percent ownership stake, while Homology owns 20 percent of the new company. Also, at any time following the three-year anniversary of the closing of the transaction, Oxford has an option to cause Homology to sell and transfer to Oxford and Homology have an option to cause Oxford to purchase from Homology, in each case all of Homology's equity ownership interest in OXB (US) LLC at a price equal to 5.5 times the revenue for the immediately preceding 12-month period, subject to a maximum amount of $74.1 million. See Note 6 to Homology's consolidated financial statements included elsewhere in this prospectus for additional information regarding the Oxford transaction.

Strategic Collaborations and Investments

On November 9, 2020, Homology entered into the Stock Purchase Agreement with Pfizer, pursuant to which Pfizer purchased 5,000,000 shares of Homology common stock through a private placement transaction at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million. Under the Stock Purchase Agreement, Pfizer was granted an exclusive right of first refusal, or ROFR, for a 30-month period to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103. The 30-month ROFR period expired on May 9, 2023. In addition to the ROFR, the Stock Purchase Agreement provided for an information sharing committee comprised of representatives of each company which served as a forum for sharing information regarding the development of HMI-102 and HMI-103 during the ROFR period. Additionally, Pfizer designated a member to join Homology's Scientific Advisory Board to participate in matters related to the development of these programs.

Strategic Review and Reduction in Force

On July 25, 2023, Homology's board of directors approved a process to explore, review and evaluate a range of potential strategic options available to Homology, including, without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. Therefore, based on cost-reduction initiatives intended to reduce Homology's ongoing operating expenses and maximize shareholder value as it evaluated strategic options, Homology's board of directors also approved a reduction in its workforce by approximately 80 employees during the third quarter of 2023 and an additional 6 employees during the fourth quarter of 2023. In connection with this corporate restructuring, Homology recorded a restructuring charge for severance and related costs of $10.3 million in its consolidated statements of operations during the year ended December 31, 2023.

Cash Flows

Homology's cash, cash equivalents and short-term investments totaled $82.7 million and $175.0 million as of December 31, 2023 and 2022, respectively. Homology had no indebtedness as of December 31, 2023 and 2022.

The following table summarizes Homology's sources and uses of cash for each of the periods presented:

	For the Year ended December 31,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (96,230)	$(113,661)
Net cash provided by investing activities	101,326	36,716
Net cash provided by financing activities	184	596
Net change in cash, cash equivalents and restricted cash	$ 5,280	$ (76,349)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $96.2 million, which was primarily utilized for the funding of Homology's operating expenses of $102.6 million as Homology incurred expenses associated with research and development activities prior to its decision to stop further development of its programs. Such activities included clinical trial activities associated with Homology's HMI-103 and HMI-203 programs, preclinical development activities for HMI-104 and research activities on other applications for its technology, adjusted for non-cash expenses of $23.9 million. Non-cash expenses includes an $25.9 million loss from Homology's equity method investment in OXB (US) LLC, $7.3 million of stock-based compensation expense and noncash lease expense of $2.1 million, partially offset by an $8.9 million net gain recognized on the termination of its corporate lease and accretion on short-term investments of $2.9 million. The change in operating assets and liabilities of $7.2 million was driven by decreased accrued expenses and other liabilities of $11.7 million, decreased operating lease liabilities of $1.4 million and decreased deferred revenue of $1.2 million, partially offset by decreased prepaid expenses and other current assets of $5.0 million increased accounts payable of $2.1 million.

Net cash used in operating activities for the year ended December 31, 2022 was $113.7 million, which was primarily utilized for the funding of Homology's operating expenses of $136.5 million, as Homology incurred expenses associated with research and development activities including clinical trial activities associated with Homology's HMI-103, HMI-203 and HMI-102 programs, preclinical development activities including IND-enabling studies for HMI-104 and research activities on other applications for Homology's technology, adjusted for non-cash expenses of $112.0 million, which includes the one-time gain of $131.2 million recognized on the sale of Homology's manufacturing business to Oxford, and a change in operating assets and liabilities of $3.4 million. The change in operating assets and liabilities was driven by increased accrued expenses and other

liabilities of $7.4 million largely due to materials produced for us by OXB (US) LLC and accrued for at year-end, offset by decreased deferred revenue of $3.2 million and decreased accounts payable of $1.0 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2023 was $101.3 million, primarily due to proceeds from maturities of short-term investments of $174.2 million, offset by purchases of short-term investments of $73.2 million.

Net cash provided by investing activities for the year ended December 31, 2022 was $36.7 million, primarily due to $130.0 million of cash received from Oxford pursuant to the OXB (US) LLC Transaction (see Note 6 to Homology's consolidated financial statements included elsewhere in this prospectus). Homology also had proceeds from maturities of short-term investments of $65.5 million. These two items were offset by purchases of short-term investments of $157.5 million and purchases of property and equipment of $1.3 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $0.2 million, primarily due to proceeds from the issuance of common stock pursuant to Homology's employee stock purchase plan.

Net cash provided by financing activities for the year ended December 31, 2022 was $0.6 million, due to proceeds from the issuance of common stock pursuant to Homology's employee stock purchase plan.

Funding Requirements

Operating expenses decreased during the year ended December 31, 2023 as compared to the year ended December 31, 2022. As of December 31, 2023, Homology had cash, cash equivalents, and short term investments of $82.7 million.

Following the Merger, the business of Legacy Q32 became Homology's business, and Homology does not expect any further development of its product candidates or programs that would require additional funding. The funding requirements of the Company will reflect the funding requirements for the development of its product candidates and programs. For a discussion of the Company's funding requirements, see the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations–Liquidity and Capital Resources–Funding Requirements*" in this prospectus.

Contractual Obligations

As of December 31, 2023, Homology had non-cancelable operating leases with total future minimum lease payments of $1.4 million, of which all will be payable in 2024. These minimum lease payments exclude Homology's share of the facility operating expenses, real-estate taxes and other costs that are reimbursable to the landlord under the leases. These payments are for operating leases for Homology's former corporate headquarters in Bedford, Massachusetts, comprised of office, manufacturing and lab space that expire in June 2030 and May 2032. Under the terms of the OXB (US) LLC Transaction, Homology's leases for this space has been assigned to OXB (US) LLC effective March 10, 2022, with Homology subleasing a portion of lab and office space back from OXB (US) LLC. Homology's sublease expires on December 31, 2024. On September 25, 2023, Homology signed and executed a release letter with its lessor related to its headquarters in Bedford, MA. The lessor agreed to release Homology of all obligations under the lease effective October 1, 2023 in exchange for a $0.1 million cash payment. On October 1, 2023, Homology derecognized the right-of-use asset and operating lease liability and recorded the difference as a gain within other income on the consolidated statements of operations. See Note 10 to Homology's consolidated financial statements included elsewhere in this prospectus for additional information regarding Homology's lease agreement.

Homology's agreements with certain institutions to license intellectual property include potential milestone and success fees, sublicense fees, royalty fees, licensing maintenance fees, and reimbursement of patent maintenance costs that Homology may be required to pay. Homology's agreements to license intellectual property include potential milestone payments that are dependent upon the development of products using the intellectual property licensed under the agreements and contingent upon the achievement of development or regulatory approval milestones, as well as commercial milestones. These potential obligations are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty.

Prior to Homology's decision to stop further development of its products, Homology entered into contracts in the normal course of business with CROs and CMOs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally did not contain any minimum purchase commitments and were cancelable by Homology upon prior notice of 30 days. Pursuant to the terms of the Supply Agreement with OXB (US) LLC entered into in March 2022, Homology agreed to purchase from OXB (US) LLC at least 50% of its clinical supply requirements of AAV-based products during the initial term of the Supply Agreement. Homology was committed to purchase a minimum number of batches of drug substance and drug product, as well as process development services, totaling approximately $29.7 million in 2023 under the Supply Agreement. Homology does not have any commitments to purchase products or services from OXB (US) LLC in 2024. The Supply Agreement provides for an initial term of three years, which period may be extended for an additional one-year term. After the initial term, Homology will have the right to terminate the Supply Agreement for convenience or other reasons specified in the Supply Agreement upon prior written notice. Either Party may terminate the Supply Agreement upon an uncured material breach by the other Party or upon the bankruptcy or insolvency of the other Party.

BUSINESS

On March 25, 2024, we completed the previously announced business combination with Legacy Q32 in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Legacy Q32, with Legacy Q32 surviving as our wholly owned subsidiary (such business combination, the Merger). In connection with the completion of the Merger, we changed our name from "Homology Medicines, Inc." to "Q32 Bio Inc.," and our business became primarily the business conducted by Legacy Q32. We are now 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. 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, or the Code.

As used in this Business Section, the words "Company," "we," "our," "us" and "Q32" refer, collectively to Q32 Bio Inc. and its consolidated subsidiaries following completion of 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 the 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 the body's first line of defense employing such as monocytes, macrophages, neutrophils, dendritic cells and natural killer cells leukocytes 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 it to build a broad and diverse pipeline in the long term. We have multiple product candidates across a variety of autoimmune and inflammatory diseases with clinical readouts for our two lead programs expected in 2024 and 2025.

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. Bempikibart is being studied in two double-blind, placebo-controlled Phase 2 clinical trials designed to establish proof of clinical concept and evaluate our selected Phase 2 dose. One trial is evaluating the use of bempikibart for the treatment of atopic dermatitis, or AD, and one is evaluating bempikibart for the treatment of alopecia areata, or AA. Enrollment in both clinical trials remains ongoing and we expect to report topline data from both Phase 2 clinical trials in the second half of 2024.

ADX-097, 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. We are developing ADX-097 for the treatment of renal and other complement-mediated diseases of high unmet need, including lupus nephritis, or LN, immunoglobulin A, or IgA, nephropathy, or IgAN, complement component 3 glomerulopathy, or C3G, and anti-neutrophil cytoplasmic antibody, or ANCA-associated vasculitis, or AAV. We have completed a Phase 1 clinical trial of ADX-097 in healthy volunteers. We expect to initiate an open-label

Phase 2 renal basket program in the first half of 2024, with initial data expected by year-end 2024, and initiate a Phase 2 clinical trial in AAV, with topline data from both the renal basket and AAV trials anticipated in the second half of 2025.

In addition to ADX-097, we are also engaged in additional pipeline efforts to expand therapeutic opportunities within complement-mediated diseases.

Our development pipeline is shown in the figure below.

Figure 1: Our Development Pipeline

Note: AAV = Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis; IgAN = IgA Nephropathy; LN = Lupus Nephritis; C3G = C3 Glomerulopathy. (1) Regained full development and commercial rights in November 2023.

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 its acquisition of Horizon plc, we 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 us and Horizon Therapeutics Ireland DAC, or Horizon. In November 2023, we 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, we 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, we 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 "*Our Business—Collaboration and License Agreements.*"

We have completed a Phase 1 study that showed bempikibart was well tolerated and exhibited a pharmacokinetics, or PK, / pharmacodynamic, or PD, profile supporting dosing of no more frequently than once every two weeks. There were no severe or serious adverse events, or AEs, reported and there was no impact of any observed anti-drug antibodies, or ADAs, on pharmacology or safety. We are currently conducting two Phase 2 clinical trials, one in each of AA and AD, with topline data for both clinical trials expected in the second half of 2024.

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.

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. We expect to initiate an open-label Phase 2 renal basket program in the first half of 2024 and a Phase 2 clinical trial in AAV in the first half of 2025.

In complement mediated proteinuric renal diseases (e.g., LN, IgAN and C3G), there remains substantial unmet need for therapeutics that can more effectively mitigate proteinuria and improve long-term kidney outcomes. Additionally, in AAV, even with optimal treatment, successful attainment and long-term maintenance of remission remains challenging and the therapeutics used as part of standard of care, or SOC, treatment are themselves associated with significant infection related morbidity. We believe that the tissue-directed approach to addressing complement dysregulation has the potential to drive improved efficacy and better safety across these 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 (e.g., LN and AAV).

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. To date, eight complement inhibitors have been approved for various indications with cumulative sales of nearly $6 billion in 2022. 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, Chief Scientific Officer and President of Research, 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, 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 extensive experience in 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:

- ***Complete our Phase 2 AD trial with bempikibart.*** We plan to complete the ongoing Phase 2 clinical trial for bempikibart in AD with topline results expected in the second half of 2024;
- ***Complete our Phase 2 AA trial with bempikibart.*** We plan to complete the ongoing Phase 2 clinical trial for bempikibart in AA with topline results expected in the second half of 2024;
- ***Complete a renal basket program with ADX-097.*** We plan to initiate a renal basket program in the first half of 2024 with initial data expected by year-end 2024;

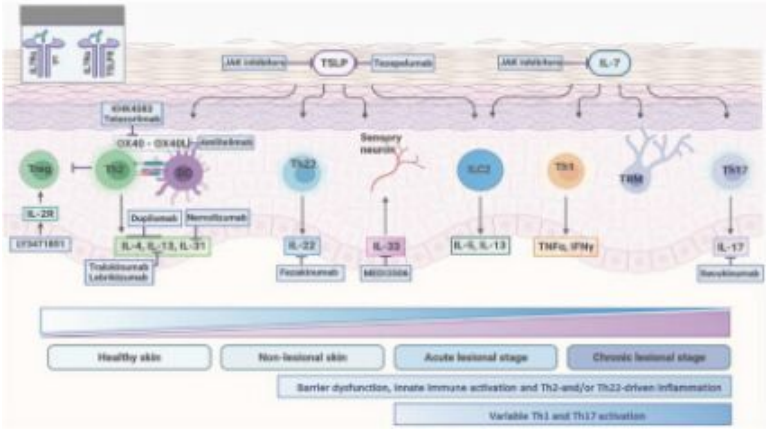
- ***Complete Part A of our Phase 2 AAV trial with ADX-097.*** We plan to initiate Part A of our Phase 2 AAV trial in the first half of 2025 with topline results expected in the second half of 2025; and
- ***Leverage our deep expertise in tissue targeted complement therapeutic development to build a broad portfolio.*** We are engaged in research activities to advance our pipeline of additional candidates targeting complement inhibition.

Our Programs

Bempikibart in AD and AA

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 AD and AA. The figures below illustrate the mechanistic rationale for bempikibart in AD and AA.

Figure 17: Bempikibart Has the Potential to Modulate Immune Cells Important in Both Acute and Chronic AD Pathogenesis



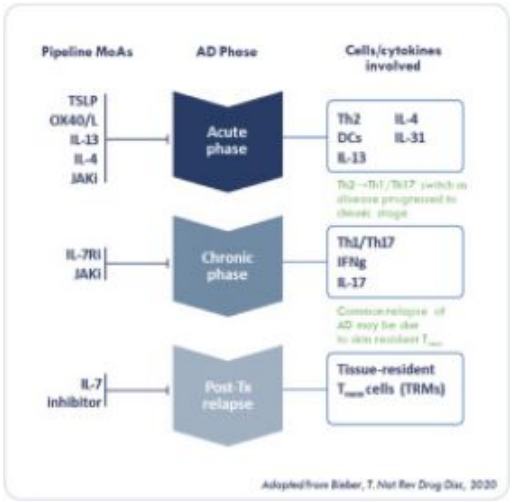
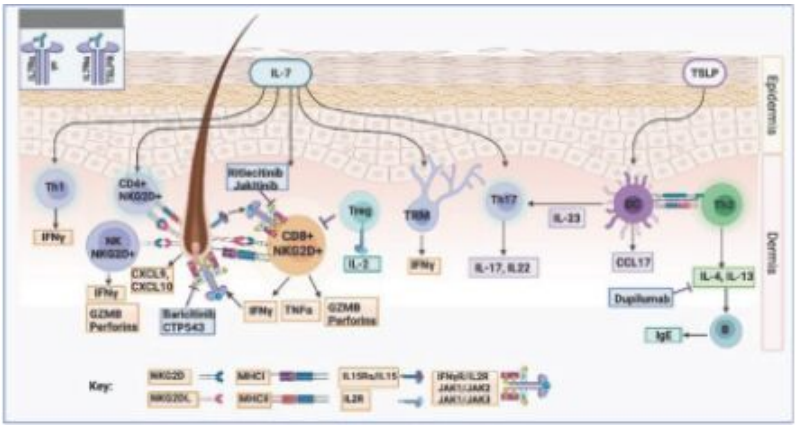
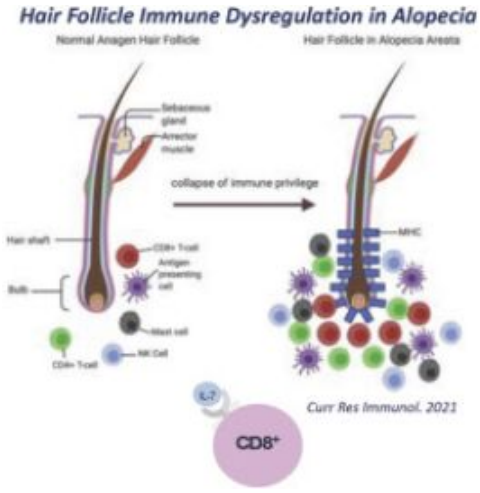


Figure 18: Bempikibart Has the Potential to Block TH1-and TH2-Driven Disease Pathology in AA





In October 2023, Amgen Inc., or Amgen, completed the acquisition of Horizon plc. Following its acquisition of Horizon plc, we agreed with Amgen to mutually terminate the Horizon Agreements. In November 2023, we entered into the Horizon Termination Agreement with Horizon pursuant to which Horizon's option to acquire the bempikibart program was terminated. As a result, we 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, we 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 "*Our 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.

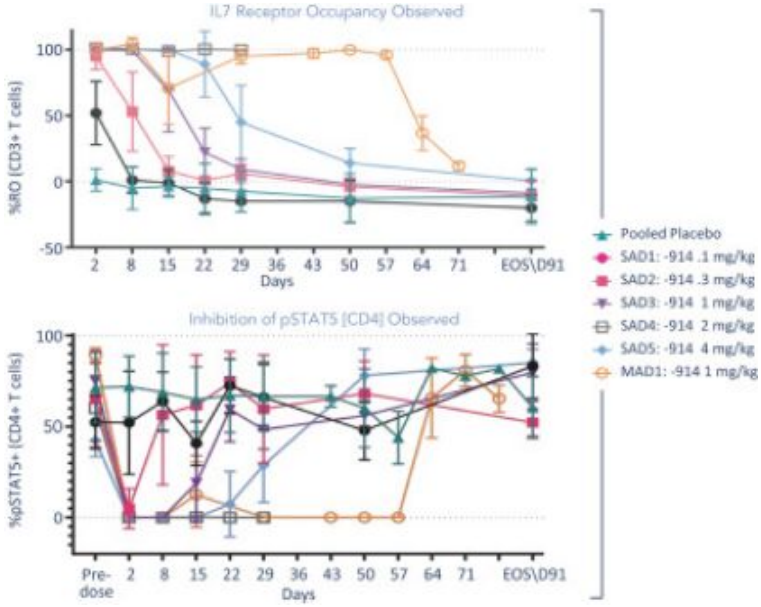
Bempikibart was generally well tolerated in all preclinical studies described above. The no-observed-adverse-effect level, or NOAEL, in the 6-month GLP study was 150 mg/kg, the highest dose tested, with exposure >50x the anticipated area under the curve at the dose presently being utilized for the ongoing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

Phase 1 Clinical Trial Results

We have completed a Phase 1 study, ADX-914-001, to assess the safety, PK, and PD of bempikibart after subcutaneous, or SC, administration in healthy volunteers. As seen in Figure 19 below, pharmacodynamic analyses showed bempikibart treatment at SC doses achieving ≥95% RO demonstrated >90% inhibition of IL-7 mediated intracellular signaling, as demonstrated by phosphorylation of STAT5, or pSTAT5, in T-cells. Figure 19 also shows doses of bempikibart as low as 0.3mg/kg achieved full RO and pSTAT5 inhibition over a period of up to 48 hours; doses greater than 1 mg/kg 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 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.

Figure 19: Bempikibart Phase 1 Clinical Data Support Clinical Development

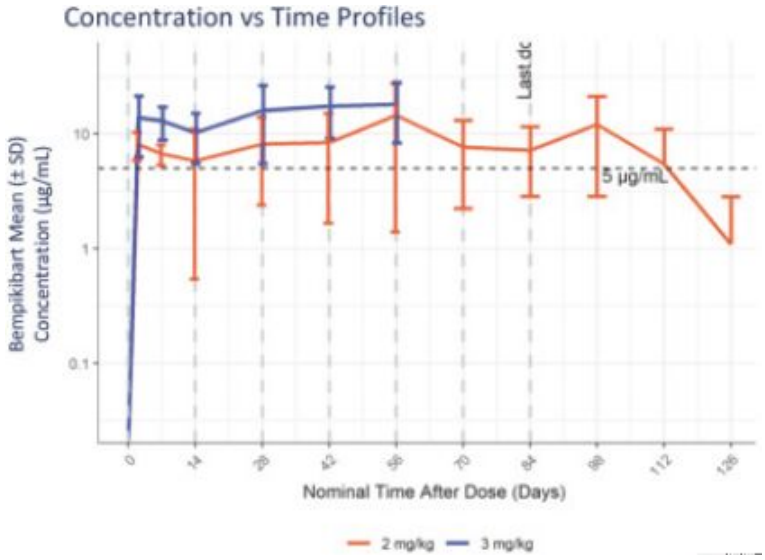


RO: Receptor occupancy; pSTAT5: phosphorylated STAT5; MAD: multiple ascending dose (note: MAD1 cohort dosed once every 2 weeks); SAD: single ascending dose; EOS: end of study

Pharmacology Sub-study in Patients with AD

Study ADX-914-202 is an ongoing, two-part, Phase 2, randomized, double-blind, placebo-controlled, proof-of-concept study in adult subjects with persistent moderate to severe AD, consisting of Part A and Part B. Part A evaluated PK/PD, as well as preliminary efficacy and tolerability, to support dose selection for Part B, which is evaluating the efficacy of bempikibart in AD, as well as for ADX-914-203, a trial evaluating the safety, efficacy, and dose selection of bempikibart in AA. To date, bempikibart has been generally well tolerated, with no notable safety findings (see figure below for a summary of this interim blinded data from Part A). Based on data from both ADX-914-001 and Part A of ADX-914-202, a dose of 200 mg administered subcutaneously every two weeks has been selected as the Phase 2 dose for both Part B of ADX-914-202 and for ADX-914-203 and enrollment in both trials is ongoing. Figure 20 shows PK data from Part A of ADX-914-202, which supports the ongoing development program.

Figure 20: Bempikibart Phase 2 AD Part A PK Data



The Role of IL-7 and TSLP in AD and AA

AD

There is evidence for the involvement of IL-7 and its actions on T cells in the pathobiology underlying AD. IL-7–overexpressing mice spontaneously develop chronic dermatitis and show an increased number of lymphocytes in skin. There is a growing body of evidence from mouse, non-human primates, or NHPs, and man on the importance of tissue-resident memory cells, or TRMs, in skin inflammatory disorders, including AD.

TSLP is also strongly implicated in the pathogenesis of AD and this cytokine is highly expressed in AD skin lesions. TSLP plays a role in activating group 2 innate lymphoid cells, which are enriched in the skin of patients with AD. In rodent models of disease, attenuation of TSLP signaling leads to improvement in keratosis, acanthosis, and dermal mononuclear cell infiltration.

Rationale for Dual IL7-R/TSLP-R Inhibition in AD

Early AD is characterized by activation of the skin innate immune response alongside a core Th2-T helper cell adaptive response. Later in the disease, a widening of the adaptive immunity is evident with Th1, Th17, and Th22 responses becoming more relevant. Within this framework, TSLP and IL-7 may act as sequential mediators of AD initiation (via Th2 pathways) and progression (via Th1 and/or Th17), respectively (see figure 17 above).

Dual IL-7/TSLP blockade with bempikibart could represent an important therapeutic modality considering the evolving understanding of the immunopathology underlying AD in humans.

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 AD and AA

AD is the most common chronic inflammatory skin disease. The majority of AD starts in infancy or childhood, with the remaining disease burden developing during adulthood. The prevalence in children varies from 2.7% to 20.1% by geography and ranges from 2.1% to 4.9% in adults. The disease is heterogeneous in its natural history, and individual trajectories are variable.

Historically, the main therapeutic approaches have included avoidance of triggers, paired with the use of topical agents that are intended to exert local control of skin lesions and/or itch, and broad-spectrum immunosuppressive agents for more severe or high surface area disease. Many of these commonly used treatments have provided limited improvements in affected total body surface, severity of disease for any given body area involvement and/or resolution in itch varying among treated populations, and potentially not all have been achieved in the same patient. Approved topical therapeutics have also been associated with substantial safety concerns. For example, topical calcineurin inhibitors including tacrolimus and pimecrolimus, both of which carry boxed warnings for potential safety risks, including skin cancers and lymphomas.

More recently, systemic, targeted, immunomodulating biologics have been approved for use in AD. The anti–IL-4Rα antibody dupilumab, which inhibits IL-4 and IL-13 signaling (and obtained U.S. approval in 2016 and European Union, or EU, approval in 2017), was the first systemic biologic to become available for the treatment of patients with AD. The small-molecule Janus kinase, or JAK, inhibitors baricitinib (EU 2020 approval date), upadacitinib and abrocitinib (US 2021 approval dates) and the anti–IL-13 antibody tralokinumab (US 2021 approval date) have also been approved for use in AD. Despite these recent approvals, these therapeutics either narrowly address only partial elements of the disease biology or are associated with potential serious, long-term safety concerns, thus there remains a continued unmet medical need. Ideally, disease management evolves to account for the clinical, and likely biologic, heterogeneity characteristic of the disease.

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, including AD and AA, 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 have advanced bempikibart into two ongoing Phase 2 studies, ADX-914-202 (AD) and ADX-914-203 (AA).

Study ADX-914-202

This is an ongoing, two-part, Phase 2, proof-of-concept study in adults with persistent moderate to severe disease as defined by the EASI score. Part A is the PK/PD run-in portion of the study and was conducted to inform dose selection for the subsequent Part B portion and for the Phase 2 study in AA. Bempikibart or placebo will be dosed SC every two weeks for 12 weeks, with a follow-up period of 12 weeks.

The study will recruit adults with chronic AD who have moderate to severe disease activity at the time of consent and who, in the opinion of the Investigator, have a history of inadequate response to previous therapy. In total, approximately 110 subjects will be enrolled.

The primary objective of Part A is to identify the recommended bempikibart dose for Part B. We conducted an interim analysis to review the preliminary PK and safety data from Part A, and 200 mg was selected as the recommended Phase 2 dose for Part B.

The primary objective of Part B is to evaluate the efficacy of bempikibart vs placebo. The primary endpoint of Part B is the mean percentage change from Baseline in EASI score at Week 14 for bempikibart (200 mg) vs placebo.

Study ADX-914-203

Study ADX-914-203 is an ongoing Phase 2 proof-of-concept trial to assess the efficacy, safety, and tolerability of bempikibart in participants with severe AA, as defined by the SALT score. In the study, bempikibart or placebo will be dosed SC for 24 weeks, with a follow-up period of 12 weeks.

The study will recruit adults with a current episode of severe hair loss with no spontaneous improvement over the past 6 months, along with the Investigator’s assessment that hair loss has been stable for at least 3 months and regrowth is possible.

Approximately 40 participants will be enrolled and randomly assigned (3:1) to receive 200 mg bempikibart or matching placebo administered SC every two weeks for 24 weeks. The primary efficacy endpoint is the mean relative percent change in SALT score at 24 weeks compared with baseline.

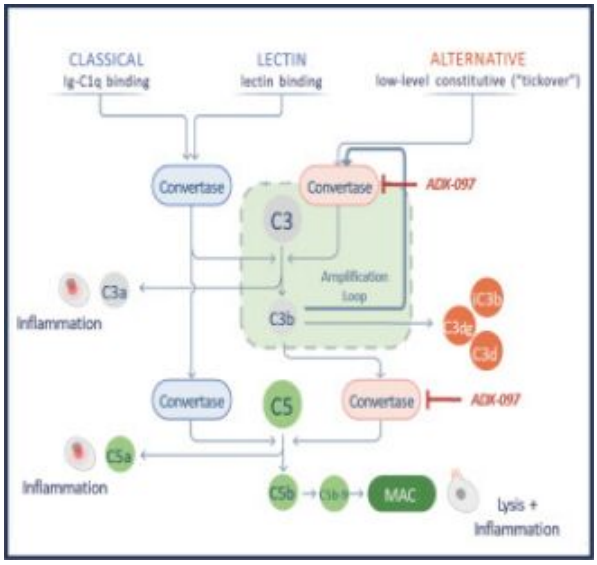
ADX-097 in LN, IgAN, C3G and AAV

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



MAC: Membrane attack complex.

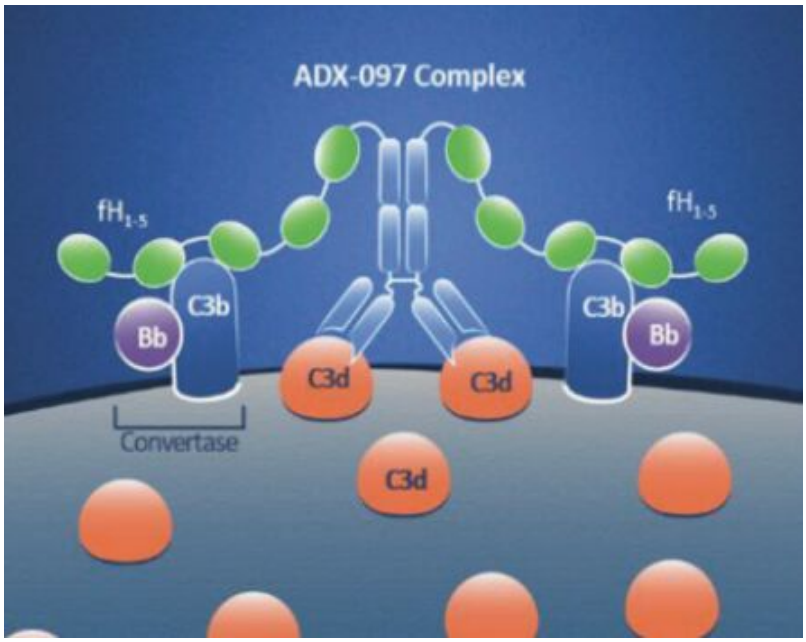
Under normal conditions, inactivation of convertases, to maintain proper balance of the complement system, is endogenously controlled by several complement negative regulatory proteins. Among these is fH, a protein that binds and inactivates AP convertases. Factor H both catalyzes dissociation of AP 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 22 for a depiction of ADX-097’s targeted mechanism of action.

Figure 22: 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, particularly in our renal basket program and AAV Phase 2 clinical trial.

We have completed a robust preclinical and translational package and has also completed a Phase 1 clinical trial in healthy volunteers. We plan to initiate our clinical program in patients with ADX-097 in the first half of 2024.

We intend to further evaluate ADX-097's efficacy and safety profile using biomarkers and functional endpoints in our planned clinical studies. AAV and other renal diseases have established biomarkers and defined clinical trial endpoints. Current standard of care allows for the possibility of attaining biopsies and, therefore, detailed examination of ADX-097 binding to its target and impact on the relevant complement fragments. Together with urinary markers of complement activation, this data set is expected to provide supportive proof of mechanism and demonstration of target engagement in the diseased tissue.

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 that we believe supports our planned dosing for our Phase 2 renal basket program and AAV clinical trial.

Preliminary 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 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 23 and Figure 24 for a summary of ADX-0972-101 PK and PD data.

Figure 23: ADX-097-101: Plasma ADX-097 Concentrations and % of Baseline Wieslab AP Activity After Single Dose IV of ADX-097

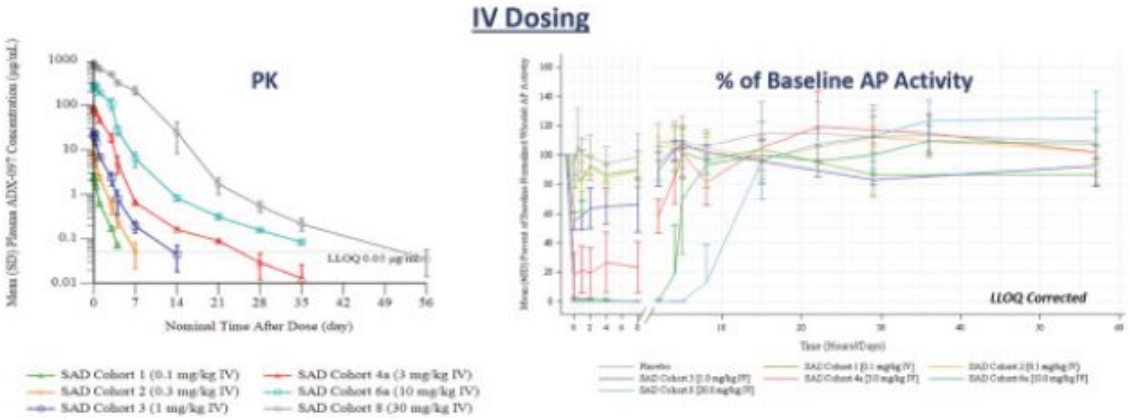
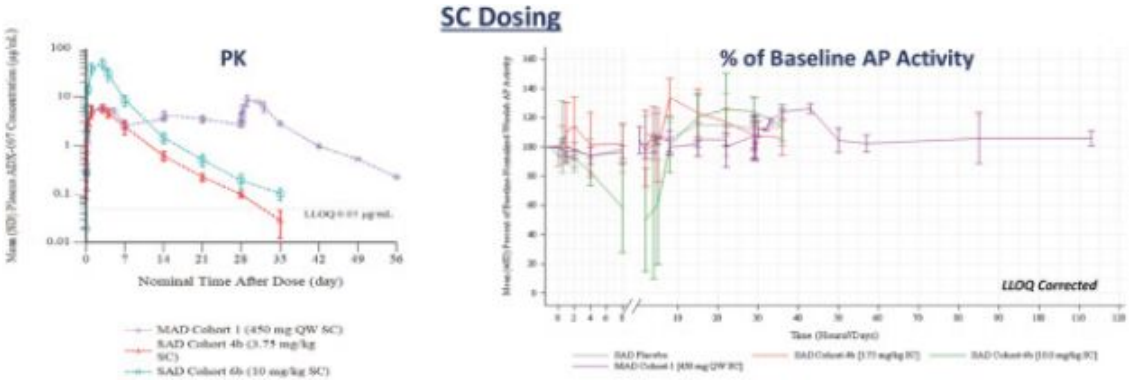


Figure 24: ADX-097-101: Plasma ADX-097 Concentrations and % of Baseline Wieslab AP Activity After Single/Multiple Dose SC of ADX-097



The Role of Complement in LN, IgAN and C3G

LN is an autoimmune disease that occurs in approximately 50% of patients with systemic lupus erythematosus. It is associated with glomerular immune complex, or IC, deposition, derived either from the circulation or formed in situ from autoantibodies directed against nuclear and cellular antigens, that activates complement resulting in intrarenal inflammation. AP activation has been shown to contribute to complement-mediated tissue injury in LN. LN is divided into 6 histopathological classes according to the International Society of Nephrology/Renal Pathology Society system, based on glomerular IC deposit location, the extent of glomerular involvement, and whether the injury pattern reflects active or chronic disease. The use of immunosuppressive medications is common in the treatment of lupus nephritis. While these drugs can help control the autoimmune response that leads to kidney inflammation, they also increase the risk of infectious complications. Treating physicians are seeking to reduce immunosuppressive medications and enhance safety.

IgAN is an IC-mediated glomerulonephritis characterized by mesangial IgA deposition, activation of complement and glomerular inflammation. The role of complement in mediating local tissue injury in IgAN is widely recognized. Kidney biopsies reveal deposition of complement proteins such as fH, properdin, C4d, mannose-binding lectin, active C3 fragments, and C5b-9, supporting involvement of both the AP and LP. Immune complexes formed from immunoglobulin G, or IgG, autoantibodies and the altered galactose-deficient IgA1 molecules to which they are directed, together with C3 products, contribute to mesangial proliferation and glomerular inflammation. C3 fragments are found in the same distribution as IgA in up to 90% of cases, with increasing mesangial C3 fragment deposition adversely affecting kidney survival. In contrast, individuals with the protective complement fH related protein 3, or CFHR3-1, deletion have reduced glomerular C3 fragment deposition, believed to result from the more effective AP regulation.

C3G is a rare kidney disease caused by dysregulation of the complement AP. Comprising 2 major subgroups, dense deposit disease, or DDD, and C3 glomerulonephritis, or C3GN, it is characterized by C3-dominant glomerular staining by immunofluorescence, of at least 2 orders of intensity greater (on a 0 – 3+ scale) than any other immune reactant (e.g., immunoglobulins). Complement dysregulation can result from genetic mutations in both fluid-phase and surface-bound negative regulator protein fH, or activating proteins, and may also be acquired in the setting of autoantibodies (e.g., directed against fH or which stabilize the C3 convertases (C3 nephritic factors)). Such autoantibodies are more commonly reported in DDD than C3GN. The uncontrolled AP activation common to all results in glomerular C3 fragment deposition and MAC formation.

Current Treatment Landscape and Unmet Need in LN, IgAN and C3G

LN affects 10-250 individuals per million and predominantly women of reproductive age. With heterogeneous pathophysiology, to which genetic and environmental factors likely contribute, the incidence of LN in the U.S. is higher in black (34%-51%), Hispanic (31%-43%), and Asian (33%-55%) patients, compared with white (14%-23%) patients.

The presence of LN increases mortality, with death attributable to renal involvement occurring in 5-25% of patients with proliferative disease (class III, IV, or III/IV + V) within 5 years of onset. Progression to end-stage kidney disease, or ESKD, occurs in 10-30% of those affected by LN, in whom those with proliferative disease are most at risk. Patients with persistently low isolated C3 hypocomplementemia also have an increased risk of ESKD and death. Critical to renal survival is the attainment of a complete clinical response, associated with 92% kidney survival at 10 years, compared to only 43% in partial responders and 13% in non-responders. Despite the continuing development of immunomodulatory agents and supportive care, the prognosis associated with LN has not improved substantially in the past decade, with ESKD still developing in 5-30% of patients within 10 years of LN diagnosis. In prior studies, repeat biopsies after approximately 6 months of treatment in patients with a complete clinical response showed significant persistent histologic activity in a number of cases.

Patient management is determined by disease severity, with non-proliferative forms of LN (with sub–nephrotic range proteinuria and normal glomerular filtration rate, or GFR) typically treated conservatively with renin angiotensin aldosterone system, or RAAS, blockade and immunomodulation with antimalarials (e.g., hydroxychloroquine). Immunosuppression is reserved in these classes for extrarenal manifestations only, while proliferative forms of LN (class III, IV, or III/IV+V) and class V LN with nephrotic syndrome are treated with systemic immunosuppression, combined with high-dose corticosteroids, in an induction phase typically lasting 3 to 6 months. Immunosuppression is continued and gradually reduced in an extended maintenance phase (to reduce the risk of flare), potentially lasting several years. While there have been recent approvals for the treatment of LN (with belimumab and voclosporin), unmet therapeutic need remains due to the limited number of treatment options.

IgAN is the most common primary glomerular disease worldwide, with an estimated incidence of 2-28 individuals per million population per year, dependent on geography. Typically occurring in patients aged between 20 and 30 years, up to 50% of patients progress to ESKD within 20 years of clinical presentation. Patients who undergo transplantation are also at risk of disease recurrence, which occurs in approximately 30% of transplant recipients.

Proteinuria is a recognized risk factor for the progression of IgAN, with time-average proteinuria shown to be the most important predictor of rate of kidney function decline. A quantitative estimate determined that each incremental gram of proteinuria above 1g per day was associated with a 10- to 25-fold more rapid rate of kidney function decline. Reducing proteinuria to below 1g/d is therefore regarded as a treatment target in IgAN, with patients achieving this target observed to have a similar rate of disease progression and kidney survival, irrespective of their initial proteinuria and comparable to those whose proteinuria never exceeded 1g/d.

Current SOC for IgAN as described in the Kidney Disease Improving Global Outcomes 2021 guidelines, consists of RAAS inhibition as first line therapy. However, RAAS inhibition does not affect the underlying disease pathology, with less than half of patients achieving sustained proteinuria levels of < 1g/d (partial remission). The long-term clinical benefit of glucocorticoids, or GCs, has not been established and a 6-month course is only suggested with extreme caution in those at high risk of progressive chronic kidney disease. Antibody depleting strategies, such as rituximab, are not recommended due to the paucity of evidence for their efficacy and both treatment approaches carry safety concerns, which are reflected in current treatment guidelines (e.g., KDIGO).

C3G is a rare kidney disease caused by dysregulation of the complement AP. Comprising 2 major subgroups, DDD and C3GN, it is characterized by C3-dominant glomerular staining by immunofluorescence, of at least 2 orders of intensity greater (on a 0–3+ scale) than any other immune reactant (e.g., immunoglobulins).

With an estimated incidence of 1-3 patients per million, C3GN is reportedly more common than DDD in patients with familial C3G. DDD tends to be diagnosed at a younger age, predominantly in children and young adults, but has been reported in older adults. Presentation varies from nephritic syndrome, asymptomatic and low-grade proteinuria to nephrotic syndrome, or rapidly progressive glomerulonephritis, with 50% progressing to ESKD within 10 years. Isolated C3 hypocomplementemia is seen in most patients.

The treatment paradigm for C3G has not been well established. In addition to the standard conservative measures, such as RAAS inhibition and blood pressure control, other tested approaches have included immunosuppression, plasma exchange and complement inhibition with varying degrees of success, and significant therapeutic need remains.

The Role of Complement in AAV

The ANCA-associated vasculitides are a group of autoimmune disorders characterized by severe inflammation of small blood vessels induced by infiltration of neutrophils into vessel walls. Autoimmunity is characterized by the development of autoantibodies to the neutrophil proteins leukocyte proteinase 3 or myeloperoxidase. Patients with AAV typically present with severe organ-threatening or life-threatening disease, although less severe presentations can also occur.

AP complement activation is detected in AAV tissue lesions and is thought to be a major driver of disease pathogenesis. Complement factor B-or C5-deficient mice do not develop glomerulonephritis in an anti-MPO induced model of AAV. Biomarkers of AP activation, including deposits of C3d, Bb fragment of factor B, or Bb, and C5b-9 are detected in glomeruli and extraglomerular small vessels of AAV kidneys, and Bb, C3a, C5a, and C5b-9 are elevated in urine and serum from AAV patients. Furthermore, serum Bb correlates with disease activity and outcome, and serum C3c concentration correlates with severity of AAV lesions in the kidney. In AAV, hypocomplementemia, as a result of complement overactivation, is reported to be associated with more advanced renal involvement, higher likelihood of treatment resistance, and worse prognosis.

Current Treatment Landscape and Unmet Need in AAV

AAV is a rare disease with a historical estimated global prevalence of 46 to 421 cases per million persons, depending on the population studied and the specific subtype of AAV. The annual incidence of AAV ranges from 10 to 20 cases per million population, with wide variation across geographic regions and substantial variation in the relative incidence of granulomatosis with polyangiitis, or GPA, and microscopic polyangiitis, or MPA, among Europe, the U.S., and Asia.

The presentation and natural history of AAV can be highly variable, and the spectrum of disease may range from relatively mild and localized to the upper respiratory tract, to life-threatening involvement of multiple organ systems. Additionally, disease activity can fluctuate, and relapses may occur. In the current era with SOC, 1-year mortality rates range from approximately 5% to 20% and 5-year mortality can be as high as 50% for the MPA subtype. The highest mortality rates are observed in patients with severe renal involvement, pulmonary hemorrhage, or other life-threatening complications. Severe AAV requires intensive treatment, including high-dose GCs immunosuppressive agents, and sometimes plasma exchange. Despite aggressive therapy, managing severe disease can be challenging, and many patients experience treatment-resistant disease or suffer from irreversible organ damage prior to attainment of disease remission. Furthermore, infections are a leading cause of adverse outcomes, including death, in patients with AAV, a risk generally ascribed to immune-suppressive effects of the treatment regimens used to achieve disease remission. In recent years, intense focus has been on the likely role of GCs in conferring this risk, and there is general acceptance that the reduction and/or elimination of GC in the treatment of AAV is a desirable goal. Avacopan, a recently approved complement C5a receptor inhibitor for AAV, supports complement involvement in the disease but labelling language states that it “does not eliminate glucocorticoid use” and includes warning and precaution language guiding around its use “in patients with underlying conditions that may predispose them to infection.”

Further Clinical Development of ADX-097: Clinical Trial Plan

Based on the preliminary data from our Phase 1 clinical trial, we plan to initiate a program in human complement-mediated kidney diseases in 2024 and a Phase 2 clinical trial in AAV in the first half of 2025.

The Renal Basket Program

The planned ADX-097-201 study is designed as a basket program to evaluate the safety, PK, PD, and clinical activity of ADX-097 in patients with LN, IgAN or C3G. The primary objective of the study is to evaluate the safety and tolerability of ADX-097 when administered weekly to patients. Key secondary efficacy and exploratory objectives include clinical markers of disease activity, biomarkers of complement activation and organ injury, and pharmacology.

All disease groups will be open label, with a total of up to 30 participants planned for enrollment. Patients will be dosed with a single SC dose weekly for up to 26 weeks. Participants in each disease group will be open to enroll into the study.

AAV

The planned ADX-097-202 study is a Phase 2 study in adults with AAV, specifically GPA and MPA. The study is composed of 2 parts: an open-label Part A, and a randomized, blinded Part B. Part A of the study will assess the treatment effect of ADX-097 when given as an adjunct to SOC therapy, with the goal of demonstrating initial proof of clinical efficacy. The intent of Part B of the study is to assess the ability of ADX-097 to reduce or eliminate the use of oral glucocorticoids to support induction of remission.

Expanding Our Pipeline of Complement Therapeutics

By leveraging our extensive experience building fusion biologics and our deep understanding of the complement system, we aim to create a sustainable pipeline of novel and localized complement inhibitors that are customized for diverse indications. We expect additional preclinical data in 2024 from our ongoing pipeline efforts in support of advancement of one or more research and development candidates in 2025.

Collaboration and License Agreements

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 breaches certain obligations under the Colorado License Agreement and fails to cure such breach. The Colorado License Agreement will terminate automatically upon our dissolution, insolvency, or bankruptcy.

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, we were 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 we 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 its acquisition of Horizon plc, we agreed with Amgen to mutually terminate the Horizon Agreements and in November 2023, we 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, we 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, we 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.

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 and distribution of our product candidates. Because we rely on contract manufacturers, our employs and contracts 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 our ADX-097 program, as of December 31, 2023, we own one patent family relating to ADX-097, other fusion constructs of anti-C3d antibodies and different complement modulators. This family includes two issued U.S. patents, one allowed U.S. patent application, and 24 pending applications in Australia, Canada, China, Europe, Hong Kong, India, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, New Zealand, Philippines, Russia, 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.

With respect to bempikibart, as of December 31, 2023, 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 one issued U.S. patent, one issued patent in each of Japan, South Korea, and Singapore, one pending U.S. patent application, and 32 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, Russia, Saudi Arabia, South Africa, Taiwan, Thailand, United Arab Emirates Qatar, Bahrain, Egypt, Kuwait, and Oman. The issued patent is 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 owns two pending U.S. provisional patent applications related to the use of bempikibart for the treatment of atopic dermatitis and hair loss disorders. Any patents that issue from patent applications that claim priority to this U.S. provisional application are expected to expire in 2044, without accounting for potentially available patent term adjustments or extensions.

We also own one pending U.S. provisional 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 that claim priority to this U.S. provisional 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 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 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 one issued U.S. patent, one pending U.S. patent application, and one pending patent application in Europe. The issued patent 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 patent is expected to expire in 2037, without accounting for potentially available patent term adjustments or extensions in the U.S. or abroad.

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

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

In addition to patent protection, we may also rely, in some circumstances, on trade secrets to protect our technology. To that end, we also enter into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators and advisors. We also enter into agreements requiring assignment of inventions with selected consultants, scientific advisors, and collaborators. However, trade secrets are difficult to protect. These agreements may not provide meaningful protection and may be breached without an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information and know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or obtain or use information that we regard as proprietary. Although we takes 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 be commenced;
- 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;
- 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 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 facility in which it is manufactured, processed, packed or held meets 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 samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products 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. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested 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 laws, which differ by state.

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

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 FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

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.

We are also 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. In California the California Consumer Protection Act, or CCPA, which went into effect on January 1, 2020 and was amended effective January 1, 2023, establishes a new 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. Other states, including Virginia (effective January 1, 2023), Colorado (effective July 1, 2023), Connecticut (effective July 1, 2023), and Utah (effective December 31, 2023) have passed privacy legislation and more states may do so in the future, including Iowa, where the Iowa state legislature passed a comprehensive privacy legislation on March 15, 2023. State and non-U.S. laws, including for example the EU General Data Protection Regulation, 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. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

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, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. 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 will be further reduced starting in 2025 absent further legislation. 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.

In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D. Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. 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 Biden has also issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Notwithstanding the IRA and President Biden'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 completion of the Merger, we had 37 full-time employees, of which 7 have M.D. or Ph.D. degrees. Within our workforce, 27 employees are engaged in research and development and 10 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.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated.

MANAGEMENT

Executive Officers and Directors

The following table lists the names and ages, as of December 31, 2023, and positions of our executive officers and directors:

Name	Age	Position
Executive Officers:		
Jodie Morrison	48	Chief Executive Officer and Director
Lee Kalowski	43	Chief Financial Officer and President
Jason A. Campagna	54	Chief Medical Officer
Shelia M. Violette	63	Chief Scientific Officer and President of Research
Non-Employee Directors:		
Arthur Tzianabos	60	Director
Mary Thistle	64	Director
Bill Lundberg	60	Director
David Grayzel	56	Director
Diyong Xu	42	Director
Isaac Manke	47	Director
Kathleen LaPorte	62	Director
Mark Iwicki	57	Director

Executive Officers

Jodie Morrison. Ms. Morrison has served as our Chief Executive Officer and a member of the Board since 2024. Ms. Morrison previously served a member of Legacy Q32's board of directors since September 2022. Ms. Morrison also previously served as the President and Chief Executive Officer of Legacy Q32, where she had been employed since September 2022. Prior to joining Legacy Q32, Ms. Morrison was a Venture Partner at Atlas Venture from July 2021 to September 2022, Chief Executive Officer of Cadent Therapeutics from January 2019 to March 2021, and Chief Executive Officer of Keryx Biopharmaceuticals from April 2018 until December 2018. Ms. Morrison has also served as an Advisor at Atlas Venture since January 2019. She also currently sits on the board of directors of Rectify Pharmaceuticals. She has previously served as the chair of the board at Ribon Therapeutics and held board positions at Aileron Therapeutics, Akebia and Keryx. Ms. Morrison received a certificate through the Greater Boston Executive Program at the MIT Sloan School of Management, a clinical research certification from Boston University School of Medicine, and B.A. in Neuroscience from Mount Holyoke College. We believes Ms. Morrison's experience in the biopharmaceutical industry provides her with the qualifications and skills to serve on the Board.

Lee Kalowski. M.B.A. Mr. Kalowski has served as our Chief Financial Officer and President since 2024. Mr. Kalowski previously served as Legacy Q32's Interim Chief Financial Officer since October 2023 and has also served as a consultant to the life sciences industry since October 2023. Prior to joining Legacy Q32, Mr. Kalowski served as Chief Financial Officer from July 2017 to June 2023 and as President from January 2019 to June 2023 of Bicycle Therapeutics. Previously, Mr. Kalowski was Chief Financial Officer of Tokai Pharmaceuticals. Prior to Tokai, Mr. Kalowski served in global biotechnology equity research at Credit Suisse, where he covered companies in the biopharmaceutical industry as a Senior Analyst. Mr. Kalowski received a B.A. in biology and economics from Union College and an M.B.A. from The Wharton School of the University of Pennsylvania.

Jason A. Campagna, M.D., Ph.D. Dr. Campagna has served as our Chief Medical Officer since 2024. Mr. Campagna previously served as the Chief Medical Officer of Legacy Q32, where he had been employed since March 2021. Prior to this role, Dr. Campagna was Chief Medical Officer at Intercept Pharmaceuticals from November 2019 to March 2021, and where he also served as Senior Vice President and Global NASH Lead from August 2016 to November 2019. From December 2020 to March 2023, Dr. Campagna served on the board of

directors for Plantable Health. Dr. Campagna holds an M.D./Ph.D. in Molecular and Cellular Pharmacology from the University of Miami Miller School of Medicine and a B.S. in Biology from the University of Miami.

Shelia M. Violette, Ph.D. Dr. Violette has served as our Chief Scientific Officer and President of Research since 2024. Dr. Violette previously served as the Chief Scientific Officer and President of Research of Legacy Q32, where she had been employed since September 2017. Prior to this role, Dr. Violette was an Entrepreneur in Residence at Atlas Venture from November 2016 to September 2017, and she has continued to serve as an Advisor since September 2017. From July 2016 to June 2021, Dr. Violette was an Adjunct Associate Professor at Yale University School of Medicine's Department of Internal Medicine. Prior to that position, Dr. Violette held several senior roles in research at Biogen from March 2012 to October 2016. Dr. Violette currently serves on the Scientific Advisory Boards of Triveni Bio Inc., Morphic Therapeutics, Inc., Mediar Therapeutics Inc., and APIE Therapeutics Inc. Dr. Violette also served on the board of directors of Cytimmune Science from October 2021 to June 2023, and she was on the Scientific Advisory Boards of Scholar Rock Holding Corporation from April 2017 to December 2022, Enleofen Bio Pte Ltd from June 2017 to April 2020, and NuMedii, Inc. from February 2018 to February 2019. Dr. Violette holds a Ph.D. in Pharmacology from Yale University and a B.S. in Pharmacology from the Massachusetts College of Pharmacy.

Non-Employee Directors

Arthur O. Tzianabos, Ph.D. Dr. Tzianabos previously served as the Chairman of the Board since September 2022 and has served as a member of the Board since April 2016. Dr. Tzianabos has served as Venture Partner at 5AM Ventures since September 2022. Dr. Tzianabos was Homology's President and Chief Executive Officer from April 2016 to September 2022. Dr. Tzianabos joined Homology from OvaScience, Inc., a biotechnology company (which has since merged with and into Millendo Therapeutics, Inc.), where he served as President and Chief Scientific Officer from September 2013 to March 2016. Prior to OvaScience, Dr. Tzianabos spent eight years at Shire plc, a biotechnology company, where he served in positions of increasing responsibility, including Senior Director, Discovery Research, Vice President, Program Management and Senior Vice President and Head, Research and Early Development. From 1992 to 2005, Dr. Tzianabos was a faculty member at Harvard Medical School and maintained laboratories at the Channing Laboratory, Brigham and Women's Hospital and the Department of Microbiology and Molecular Genetics at Harvard Medical School. Dr. Tzianabos has served as a director of Stoke Therapeutics, Inc. (NASDAQ: STOK), a public biotechnology company, since April 2018. Dr. Tzianabos previously served as chairman of the board of directors of Akouos, Inc., a public biotechnology company, from July 2018 until its acquisition by Eli Lilly in December 2022, and a director of BIND Therapeutics, Inc., a biotechnology company, from October 2015 until its acquisition by Pfizer in July 2016. Dr. Tzianabos holds a B.S. in Biology from Boston College and a Ph.D. in Microbiology from the University of New Hampshire, and completed a Post-Doctoral Fellowship in Immunology at Harvard Medical School. We believe that Dr. Tzianabos' extensive academic and clinical experience, as well as his knowledge of the company and the industry, qualifies him to serve on the Board.

***Mary Thistle*.** Ms. Thistle has served as a member of the Board since 2018. Ms. Thistle has served as Special Advisor to the Bill & Melinda Gates Medical Research Institute, a non-profit biotech organization, from the fall of 2020 to June 2022, and previously served as the organization's Chief of Staff from January 2018 to the fall of 2020. Prior to that, she held senior leadership positions at Dimension Therapeutics, Inc., a gene therapy company, including Chief Operating Officer from 2016 to 2017 and Chief Business Officer from 2015 to 2016. Prior to joining Dimension Therapeutics, Inc., she spent six years at Cubist Pharmaceuticals, Inc., a biopharmaceutical company, where she held various leadership positions, including Senior Vice President, Business Development from 2014 to 2015, Vice President, Business Development from 2012 to 2013 and Senior Director, Business Development from 2009 to 2012. Prior to that, she held various positions at ViaCell, Inc. and PerkinElmer Inc. Ms. Thistle has served on the board of directors of Alaunos Therapeutics, Inc. (NASDAQ: TCRT), formerly known as Ziopharm Oncology, Inc. since November 2020, Entrada Therapeutics, Inc. (NASDAQ: TRDA) since May 2021 and Vigil Neuroscience, Inc. (NASDAQ: VIGL) since April 2022.

Ms. Thistle holds a B.S. in Business and Accounting from the University of Massachusetts, Boston and is a former Certified Public Accountant. We believe that Ms. Thistle's finance and business development background and industry experience qualifies her to serve on the Board.

Bill Lundberg, M.D. Dr. Lundberg has served as a member of the Board since March 2024. Dr. Lundberg previously served on Legacy Q32's board of directors since December 2017. In addition to his role at Legacy Q32, Dr. Lundberg is the Chief Executive Officer, President, Principal Financial Officer and Director of Merus NV (NASDAQ: MRUS). Prior to that role, Dr. Lundberg has served as Chief Scientific Officer at CRISPR Therapeutics AG (NASDAQ: CRSP), a biotechnology company, from January 2015 until February 2018. Dr. Lundberg also served as Vice President and Head of Transitional Medicine at Alexion Pharmaceuticals, Inc. from February 2011 until January 2015. Prior to that position, Dr. Lundberg served as Director and Chief Medical Officer of Taligen Therapeutics, Inc., a biotechnology company, which was acquired by Alexion in 2011. Prior to Taligen, he held several senior roles in clinical drug development and medical affairs at Xanthus/Antisoma, Wyeth (now Pfizer), and Genzyme. Dr. Lundberg currently serves on the board of directors of the publicly traded life science company Vor Biopharma (NASDAQ: VOR) and Merus N.V. (NASDAQ: MRUS) Dr. Lundberg holds an M.D. from Stanford University and M.B.A. from the University of Massachusetts. We believe Dr. Lundberg's experience, expertise and leadership in the biopharmaceutical industry qualifies him to serve on the Board.

David Grayzel. Mr. Grayzel has served as a member of the Board since March 2024. Mr. Grayzel was a co-founder of Legacy Q32 and previously served as a member of Legacy Q32's board of directors since 2017. Since joining Atlas in 2010, Mr. Grayzel has co-founded and served as chief executive officer of numerous companies including Arteaus Therapeutics acquired by Eli Lilly in 2014, Annovation Biopharma acquired by The Medicines Company in 2015, and was a founding board member of both Delinia acquired by Celgene in 2017, and Cadent Therapeutics acquired by Novartis in 2021. David is a co-founder and board member Vima Therapeutics, and also sits on the boards of Affinia Therapeutics, Aerovate Therapeutics (NASDAQ: AVTE), and TRIANA Biomedicines. He was previously a board director of Surface Oncology acquired by Coherus (NASDAQ: CHRS), Xilio Therapeutics (NASDAQ: XLO), and a board observer at Day One Biopharmaceuticals (NASDAQ: DAWN). Dr. Grayzel received his B.A. from Stanford University, M.D. from Harvard Medical School, and completed his internship and residency training in internal medicine at Massachusetts General Hospital. We believe Dr. Grayzel's experience as an investor and board member in the life sciences industry, as well as his scientific and medical knowledge, provides him with the qualifications and skills to serve on the Board.

Diyong Xu. Mr. Xu has served as a member of the Board since March 2024. Mr. Xu previously served as a member of Legacy Q32's board of directors since August 2020. Mr. Xu is a Principal at OrbiMed Advisors LLC, an investment firm, where he has served in various roles of increasing responsibility since August 2012. Prior to joining OrbiMed, Mr. Xu worked for Lazard Freres & Co. in its Healthcare Investment Banking Group. Mr. Xu received his M.S. in Management Science and Engineering from Stanford University, M.S. in Molecular and Cellular Biology from Dartmouth College, and B.S. in Biology from Zhejiang University. We believe Mr. Xu's experience in the life sciences industry provides him with the qualifications and skills to serve on the Board.

Isaac Manke. Dr. Manke has served as a member of the Board since March 2024. Dr. Manke previously served as a member of Legacy Q32's board of directors since October 2020. Dr. Manke is currently a General Partner at Acorn Bioventures, where he focuses on investing in small cap public and private biotechnology companies. Prior to Acorn, Dr. Manke spent 11 years at New Leaf Venture Partners (NLV) through 2019. In addition to private venture investments, during his time at NLV, Dr. Manke also led the firm's public investment activities. Dr. Manke has been a board member for several public and private biotechnology companies. Dr. Manke received a B.A. in Biology and a B.A. in Chemistry at Minnesota State University (Moorhead), and a Ph.D. in Biophysical Chemistry and Molecular Structure at the Massachusetts Institute of Technology, or MIT. We believe Dr. Manke's experience in the life sciences industry provides him with the qualifications and skills to serve on the Board.

Kathleen LaPorte. Ms. LaPorte has served as a member of the Board since 2024. Ms. LaPorte previously served as a member of Legacy Q32's board of directors since July 2021. In addition, Ms. LaPorte has served as a director of CERo Therapeutics, Inc. (NASDAQ: CERO), Bolt Biotherapeutics, Inc. (NASDAQ: BOLT), Precipio Diagnostics (NASDAQ: PRPO), 89Bio (NASDAQ: ENTB) and Elysium Therapeutics. Ms. LaPorte also serves as the chair of the compensation committee of CERo Therapeutics since 2024, and the chair of the audit committees of both Bolt Biotherapeutics and Precipio Diagnostics, since 2020 and 2019, respectively. Ms. LaPorte serves as the chair of the compensation committee and a member of the nominating and governance committee of 89Bio. Ms. LaPorte co-founded New Leaf Ventures, served as a General Partner of The Sprout Group from 1993 until 2005, and was Chief Business Officer and Chief Executive Officer of Nodality Inc from 2014 until 2016. Prior to her current roles, Ms. LaPorte served on the California Institute for Regenerative Medicine. Ms. LaPorte holds a B.S. degree in Biology from Yale University and a M.B.A. from the Stanford University Graduate School of Business. We believe Ms. LaPorte's significant leadership experience in the biopharmaceutical industry provides her with the qualifications and skills to serve on the Board.

Mark Iwicki. Mr. Iwicki has served as a member of the Board since March 2024. Mr. Iwicki previously served as the Chairman of Legacy Q32's board of directors since 2020. Mr. Iwicki currently serves as chairman and Chief Executive Officer of Kala Bio, Inc. (NASDAQ: KALA) Prior to this role, Mr. Iwicki served as President and Chief Executive Officer of Civitas Therapeutics, Inc. or Civitas, a biopharmaceutical company from January 2014 until November 2014, as well as President and Chief Executive Officer of Blend Therapeutics, Inc., or Blend, a pharmaceutical company, from December 2012 until January 2014. Prior to Blend, Mr. Iwicki served as President and Chief Executive Officer of Sunovion Pharmaceuticals Inc., or Sunovion, a pharmaceutical company from October 2007 until June 2012. Prior to joining Sunovion, Mr. Iwicki was Vice President and Business Unit Head at Novartis Pharmaceuticals Corporation, a biopharmaceutical company. He was at Novartis from March 1998 to October 2007. Prior to that, Mr. Iwicki held management positions at Astra Merck Inc. and Merck & Co., Inc. In addition to serving as Executive Chairman of our Board of Directors, Mr. Iwicki also currently serves on the boards of Akero Therapeutics, Third Harmonic, Aerovate and Merus. Mr. Iwicki holds a B.S. in Business Administration from Ball State University and an M.B.A. from Loyola University. We believe Mr. Iwicki's significant leadership and investment experience in the biopharmaceutical industry provides him with the qualifications and skills to serve on the Board.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, our Board. There are no family relationships among any of our directors or executive officers.

Our Board of Directors

Our Board currently consists of eight directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term.

Committees of Our Board of Directors

The standing committees of our Board are the following: audit committee, compensation committee, nominating and corporate governance committee and research and development committee, and each operates pursuant to a charter. Our Board may establish other committees from time to time to assist us and our Board.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;

- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- establishing policies regarding hiring employees from the independent registered public accounting firm and procedures for the receipt and retention of accounting-related complaints and concerns;
- meeting independently with our internal auditing staff, if any, independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by the SEC rules.

The audit committee consists of Kathleen LaPorte, Mary Thistle and Mark Iwicki. Kathleen LaPorte serves as the chair of the audit committee and is a financial expert under the rules of the SEC. To qualify as independent to serve on our audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from us, other than for service as a director, or be an affiliated person of us. We believe that the composition of the audit committee complies with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Committee

Our compensation committee oversees policies relating to compensation and benefits of our officers and employees. Among other matters, the compensation committee's responsibilities include:

- reviewing and approving, or recommending for approval by the Board, the compensation of our CEO and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to the Board of Directors with respect to director compensation;
- periodically evaluating the Company's succession plans for the Chief Executive Officer and other executive officers;
- overseeing and periodically reviewing matters related to the Company's human capital management as well as the Company's human key capital policies and practices, including with respect to diversity, equity and inclusion, workplace culture, and equitable pay practices;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual compensation committee report, to the extent required by SEC rules.

The compensation committee consists of Mark Iwicki, Bill Lundberg and Isaac Manke. Mark Iwicki serves as the chair of the compensation committee. Each member of the compensation committee is a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. We believe that the composition of the compensation committee complies with the applicable requirements of the rules and regulations of Nasdaq.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

- developing and recommending to our board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating our board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of our board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our committees;
- reviewing and recommending to our board of directors appropriate corporate governance guidelines; and
- overseeing the evaluation of the board of directors.

The nominating and corporate governance committee consists of Mary Thistle, Kathleen LaPorte, and Diyong Xu. Mary Thistle serves as the chair of the nominating and corporate governance committee. We believe that the composition of the nominating and corporate governance committee meets the requirements for independence under, and the functioning of such nominating and corporate governance committee complies with, any applicable requirements of the rules and regulations of Nasdaq.

Research and Development Committee

Our research and development committee assists our Board with oversight of our research and development activities. Among other matters, the research and development committee's responsibilities include:

- reviewing, evaluating, and advising our board of directors and management regarding the long-term strategic goals and objectives and the quality and direction of our research and development programs;
- monitoring and evaluating trends in research and development, and recommending to our board of directors and management emerging technologies for building our technological strength;
- regularly reviewing our research and development pipeline; and
- assisting our board of directors with its oversight responsibility for enterprise risk management in areas affecting our research and development.

The research and development committee consists of Bill Lundberg, Arthur Tzianabos and David Grayzel. Bill Lundberg serves as the chair of the research and development committee.

Compensation Committee Interlocks and Insider Participation

Each member of the compensation committee will be a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who is serving on our board of directors or compensation committee.

Non-Employee Director Compensation

Prior to the Merger, Legacy Q32 did not have a formal policy to provide any cash or equity compensation to its non-employee directors for their service on its board of directors or committees of its board of directors, nor

did any non-employee director receive any compensation for serving on Legacy Q32's board of directors, except for Mark Iwicki who received an annual payment of $50,000, and Kathleen LaPorte and Bill Lundberg, who each received an annual payment of $40,000.

Our Board adopted a non-employee director compensation policy that is designed to provide a total compensation package that enables us to attract and retain, on a long-term basis, high-caliber directors who are not our employees or officers or of our subsidiaries. Under the non-employee director compensation policy, our non-employee directors are eligible to receive cash retainers (which will be prorated for partial years of service) and equity awards as set forth below:

Annual Retainer for Board Membership	
Annual service on the board of directors	$ 40,000
Additional retainer for annual service as non-executive chair	$ 33,500
Additional Annual Retainer for Committee Membership	
Annual service as audit committee chair	$ 19,000
Annual service as member of the audit committee (other than chair)	$ 9,500
Annual service as compensation committee chair	$ 12,000
Annual service as member of the compensation committee (other than chair)	$ 6,000
Annual service as nominating and governance committee chair	$ 10,000
Annual service as member of the nominating and governance committee (other than chair)	$ 5,000
Annual service as research and development committee chair	$ 10,000
Annual service as member of the research and development committee (other than chair)	$ 5,000

In addition, the policy provides that, upon initial election or appointment to our board following the effective date of the policy, each new non-employee director will be granted a non-statutory stock option with a value of $228,000 (as determined in accordance with the policy), or the Director Initial Grant. The Director Initial Grant will vest one-third on the first anniversary of the grant date with the remainder in equal monthly installments over the following two years, subject to continued service as a non-employee director through the applicable vesting date. On the date of each annual meeting of our stockholders, each non-employee director who will continue as a non-employee director following such meeting will be granted an annual award of a non-statutory stock option with a value of $114,000, or the Director Annual Grant. The Director Annual Grant will vest in full on the earlier of the one-year anniversary of the grant date or on the date of our next annual meeting of stockholders, subject to continued service as a non-employee director through the applicable vesting date. The Director Initial Grant and Director Annual Grants are subject to full accelerated vesting upon our sale our company. All of the foregoing stock options would be granted with a per share exercise price equal to the fair market value of a share of our common stock on the date of grant and would have a 10 year term.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any of our non-employee directors for services as a director in a calendar year period will not exceed $1,000,000 in the first calendar year such individual becomes a non-employee director and $750,000 in any other calendar year.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of the board or any committee thereof.

Our employee directors will not receive any additional compensation for their service as a director.

EXECUTIVE AND DIRECTOR COMPENSATION

Legacy Q32 2023 Non-Employee Director Compensation

Non-Employee Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee director of Legacy Q32's Board during 2023. Ms. Morrison, Legacy Q32's Chief Executive Officer and President did not receive any additional compensation from us for her service on Legacy Q32's Board. The compensation received by Ms. Morrison as a named executive officer, or NEO, is set forth below in "*2023 Executive Compensation—2023 Summary Compensation Table.*" The information in this section, including any equity ownership, does not reflect the effect of the Merger, the conversion of Legacy Q32's common stock into our common stock or the Reverse Stock Split.

Name	Fees Paid or Earned in Cash ($)	Total ($)
Jayson Punwani (1)	—	—
David Grayzel (2)	—	—
Mark Iwicki (3)	50,000	50,000
Kathleen LaPorte (4)	40,000	40,000
Bill Lundberg (5)	40,000	40,000
Isaac Manke (6)	—	—
Diyong Xu (7)	—	—

(1) As of December 31, 2023, Mr. Punwani did not hold any outstanding equity awards.
(2) As of December 31, 2023, Mr. Grayzel did not hold any outstanding equity awards.
(3) As of December 31, 2023, Mr. Iwicki held options to purchase 933,848 shares of Legacy Q32's common stock.
(4) As of December 31, 2023, Ms. LaPorte held options to purchase 153,690 shares of Legacy Q32's common stock and holds 113,124 shares of common stock.
(5) As of December 31, 2023, Mr. Lundberg held options to purchase 231,875 shares of Legacy Q32's common stock and holds 25,000 shares of common stock.
(6) As of December 31, 2023, Mr. Manke did not hold any outstanding equity awards.
(7) As of December 31, 2023, Mr. Xu did not hold any outstanding equity awards.

Narrative to 2023 Director Compensation Table

Legacy Q32 did not have a formal non-employee director compensation program in 2023 but had entered into letter agreements with certain of its independent, non-employee directors that provided for quarterly payments of $10,000 for Ms. LaPorte and Mr. Lundberg and $12,500 for Mr. Iwicki. No non-employee director received any equity grants in 2023.

Non-Employee Director Compensation After the Merger

Following the closing of the Merger, each non-employee director will receive compensation for his or her service on the Board in accordance with our non-employee director compensation policy, which was amended and restated in connection with the closing of the Merger and now provides for the following cash and equity retainers:

- an annual cash retainer of $40,000 for members of the Board (or $73,500 for the non-executive chair of the Board);
- an additional annual cash retainer of $9,500 for service on the Audit Committee (or $19,000 for service as chair of the Audit Committee);

- an additional annual cash retainer of $6,000 for service on the Compensation Committee (or $12,000 for service as chair of the Compensation Committee);
- an additional annual cash retainer of $5,000 for service on the Nominating and Corporate Governance Committee (or $10,000 for service as chair of the Nominating and Corporate Governance Committee); and
- an additional annual cash retainer of $5,000 for service on the Research and Development Committee (or $10,000 for service as chair of the Research and Development Committee).

In addition, upon initial election or appointment, each new non-employee director will be granted a non-statutory stock option with a value of up to $228,000 (as determined in accordance with the policy). The initial grant will vest one-third on the first anniversary of the grant date with the remainder in equal monthly installments over the following two years, subject to continued service through the applicable vesting date. On the date of each annual meeting of stockholders, each non-employee director who will continue as a non-employee director following such meeting will be granted an annual award of a non-statutory stock option with a value of $114,000. The annual grants will vest in full on the earlier of the one-year anniversary of the grant date or on the date of our next annual meeting of stockholders, subject to continued service through the applicable vesting date. These director grants are subject to full accelerated vesting upon the sale of our company. All of the foregoing stock options will be granted with a per share exercise price equal to the fair market value of a share of our common stock on the grant date have a 10 year term.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for services as a director in a calendar year period will not exceed $1,000,000 in the first calendar year such individual becomes a non-employee director and $750,000 in any other calendar year.

Unless the context otherwise requires, any reference in this section of this prospectus to “Legacy Q32” refers to Legacy Q32 and its consolidated subsidiaries prior to the consummation of the Merger and any reference to “the Company,” “we,” or “us” refers to Q32 Bio Inc. and its consolidated subsidiaries after the Merger. Legacy Q32 opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies” as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for its principal executive officer and two other most highly compensated executive officers who became our executive officers in the Merger. Unless otherwise indicated, the information presented in this “Executive and Director Compensation” section is as of December 31, 2023 and does not reflect the effects of the Merger or the Reverse Stock Split.

This section discusses the material components of the executive compensation program offered to the executive officers of Legacy Q32 who would have been “named executive officers” for 2023 and who are now serving as our executive officers. Such executive officers consist of the following persons, referred to herein as Legacy Q32’s NEOs:

- Jodie Morrison, Legacy Q32’s Chief Executive Officer and President;
- Jason Campagna, Legacy Q32’s Chief Medical Officer; and
- Shelia Violette, Legacy Q32’s Chief Scientific Officer and President of Research.

Each of Legacy Q32’s NEOs serves our company in the same capacities as prior to the consummation of the Merger (other than Jodie Morrison who no longer serves as our President). This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt could vary significantly from our historical practices and currently planned programs summarized in this discussion.

2023 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to Legacy Q32's NEOs for services during the fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)(2)	Option Awards ($)(3)	All Other Compensation ($)	Total ($)
Jodie Morrison (4)	2023	525,032	327,000	223,275	600	1,075,907
Chief Executive Officer & President	2022	120,353	100,000	1,667,171	150	1,887,674
Jason Campagna	2023	459,680	220,647	—	600	689,927
Chief Medical Officer	2022	442,000	176,800	—	600	619,400
Shelia Violette						
Chief Scientific Officer and President of Research	2023	416,000	203,330	96,291	600	716,221

(1) The amounts in this column represent the total base salaries earned in fiscal year 2022 and 2023.

(2) Amounts in this column represent discretionary annual bonuses earned for performance in fiscal year 2022 and 2023, which were paid in early 2023 and 2024, respectively. For more information regarding the annual bonuses, see "—Narrative Disclosure to Summary Compensation Table—Annual Bonuses" below.

(3) The amounts reported represent the aggregate grant date fair value of the stock option awards granted to our named executive officers during 2022 and 2023, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option awards reported in this column are set forth in note 10 of Legacy Q32's audited financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these stock option awards and do not correspond to the actual economic value that may be received by Legacy Q32's named executive officers upon the exercise of the stock option awards or any sale of the underlying shares of Legacy Q32 common stock.

(4) Ms. Morrison commenced part-time employment with Legacy Q32 on September 8, 2022 and became a full-time employee on November 1, 2022.

Narrative Disclosure to the 2023 Summary Compensation Table

2023 Base Salaries

Each of Legacy Q32's NEO's base salary is a fixed component of annual compensation for performing specific duties and functions. Base salaries were adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. As of the end of the fiscal year ended December 31, 2023, the base salaries for Ms. Morrison, Mr. Campagna and Ms. Violette were $545,000, $459,680 and $416,000 respectively.

2023 Annual Bonuses

Each NEO was eligible to earn an annual incentive bonus for each year they were employed by Legacy Q32, with the target amount of such bonus opportunity set as a percentage of each NEO's annual base salary and based on achievement of certain corporate goals. The actual bonus amounts were determined by Legacy Q32's Chief Executive Officer (except with respect to her own bonus) and its board of directors, in their absolute discretion. For the fiscal year ended December 31, 2023, the target annual bonuses for Ms. Morrison, Mr. Campagna and Ms. Violette was 50%, 40%, and 40%, respectively.

Equity Incentive Compensation

On December 7, 2017, Legacy Q32's board of directors adopted the 2017 Plan. Although Legacy Q32 does not have a formal policy with respect to the grant of equity incentive awards to Legacy Q32's executive officers, Legacy Q32 believes that equity awards provide Legacy Q32's executive officers with a strong link to Legacy

Q32's long-term performance, create an ownership culture and help to align the interests of Legacy Q32's executives and Legacy Q32's stockholders. In addition, Legacy Q32 believed that equity awards with a time-based vesting feature promoted executive retention because this feature incentivized Legacy Q32's executive officers to remain in Legacy Q32's employment during the applicable vesting period. Accordingly, Legacy Q32's board of directors periodically reviewed the equity incentive compensation of Legacy Q32's NEOs and from time to time granted equity incentive awards to them. In 2022 and 2023, Legacy Q32 granted options to Legacy Q32's NEOs with the aggregate grant date fair values set forth in the Summary Compensation Table above.

Perquisites

Legacy Q32 generally did not provide perquisites to its employees, other than certain de minimis perquisites available to all of our employees, including its NEOs.

401(k) Plan

Legacy Q32 maintained the Q32 Bio Inc. 401(K) Plan, a tax-qualified retirement plan that provides eligible employees, including the NEOs, with an opportunity to save for retirement on a tax-advantaged basis. Plan participants were able to defer eligible compensation subject to applicable annual limits under the Code. Participants pre-tax or Roth contributions were allocated to each participant's individual account and were then invested in selected investment alternatives according to the participants' directions. Participants were immediately and fully vested in their contributions. Q32's 401(k) plan was intended to be qualified under Section 401(a) of the Code with its 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code.

Offer Letters with Legacy Q32's Named Executive Officers

Legacy Q32 entered into offer letters with each of its NEOs, which set forth the terms and conditions of each executive's employment relationship. The terms of which are described below.

Offer Letter with Ms. Jodie Morrison

Legacy Q32 entered into an offer letter with Ms. Morrison, dated September 8, 2022, as amended on October 19, 2023, pursuant to which Legacy Q32 employs Ms. Morrison as its Chief Executive Officer and President. Pursuant to her offer letter, Ms. Morrison receives an initial annual base salary of $250,000, which increased to $500,000 effective as of November 1, 2022 in connection with the commencement of her full-time employment and subsequently increased to $545,000 effective as of October 19, 2023 in connection with her amendment to her offer letter. Ms. Morrison is also eligible to receive a target annual bonus of 50% her base salary and is eligible to participate in the employee benefit plans generally available to Legacy Q32's employees, subject to the terms of such plans. Pursuant to Ms. Morrison's amendment to her offer letter, she will be entitled to a base salary and target annual bonus adjustment in which such compensation will be adjusted to be no less than the seventy-fifth (75th) percentile for chief executive officers at public biotechnology companies that are similar in size, development stage and location as Legacy Q32, as determined by the board of directors in its discretion, subject to Legacy Q32 going public, which such adjustment provision is expected to be triggered upon the consummation of the Merger. Finally, Ms. Morrison's offer letter provides that she is eligible for two initial equity grants in the form of stock options, which were issued to Ms. Morrison in fiscal year 2022, with a third grant to be made upon Ms. Morrison becoming Legacy Q32's full-time Chief Executive Officer and, until Legacy Q32's public listing (which will be satisfied upon the consummation of the Merger), one or more true-up stock option awards following the consummation of each preferred stock financing and Legacy Q32's public listing in which, together with previously granted awards, will represent 5% of Legacy Q32's capital stock. Such grants shall not be made in connection with Legacy Q32's public listing if such event occurs later than six months following October 19, 2023.

In the event of a "qualifying termination" (as defined in her offer letter), subject to Ms. Morrison's execution of a separation agreement and a general release of claims in favor of Legacy Q32 (and, in its sole discretion, subject to a one-year post-employment noncompetition agreement), Ms. Morrison will be entitled to receive: (i) base salary continuation for twelve (12) months following her date of termination; (ii) pro-rated annual target bonus in the amount she would have received in the year of termination (payable on the same schedule as her base salary continuation); and (iii) if Ms. Morrison elects continued COBRA healthcare coverage, continued healthcare coverage in the amount contributed by Legacy Q32 for a period of nine (9) months.

In lieu of the severance payments and benefits described in the preceding paragraph, in the event that Ms. Morrison's employment is terminated due to a qualifying termination, on or within twelve (12) months following a "change in control" (as defined in her offer letter), Ms. Morrison will be entitled to receive (i) a lump sum payment equal to base salary continuation for eighteen (18) months following her date of termination; (ii) 100% of the annual target bonus she would have received in the year of termination, payable in lump sum; (iii) if Ms. Morrison elects continued COBRA healthcare coverage, continued healthcare coverage in the amount contributed by Legacy Q32 for a period of nine (9) months; and (iv) full acceleration of any unvested time-based equity.

Offer Letter with Mr. Jason Campagna

Legacy Q32 entered into an offer letter with Mr. Campagna, dated February 11, 2021, pursuant to which Legacy Q32 employs Mr. Campagna as its Chief Medical Officer. Pursuant to his offer letter, Mr. Campagna receives an initial annual base salary of $425,000, which is subject to annual review and periodic adjustment. Mr. Campagna is also eligible to receive a target annual bonus of 40% his base salary and is also eligible to participate in the employee benefit plans generally available to Legacy Q32's employees, subject to the terms of such plans. Finally, Mr. Campagna's offer letter provides that he is eligible for two initial equity grants in the form of stock options.

In the event of a termination of Mr. Campagna's employment by Legacy Q32 without "cause" or Mr. Campagna resigns for "good reason" (as each term is defined in his offer letter), subject to Mr. Campagna's execution of a separation agreement and a general release of claims in favor of Legacy Q32, Mr. Campagna will be entitled to receive (i) base salary continuation for nine (9) months following his date of termination; and (ii) if Mr. Campagna elects continued COBRA healthcare coverage, continued healthcare coverage in the amount contributed by Legacy Q32 for a period of six (6) months.

In addition to the severance payments and benefits described in the preceding paragraph, in the event that Mr. Campagna's employment is terminated by Legacy Q32 without cause or Mr. Campagna resigns for good reason, in each case, within twelve (12) months following a "sale event" (as defined in the 2017 Plan), Mr. Campagna will also be entitled to receive (i) an additional six (6) months of continued healthcare, resulting in a total of twelve (12) months of continued healthcare; and (ii) full acceleration of the unvested equity awards referenced in his offer letter.

Offer Letter with Ms. Shelia Violette

Legacy Q32 entered into an offer letter with Ms. Violette, dated September 8, 2017, pursuant to which Legacy Q32 employs Ms. Violette as its Chief Scientific Officer. Pursuant to her offer letter, Ms. Violette receives an initial annual base salary of $300,000, which is subject to annual review and periodic adjustment. Ms. Violette is also eligible to receive a target annual bonus of 30% her base salary and is also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of such plans. Finally, Ms. Violette's offer letter provides that she is eligible for an initial equity grant in the form of restricted stock, which was issued to Ms. Violette in fiscal year 2017 and has since fully vested.

In the event of a termination of Ms. Violette's employment by Legacy Q32 without "cause" or Ms. Violette resigns for "good reason" (as each term is defined in her offer letter), subject to Ms. Violette's execution of a separation agreement and a general release of claims in favor of Legacy Q32, Ms. Violette will be entitled to

receive (i) base salary continuation for twelve (12) months following her date of termination; and (ii) if Ms. Violette elects continued COBRA healthcare coverage, continued healthcare coverage in the amount contributed by Legacy Q32 for a period of twelve (12) months.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of the NEOs as of December 31, 2023.

	Option Awards (1)				
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Jodie Morrison	09/08/2022 (2)	993,840	2,186,448	0.36	11/16/2032
	11/01/2022 (2)	861,328	2,318,960	0.36	11/16/2032
	10/19/2023 (2)	14,667	337,350	0.82	11/08/2033
Jason Campagna	03/08/2021 (3)	1,256,293	571,043	0.35	03/24/2031
	12/17/2021 (3)	186,938	186,939	0.35	12/16/2031
Shelia Violette	07/26/2018 (3)	90,837	—	0.15	12/06/2028
	09/17/2019 (3)	281,448	—	0.15	12/06/2028
	12/02/2020 (4)	607,500	202,500	0.35	12/01/2030
	03/15/2021 (5)	190,521	86,601	0.35	03/24/2031
	12/17/2021 (3)	182,299	182,299	0.36	04/26/2033

(1) Each equity award is subject to the terms of Legacy Q32's 2017 Plan and the applicable award agreement.

(2) The shares subject to the stock option vest in 48 equal monthly installments following the vesting commencement date, in each case, subject to the NEO's continuous service relationship with Legacy Q32 through each applicable vesting date; provided that, in the event that Ms. Morrison is experiences a "qualifying termination" on or within the twelve month period following a "change in control," all unvested options shall accelerate and become fully vested and exercisable.

(3) 1/4 of the shares subject to the stock option vest on the first anniversary of the vesting commencement date, and 1/48 of the shares subject to the stock option vest each month thereafter, in each case, subject to the NEO's continuous service relationship with Legacy Q32 through each applicable vesting date; provided that, for Mr. Campagna, in the event that he is terminated by Legacy Q32 without "cause" or resigns for "good reason," in each case, within twelve months following a "sale event," all unvested options shall accelerate and become fully vested and exercisable.

(4) The shares subject to the stock option vest in 16 equal quarterly installments following the vesting commencement date, in each case, subject to Ms. Violette's continuous service relationship with Legacy Q32 through each applicable vesting date.

(5) 1/4 of the shares subject to the stock option vest on the first anniversary of the vesting commencement date, and 1/16 of the shares subject to the stock option vest each quarter thereafter, in each case, subject to Ms. Violette's continuous service relationship with Legacy Q32 through each applicable vesting date.

Employee benefit and equity compensation plans and arrangements

2017 Stock Option and Grant Plan

Legacy Q32's 2017 Plan was initially adopted by its board of directors, and subsequently approved by its stockholders, on December 7, 2017.

Authorized Shares. Under Legacy Q32's 2017 Plan, Legacy Q32 has reserved for issuance an aggregate of 25,956,535 shares (which does not take into account any adjustments for the Exchange Ratio or the 1-for-18 Reverse Stock Split of Homology's common stock effected immediately prior to the Merger) of Legacy Q32

common stock. The number of shares of Legacy Q32 common stock was subject to adjustment in the event of a reorganization, stock split, reverse stock split, stock dividend, recapitalization, reclassification or other similar change in capitalization or event affecting the outstanding Legacy Q32 common stock and no more than 25,956,535 shares (which does not take into account any adjustments for the Exchange Ratio or the 1-for-18 Reverse Stock Split of Homology's common stock effected immediately prior to the Merger) may be issued pursuant to incentive stock options.

Administration. Legacy Q32's board of directors has acted as administrator of Q32's 2017 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and to determine the specific terms and conditions of each award, subject to the provisions of Q32's 2017 Plan.

Eligibility. Persons eligible to participate in Legacy Q32's 2017 Plan are Legacy Q32's full or part-time officers, employees, directors, consultants and other key persons as selected from time to time by the administrator in its discretion.

Awards. Legacy Q32's 2017 Plan permits the granting of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (ii) options that do not so qualify. The option exercise price of each option is determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option is fixed by the administrator and may not exceed ten years from the date of grant. The administrator determines at what time or times each option may be exercised. In addition, Legacy Q32's 2017 Plan permits the granting of restricted shares of common stock, unrestricted shares of common stock and restricted stock units.

Sale Events. Legacy Q32's 2017 Plan provides that upon the occurrence of a "sale event" (as defined in Legacy Q32's 2017 Plan), all outstanding stock options will terminate at the effective time of such sale event, unless the parties to the sale event agree that such awards will be assumed or continued by the successor entity. In the event of a termination of Legacy Q32's 2017 Plan and all options issued thereunder in connection with a sale event, optionees will be provided an opportunity to exercise options that are then exercisable or will become exercisable as of the effective time of the sale event prior to the consummation of the sale event. In addition, Legacy Q32 has the right to provide for cash payment to holders of options, in exchange for the cancellation thereof, in an amount equal to the difference between the value of the consideration payable per share of common stock in the sale event and the per share exercise price of such options, multiplied by the number of shares subject to such option to the extent then vested and exercisable. In the event of and subject to the consummation of a sale event, unvested restricted stock and restricted stock units (other than those becoming vested as a result of the sale event) will be forfeited immediately prior to the effective time of a sale event unless such awards are assumed or continued by the successor entity. If shares of restricted stock are forfeited in connection with a sale event, those shares of restricted stock shall be repurchased at a price per share equal to the original per share purchase price of such shares. Legacy Q32 has the right to provide for cash payment to holders of restricted stock or restricted stock units, in exchange for the cancellation thereof, in an amount per share equal to the value of the consideration payable per share of common stock in the sale event.

Amendment. Legacy Q32's board of directors may amend or discontinue Legacy Q32's 2017 Plan at any time, subject to stockholder approval where required by applicable law. The administrator of Legacy Q32's 2017 Plan may also amend or cancel any outstanding award, provided that no amendment to an award may adversely affect a participant's rights without his or her consent. The administrator of Legacy Q32's 2017 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options or effect the repricing of such awards through cancellation and re-grants.

As of December 31, 2023, options to purchase up to 23,165,393 shares of Legacy Q32's common stock were outstanding under Legacy Q32's 2017 Plan.

Employee Employment Arrangements After the Merger

Executive Employment Arrangements

Jodie Morrison

Effective as of the closing of the Merger, we entered into an employment agreement with Ms. Morrison, or the Morrison Employment Agreement, to serve as our Chief Executive Officer. The employment agreement provides for Ms. Morrison's at-will employment and an annual base salary of $645,600, an annual bonus with a target amount equal to 55% of her base salary, as well as her ability to participate in the Company's employee benefit plans generally. The Morrison Employment Agreement provides that if her employment is terminated either (i) by the Company without Cause (as defined therein) or (ii) by Ms. Morrison for Good Reason (as defined therein), within twelve months after a Change in Control (as defined in the therein), or the Change in Control Period, then Ms. Morrison will be entitled to receive, subject to signing a release, (i) a lump sum payment equal to 1.5 times the sum of (a) twelve months of base salary plus (b) the target bonus for the then-current year, (ii) COBRA health continuation for eighteen months, and (iii) 100% acceleration of all outstanding and unvested stock-based awards subject to time-based vesting. The Morrison Employment Agreement also provides that if her employment is terminated either (i) by the Company without Cause or (ii) by Ms. Morrison for Good Reason outside the Change in Control Period, then Ms. Morrison will be entitled to receive, subject to signing a release, (a) a lump sum payment of twelve months of base salary and (b) COBRA health continuation for twelve months. The Morrison Employment Agreement contains a Section 280G partial clawback, in which Ms. Morrison is entitled to receive the greater of (a) the best net after-tax amount of any payments that are subject to the excise tax imposed by Section 4999 of the Code, calculated in a manner consistent with Section 280G of the Code, and (b) the amount of parachute payments she would be entitled to receive if they were reduced to an amount equal to one dollar less than the amount at which Ms. Morrison becomes subject to excise tax imposed by Section 4999 of the Code.

Lee Kalowski

Effective as of the closing of the Merger, we entered into an employment agreement with Mr. Kalowski, or the Kalowski Employment Agreement, to serve as our Chief Financial Officer and President. The employment agreement provides for Mr. Kalowski's at-will employment and an annual base salary of $565,000, an annual bonus with a target amount equal to 40% of his base salary, as well as his ability to participate in the Company's employee benefit plans generally. The Kalowski Employment Agreement provides that if his employment is terminated either (i) by the Company without Cause (as defined therein) or (ii) by Mr. Kalowski for Good Reason (as defined therein), within twelve months after a Change in Control (as defined in the therein), or the Change in Control Period, then Mr. Kalowski will be entitled to receive, subject to signing a release, (i) a lump sum payment of (a) twelve months of base salary and (b) the target bonus for the then-current year, (ii) COBRA health continuation for twelve months, and (iii) 100% acceleration of all outstanding and unvested stock-based awards subject to time-based vesting. The Kalowski Employment Agreement also provides that if his employment is terminated either (i) by the Company without Cause or (ii) by Mr. Kalowski for Good Reason outside the Change in Control Period, then Mr. Kalowski will be entitled to receive, subject to signing a release, (a) a lump sum payment of twelve months of base salary and (b) COBRA health continuation for twelve months. The Kalowski Employment Agreement contains a Section 280G partial clawback, in which Mr. Kalowski is entitled to receive the greater of (a) the best net after-tax amount of any payments that are subject to the excise tax imposed by Section 4999 of the Code, calculated in a manner consistent with Section 280G of the Code, and (b) the amount of parachute payments he would be entitled to receive if they were reduced to an amount equal to one dollar less than the amount at which Mr. Kalowski becomes subject to excise tax imposed by Section 4999 of the Code.

Jason Campagna

Effective as of the closing of the Merger, we entered into an employment agreement with Dr. Campagna, or the Campagna Employment Agreement, to serve as our Chief Medical Officer. The employment agreement provides

for Dr. Campagna's at-will employment and an annual base salary of $500,000, an annual bonus with a target amount equal to 40% of his base salary, as well as his ability to participate in the Company's employee benefit plans generally. The Campagna Employment Agreement provides that if his employment is terminated either (i) by the Company without Cause (as defined therein) or (ii) by Dr. Campagna for Good Reason (as defined therein), within twelve months after a Change in Control (as defined in the therein), or the Change in Control Period, then Dr. Campagna will be entitled to receive, subject to signing a release, (i) a lump sum payment of (a) twelve months of base salary and (b) the target bonus for the then-current year, (ii) COBRA health continuation for twelve months, and (iii) 100% acceleration of all outstanding and unvested stock-based awards subject to time-based vesting. The Campagna Employment Agreement also provides that if his employment is terminated either (i) by the Company without Cause or (ii) by Dr. Campagna for Good Reason outside the Change in Control Period, then Dr. Campagna will be entitled to receive, subject to signing a release, (a) a lump sum payment of nine months of base salary and (b) COBRA health continuation for nine months. The Campagna Employment Agreement contains a Section 280G partial clawback, in which Dr. Campagna is entitled to receive the greater of (a) the best net after-tax amount of any payments that are subject to the excise tax imposed by Section 4999 of the Code, calculated in a manner consistent with Section 280G of the Code, and (b) the amount of parachute payments he would be entitled to receive if they were reduced to an amount equal to one dollar less than the amount at which Dr. Campagna becomes subject to excise tax imposed by Section 4999 of the Code.

Shelia M. Violette

Effective as of the closing of the Merger, we entered into an employment agreement with Dr. Violette, or the Violette Employment Agreement, to serve as our Chief Scientific Officer and President of Research. The employment agreement provides for Dr. Violette's at-will employment and an annual base salary of $455,000, an annual bonus with a target amount equal to 40% of her base salary, as well as her ability to participate in the Company's employee benefit plans generally. The Violette Employment Agreement provides that if her employment is terminated either (i) by the Company without Cause (as defined therein) or (ii) by Dr. Violette for Good Reason (as defined therein), within twelve months after a Change in Control (as defined in the therein), or the Change in Control Period, then Dr. Violette will be entitled to receive, subject to signing a release, (i) a lump sum payment of (a) twelve months of base salary and (b) the target bonus for the then-current year, (ii) COBRA health continuation for twelve months, and (iii) 100% acceleration of all outstanding and unvested stock-based awards subject to time-based vesting. The Violette Employment Agreement also provides that if her employment is terminated either (i) by the Company without Cause or (ii) by Dr. Violette for Good Reason outside the Change in Control Period, then Dr. Violette will be entitled to receive, subject to signing a release, (a) a lump sum payment of (i) twelve months of base salary and (ii) the target bonus for the then-current year, (b) COBRA health continuation for twelve months and (c) 100% acceleration of all outstanding and unvested stock-based awards subject to time-based vesting. The Violette Employment Agreement contains a Section 280G partial clawback, in which Dr. Violette is entitled to receive the greater of (a) the best net after-tax amount of any payments that are subject to the excise tax imposed by Section 4999 of the Code, calculated in a manner consistent with Section 280G of the Code, and (b) the amount of parachute payments she would be entitled to receive if they were reduced to an amount equal to one dollar less than the amount at which Dr. Violette becomes subject to excise tax imposed by Section 4999 of the Code.

2017 Stock Option and Grant Plan

We assumed, effective as of the closing of the Merger, the 2017 Stock Option and Grant Plan of Legacy Q32 (the "2017 Plan") as well as the outstanding awards granted thereunder, the award agreements evidencing the grants of such awards and the remaining shares available under the 2017 Plan.

2024 Stock Option and Grant Plan

The 2024 Stock Option and Grant Plan, or the 2024 Plan, allows us to make equity and equity-based incentive awards to officers, employees, directors and consultants. We anticipate that providing such persons with a direct

stake in our company will assure a closer alignment of the interests of such individuals with those of ours and our stockholders, thereby stimulating their efforts on our behalf and strengthening their desire to remain with us.

The initial maximum aggregate number of shares that may be issued under the 2024 Plan is 2,839,888 shares (which takes into account the 1-for-18 Reverse Stock Split of our common stock effected immediately prior to the Merger) before giving effect to the proposed Reverse Stock Split, or the Initial Limit. The 2024 Plan provides that the number of shares initially 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, or the Annual Increase. This limit is subject to adjustment in the event of a reorganization, recapitalization, reclassification, stock split, stock dividend, reverse stock split or other similar change in our capitalization. The maximum aggregate number of shares that may be issued upon exercise of incentive stock options under the 2024 Plan shall not exceed the Initial Limit cumulatively increased on January 1, 2025 and on each January 1 thereafter by the lesser of the Annual Increase or 2,839,888 shares (which takes into account the 1-for-18 Reverse Stock Split of Homology's common stock effected immediately prior to the Merger). Shares underlying any awards under the 2024 Plan and the shares underlying awards under the Q32 2017 Plan or Homology Incentive Plans that are forfeited, canceled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) shall be added back to the shares available for issuance under the 2024 Plan and, to the extent permitted under Section 422 of the Code and the regulations promulgated thereunder, the shares that may be issued as incentive stock options. Awards that may be settled solely in cash will not be counted against the shares available for issuance under the 2024 Plan and will not reduce the shares authorized for grant to a grantee in any calendar year.

The 2024 Plan contains a limitation whereby the value of all awards under the 2024 Plan and all other cash compensation paid to any non-employee director for services as a non-employee director may not exceed $750,000 in any calendar year; provided, however, that such amount will be $1,000,000 for the first calendar year a non-employee director is initially appointed to our board of directors.

The 2024 Plan will be administered by our board of directors, the compensation committee of our board of directors or such other similar committee pursuant to the terms of the 2024 Plan. The plan administrator, which initially will be the compensation committee of our board of directors, will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2024 Plan. The plan administrator may delegate to a committee consisting of one or more officers the authority to grant stock options and other awards to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not members of the delegated committee, subject to certain limitations and guidelines. Persons eligible to participate in the 2024 Plan will be our officers, employees, non-employee directors and consultants of as selected from time to time by the plan administrator in its discretion.

The 2024 Plan permits the granting of both options to purchase shares intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. Options granted under the 2024 Plan will be non-qualified options if they fail to qualify as incentive stock options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of ours and our subsidiaries. Non-qualified options may be granted to any persons eligible to receive awards under the 2024 Plan. The option exercise price of each option will be determined by the plan administrator but generally may not be less than 100% of the fair market value of our share on the date of grant or, in the case of an incentive stock option granted to a 10% stockholder, 110% of such share's fair market value. The term of each option will be fixed by the plan administrator and may not exceed ten years from the date of grant or, in the case of an incentive stock option granted to a ten percent stockholder, five years from the date of grant. The plan administrator will determine at what time or times each option will vest and may be exercised, including the ability to accelerate the vesting of such options.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the plan administrator or by delivery (or attestation to the ownership) of shares that are beneficially owned by the optionee free of restrictions or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the plan administrator may permit non-qualified options to be exercised using a "net exercise" arrangement that reduces the number of shares issued to the optionee by the largest whole number of shares with fair market value that does not exceed the aggregate exercise price.

The plan administrator may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price generally may not be less than 100% of the fair market value of our share on the date of grant. The term of each stock appreciation right will be fixed by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each stock appreciation right will vest and may be exercised, including the ability to accelerate the vesting of such stock appreciation right.

The plan administrator may award restricted shares and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with our company through a specified vesting period. The plan administrator may also grant shares that are free from any restrictions under the 2024 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant. The plan administrator may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares.

The plan administrator may grant cash-based awards under the 2024 Plan to participants.

The 2024 Plan requires the plan administrator to make appropriate adjustments to the number of shares of common stock that are subject to the 2024 Plan, to certain limits in the 2024 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

The 2024 Plan provides that upon the effectiveness of a "sale event," as defined in the 2024 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2024 Plan. To the extent that awards granted under the 2024 Plan are not assumed, continued or substituted by the successor entity, all awards granted under the 2024 Plan shall terminate. In addition, except as may be otherwise provided in the relevant award agreement, all stock options and stock appreciation rights with time-based vesting conditions or restrictions that are not vested and/or exercisable immediately prior to the effective time of the sale event shall become fully vested and exercisable as of the effective time of the sale event, all other awards with time-based vesting conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals shall become vested and nonforfeitable in connection with a sale event at the greater of (A) target levels or (B) actual performance. In the event of such termination, individuals holding options and stock appreciation rights will, for each such award, either (a) receive a payment in cash or in kind for each share subject to such award that is exercisable in an amount equal to the per share cash consideration payable to stockholders in the sale event less the applicable per share exercise price (provided that, in the case of an option or stock appreciation right with an exercise price equal to or greater than the per share cash consideration payable to stockholders in the sale event, such option or stock appreciation right shall be cancelled for no consideration) or (b) be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. The plan administrator shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other awards in an amount equal to the per share cash consideration payable to stockholders in the sale event multiplied by the number of vested shares under such awards.

Participants in the 2024 Plan are responsible for the payment of any federal, state or local taxes that we are required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. The plan administrator may cause any of our tax withholding obligation to be satisfied, in whole or in part, by us withholding from shares to be issued pursuant to an award a number of shares with an aggregate fair market value that would satisfy the withholding amount due. The plan administrator may also require any of our tax withholding obligation to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares issued pursuant to any award are immediately sold and proceeds from such sale are remitted to us in an amount that would satisfy the withholding amount due.

The 2024 Plan generally does not allow for the transfer or assignment of awards, other than by will or by the laws of descent and distribution or pursuant to a domestic relations order; however, the plan administrator may permit the transfer of non-qualified stock options by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners. All awards will be subject to our clawback policy as set forth in such clawback policy or the applicable award agreement.

The plan administrator may amend or discontinue the 2024 Plan and the plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder's consent. The plan administrator is specifically authorized to reduce the exercise price of outstanding options or stock appreciation rights, effect the repricing of such awards through cancellation and re-grants or cancel such awards in exchange for cash or other awards without prior stockholder approval. Certain amendments to the 2024 Plan require the approval of our stockholders.

No awards may be granted under the 2024 Plan after the date that is ten years from the Effective Time. No awards under the 2024 Plan have been made prior to the date hereof.

2024 Employee Stock Purchase Plan

An aggregate of 120,836 shares (which takes into account the 1-for-18 Reverse Stock Split of our common stock effected immediately prior to the Merger), were initially reserved and available for issuance under the 2024 Employee Stock Purchase Plan, or the 2024 ESPP. The 2024 ESPP provides that the number of shares initially reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2025, by the lesser of a number of shares equal to 241,677, 1% of the outstanding number of shares on the immediately preceding December 31, or such lesser amount as determined by the plan administrator. If our capital structure changes because of a stock dividend, stock split or similar event, the number of shares that can be issued under the 2024 ESPP will be appropriately adjusted.

The 2024 ESPP will be administered by the person or persons appointed by our board of directors. Initially, the compensation committee of our board of directors will administer the plan and will have full authority to make, administer and interpret such rules and regulations regarding the 2024 ESPP as it deems advisable. Any employee of ours or one of our subsidiaries that has been designated to participate in the 2024 ESPP is eligible to participate in the 2024 ESPP so long as the employee is customarily employed for more than 20 hours a week. No person who owns or holds, or as a result of participation in the 2024 ESPP would own or hold, shares or options to purchase shares, that together equal to 5% or more of total combined voting power or value of all classes of stock of ours or any parent or subsidiary is entitled to participate in the 2024 ESPP. No employee may exercise an option granted under the 2024 ESPP that permits the employee to purchase shares having a value of more than $25,000 (determined using the fair market value of the stock at the time such option is granted) in any calendar year.

Participation in the 2024 ESPP is limited to eligible employees who authorize payroll deductions equal to a whole percentage of base pay to the 2024 ESPP. Employees may authorize payroll deductions, with a minimum of 1% of base pay and a maximum of 15% of base pay.

Immediately following completion of the Merger, we have a total of approximately 37 employees who will be eligible participate the 2024 ESPP. Once an employee becomes a participant in the 2024 ESPP, that employee will automatically participate in successive offering periods, as described below, until such time as that employee withdraws from the 2024 ESPP, becomes ineligible to participate in the 2024 ESPP, or his or her employment ceases.

We may make one or more offerings under the 2024 ESPP, consisting of one or more purchase periods, for employees to purchase shares under the 2024 ESPP, which is referred to as an "offering period." The plan administrator may, in its discretion, determine when each offering shall occur, including the duration of any offering period; provided, that no offering period will exceed 27 months in duration. Shares are purchased on the last day of each purchase period or if such purchase period is the last purchase period of the offering period, the last day of such offering period, with that day being referred to as an "exercise date." Unless otherwise determined by the plan administrator, participants will only be permitted to participate in one offering at a time.

On the first day of an offering period, employees participating in that offering period will be granted an option to purchase shares. On the exercise date of each purchase period, the employee is deemed to have exercised the option, at the exercise price, for the lowest of (i) a number of shares determined by dividing such employee's accumulated payroll deductions or contributions on such exercise date by the exercise price; (ii) a number of shares determined by dividing $25,000 by the fair market value per share on the first day of the offering period; or (iii) such lesser number as established by the plan administrator in advance of the offering. The exercise price is equal to the lesser of (i) 85% the fair market value per share on the first day of the offering period or (ii) 85% of the fair market value per share on the exercise date. The maximum number of shares that may be issued to any employee under the 2024 ESPP in a calendar year is a number of shares determined by dividing $25,000, valued at the start of the offering period, or such other lesser number of shares as determined by the plan administrator from time to time.

In general, if an employee is no longer a participant on an exercise date, the employee's option will be automatically terminated, and the amount of the employee's accumulated payroll deductions will be refunded.

Except as may be permitted by the plan administrator in advance of an offering, a participant may not increase or decrease the amount of his or her payroll deductions during any offering period but may increase or decrease his or her payroll deduction with respect to the next offering period by filing a new enrollment form at least 15 business days before the first day of such offering period, or such other deadline established by the plan administrator. A participant may withdraw from an offering period at any time without affecting his or her eligibility to participate in future offering periods. If a participant withdraws from an offering period, that participant may not again participate in the same offering period, but may enroll in subsequent offering periods. An employee's withdrawal will be effective as of the next business day following the date that the plan administrator receives the employee's written notice of withdrawal under the 2024 ESPP.

In the case of and subject to the consummation of a "sale event," the plan administrator, in its discretion, and on such terms and conditions as it deems appropriate, is hereby authorized to take any one or more of the following actions under the 2024 ESPP or with respect to any right under the 2024 ESPP or to facilitate such transactions or events: (a) to provide for either (i) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (ii) the replacement of such outstanding option with other options or property selected by the plan administrator in its sole discretion; (b) to provide that the outstanding options under the 2024 ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (c) to make adjustments in the number and type of shares (or other securities or property) subject to outstanding options under the 2024 ESPP and/or in the terms and conditions of outstanding options and options that may be granted in the future; (d) to provide that

the offering with respect to which an option relates will be shortened by setting a new exercise date on which such offering will end; and (e) to provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

The 2024 ESPP will automatically terminate on the 10-year anniversary of the Effective Time. Our board of directors may, in its discretion, at any time, terminate or amend the 2024 ESPP.

Senior Executive Cash Incentive Bonus Plan

Our board adopted a Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan became effective following completion of the Merger and provides for cash bonus payments based upon the attainment of performance objectives established by our compensation committee. The performance objectives may be related to financial and operational metrics with respect to us and/or any of our subsidiaries, or corporate performance goals, as well as individual performance objectives.

Our compensation committee may select corporate performance goals from among the following: developmental, publication, clinical or regulatory milestones; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions, licenses, or strategic transactions; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; total shareholder return; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention, and recruiting and other human resources matters; operating income and/or net annual recurring revenue; or any other performance goal selected by the compensation committee, any of which may be (A) measured in absolute terms or compared to any incremental increase, (B) measured in terms of growth, (C) compared to another company or companies or to results of a peer group, (D) measured against the market as a whole and/or as compared to applicable market indices and/or (E) measured on a pre-tax or post-tax basis (as applicable).

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive officer at the beginning of each performance period. The corporate performance goals will be measured at the end of each performance period. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but no later than two and one-half months after the end of the fiscal year in which such performance period ends, unless otherwise determined by the compensation committee. Subject to the rights contained in any agreement between the executive officer and us or unless otherwise determined by the compensation committee, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan will also permit the compensation committee to approve additional bonuses to executive officers in its sole discretion.

HOMOLOGY EXECUTIVE AND DIRECTOR COMPENSATION

Unless the context otherwise requires, any reference in this section of this prospectus to "Homology" refers to Homology Medicines, Inc. and its consolidated subsidiaries prior to the consummation of the Merger and any reference to "the Company," "we," or "us" refers to Q32 Bio Inc. and its consolidated subsidiaries after the Merger. Immediately after closing of the Merger, Paul Alloway resigned as our President, Chief Operating Officer and Secretary and principal executive officer, and Charles Michaud, Jr. resigned as our Vice President, Corporate Controller and Treasurer and principal financial officer and principal accounting officer. Unless otherwise indicated, the information presented in this "Homology Executive and Director Compensation" section is as of December 31, 2023 and does not reflect the effects of the Merger or the Reverse Stock Split.

Homology Executive Compensation

This section discusses the material components of Homology's 2023 compensation program for Homology's executive officers who are named in the 2023 Summary Compensation Table below. These "named executive officers" and their positions are:

- Paul Alloway, Ph.D., J.D., President, Chief Operating Officer and Secretary;
- Charles Michaud, Jr., Vice President, Corporate Controller and Treasurer;
- Albert Seymour, Ph.D., Former President and Chief Executive Officer;
- W. Bradford Smith, Former Chief Financial and Business Officer and Treasurer; and
- Julie Jordan, M.D., Former Chief Medical Officer.

2023 Summary Compensation Table

The following table sets forth information concerning the compensation of Homology's named executive officers for the years ended December 31, 2023 and 2022:

Name and principal position	Fiscal Year	Salary $ (1)	Bonus $ (5)	Option Awards $ (6)	Stock Awards $ (7)	Non-Equity Incentive Plan Compensation $	All Other Compensation $ (8)	Total $
Paul Alloway, Ph.D., J.D.	2023	468,189	92,485	173,889	43,200	—	8,700	786,463
President, Chief Operating Officer and Secretary	2022	415,700	70,771	163,828	43,360	166,280	8,700	868,639
Charles Michaud, Jr.	2023	317,213	46,996	51,955	12,800	—	8,700	437,664
Vice President, Corporate Controller and Treasurer								
Albert Seymour, Ph.D.	2023	563,390(2)	—	670,110	168,000	—	325,160	1,726,660
Former Chief Executive Officer	2022	527,554	—	323,003	87,430	250,800	8,700	1,197,486
W. Bradford Smith	2023	452,817(3)	—	225,844	57,600	—	233,549	969,810
Former Chief Financial and Business Officer	22	460,900	66,094	217,287	56,910	184,360	8,700	994,251
Julie Jordan, M.D.	2023	292,298(4)	—	151,623	38,400	—	250,065	732,386
Former Chief Medical Officer								

(1) In connection with the execution of the Merger Agreement, Homology paid out accrued vacation in the amount of $35,571 for Dr. Alloway and $24,101 for Mr. Michaud.

(2) Dr. Seymour terminated employment on November 17, 2023. The amount reported in the salary column for 2023 is comprised of $518,229 in base salary for his employment prior to his resignation and $45,161 in accrued vacation paid in connection with his resignation.

(3) Mr. Smith terminated employment on November 17, 2023. The amount reported in the salary column for 2023 is comprised of $419,038 in base salary for his employment prior to his resignation and $33,779 in accrued vacation paid in connection with his resignation.

(4) Dr. Jordan terminated employment on August 3, 2023. The amount reported in the salary column for 2023 is comprised of $274,831 in base salary for her employment prior to her resignation and $17,467 in accrued vacation paid in connection with her resignation.

(5) Amounts reported in the bonus column for 2023 for Dr. Alloway and Mr. Michaud are cash bonuses approved by Homology's Board of Directors in connection with the Merger. The bonuses were paid in January 2024.

(6) Amounts reflect the full grant date fair value of stock options granted during the applicable year computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. Homology provided information regarding the assumptions used to calculate the value of all option awards in Note 14 to Homology's consolidated financial statements included its 2023 Annual Report. For Drs.

Seymour and Jordan and Mr. Smith, the amounts include $36,373, $5,712 and $21,789, respectively, representing the incremental fair value attributable to modifications made to such individual's stock options.

(7) Amounts reflect the full grant date fair value of restricted stock units granted during the applicable year computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. Homology provided information regarding the assumptions used to calculate the value of all restricted stock units in Note 14 to Homology's consolidated financial statements included in its 2023 Annual Report. For Drs. Seymour and Jordan and Mr. Smith, the amounts include $41,271, $6,184 and $22,537, respectively, representing the incremental fair value attributable to modifications made to such individual's restricted stock units.

(8) Amounts shown for Dr. Alloway and Mr. Michaud represent 401(k) matching contributions. For Dr. Seymour, the amount shown includes (i) $8,700 in 401(k) matching contributions, (ii) $316,460 in cash severance payments paid pursuant to his separation agreement. For Mr. Smith, the amount shown includes (i) $8,700 in 401(k) matching contributions; (ii) $220,284 in cash severance payments paid pursuant to his separation agreement and (iii) $4,565 in consulting fees paid for services rendered during 2023. For Dr. Jordan, the amount shown includes (i) $8,700 in 401(k) matching contributions and (ii) 241,365 in cash severance payments paid pursuant to her separation agreement. For additional information, refer to the discussion below under the headings "Narrative Disclosure to Summary Compensation Table—Retirement Plans" and "—Employment Arrangements."

Narrative Disclosure to Summary Compensation Table

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

2023 Salaries

The named executive officers receive a base salary to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. The following table shows the annual base salaries for 2023 of Homology's named executive officers. While Dr. Alloway served as the Chief Legal Officer and Secretary, his 2023 annual base salary was $428,171. Dr. Alloway's 2023 annual base salary increased to $462,425 when he was appointed as the President, Chief Operating Officer and Secretary on November 17, 2023. While Mr. Michaud served as Vice President, Corporate Controller, his 2023 annual salary was $290,100, which was increased to $313,308 when he was appointed as the Vice President, Corporate Controller and Treasurer on November 17, 2023. The 2023 annual base salaries for Homology's other named executive officers became effective January 1, 2023.

Name	2023 Annual Base Salary ($)
Paul Alloway, Ph.D., J.D.	462,425
Charles Michaud, Jr.	313,308
Albert Seymour, Ph.D.	587,100(1)
W. Bradford Smith	474,727(2)
Julie Jordan, M.D.	462,000(3)

(1) Dr. Seymour's employment with Homology terminated on November 17, 2023.

(2) Mr. Smith's employment with Homology terminated on November 17, 2023.

(3) Dr. Jordan's employment with Homology terminated on August 3, 2023.

2023 Bonuses

Homology offered its named executive officers the opportunity to earn annual cash bonuses to compensate them for attaining short-term company and individual goals as approved by its Board of Directors. The 2023 target bonus amounts, expressed as a percentage of annual base salary, of Homology's named executive officers were 40% for Dr. Alloway, 30% for Mr. Michaud, 55% for Dr. Seymour, 40% for Mr. Smith and 40% for Dr. Jordan.

In connection with Homology's entry into the Merger Agreement, and the employment arrangements entered into contemporaneously therewith, in November 2023, Homology's Board of Directors approved cash bonuses equal to 50% of the named executive officers' target annual bonuses for 2023. For Dr. Alloway and Mr. Michaud, the amounts paid are set forth in the Bonus column of the "2023 Summary Compensation Table" above. For Drs. Seymour and Jordan and Mr. Smith, the amounts paid are a component of severance pay, included in the All Other Compensation column of the "2023 Summary Compensation Table" above.

Equity Compensation

Homology generally offered stock options and restricted stock units to its employees, including its named executive officers, as the long-term incentive component of its compensation program.

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

Each restricted stock unit represents a contingent right to receive one share of Homology's common stock upon vesting. In general, restricted stock units vest annually in three equal installments on January 1st of each year after the grant date, subject to the holder's continued service with us through the applicable vesting date.

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

In February 2023, Homology's named executive officers were granted the stock options and restricted stock units set forth in the table below under its 2018 Incentive Award Plan. Stock options were granted with exercise prices equal to the fair market value of Homology's common stock on the date of grant, as determined under the terms of its 2018 Incentive Award Plan, and are subject to the standard vesting schedule for periodic awards described above. Restricted stock units are subject to the standard vesting schedule described above.

	February 23, 2023	
Named Executive Officer	Stock Options Granted	Restricted Stock Units Granted
Paul Alloway, Ph.D., J.D.	164,000	27,000
Charles Michaud, Jr.	49,000	8,000
Albert Seymour, Ph.D.	632,000	105,000
W. Bradford Smith	213,000	36,000
Julie Jordan, M.D.	143,000	24,000

Please refer to Homology's Outstanding Equity Awards at 2023 Fiscal Year End table below for additional information regarding the stock options and restricted stock units held by Homology's named executive officers.

Retirement Plans

Homology maintained a 401(k) retirement savings plan for its employees, including its named executive officers, who satisfy certain eligibility requirements. Homology's named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. For 2023, Homology provided matching contributions under the plan of 50% of the first 6% of each participant's eligible compensation contributed. Employee contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their own contributions. Employer contributions vest over three years according to the employees' years of service. Homology believes that providing a vehicle for tax deferred retirement savings though its 401(k) plan adds to the overall desirability of its executive compensation package and further incentivized its employees, including its named executive officers, in accordance with its compensation policies.

Employee Benefits

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

Except for the benefits described above, Homology does not typically provide perquisites or personal benefits to its named executive officers.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table summarizes the number of shares of Homology's common stock (which do not reflect the effects of the Merger or the Reverse Stock Split) underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2023.

	Option Awards					Stock Awards	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Per Share Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(2)	Market Value of Shares or Units of Stock That Have Not Vested ($)(3)
Paul Alloway, Ph.D., J.D.	5/1/2020(4)	111,979	13,021	12.66	5/5/2030	—	—
	1/1/2021	57,604	21,396	13.78	2/5/2031	—	—
	1/1/2022	45,520	49,480	2.71	2/24/2032	—	—
	1/1/2023	37,583	126,417	1.60	2/23/2033	—	—
	1/1/2021(5)	—	—	—	—	4,420	2,687
	1/1/2022	—	—	—	—	10,720	6,518
	1/1/2023	—	—	—	—	27,000	16,416
Charles Michaud, Jr.	7/1/2020	21,875	3,125	15.58	7/8/2030	—	—
	1/1/2021	7,145	2,655	13.91	2/16/2031	—	—
	1/1/2022	9,247	10,053	2.71	2/24/2032	—	—
	1/1/2023	11,229	37,771	1.60	2/23/2033	—	—
	1/1/2021	—	—	—	—	544(6)	331

Name	Option Awards					Stock Awards	
	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Per Share Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(2)	Market Value of Shares or Units of Stock That Have Not Vested ($)(3)
	1/1/2022	—	—	—	—	2,144(7)	1,304
	1/1/2023	—	—	—	—	8,000	4,864
Albert Seymour, Ph.D.	1/1/2018	76,417	—	6.63	12/7/2027	—	—
	3/27/2018	66,501	—	16.00	3/27/2028	—	—
	1/1/2019	74,000	—	24.28	12/14/2028	—	—
	1/1/2020	107,708	2,292	19.92	12/11/2029	—	—
	1/1/2021	56,875	21,125	13.78	2/5/2031	—	—
	1/1/2022	61,333	66,667	2.71	2/24/2032	—	—
	4/21/2022	24,999	35,001	1.78	4/21/2032	—	—
	9/6/2022	7,187	15,813	2.18	9/6/2032	—	—
	1/1/2023	144,833	487,167	1.60	2/23/2033	—	—
	1/1/2021	—	—	—	—	533	324
	1/1/2022	—	—	—	—	7,975	4,849
	9/6/2022	—	—	—	—	8,481	5,156
	1/1/2023	—	—	—	—	74,527	45,312
W. Bradford Smith	4/5/2017	89,904	—	0.63	4/6/2027	—	—
	1/1/2018	63,496	—	6.63	12/7/2027	—	—
	3/27/2018	49,711	—	16.00	3/27/2028	—	—
	1/1/2019	88,000	—	24.28	12/14/2028	—	—
	1/1/2020	108,687	2,313	19.92	12/11/2029	—	—
	1/1/2021	88,958	33,042	13.78	2/5/2031	—	—
	1/1/2022	60,375	65,625	2.71	2/24/2032	—	—
	1/1/2023	48,812	164,188	1.60	2/23/2033	—	—
	1/1/2021	—	—	—	—	820	499
	1/1/2022	—	—	—	—	7,975	4,849
	1/1/2023	—	—	—	—	25,552	15,536
Julie Jordan, M.D.	5/3/2021	36,562	—	6.53	6/2/2031	—	—
	1/1/2022	22,166	—	2.71	2/24/2032	—	—
	1/1/2022	3,562	—	3.59	3/2/2032	—	—
	1/1/2023	20,854	—	1.60	2/23/2033	—	—

(1) Stock options have a term of ten years from the grant date and, unless otherwise indicated, vest and become exercisable in 48 equal monthly installments based upon the executive's completion of each full month of service following the vesting commencement date, subject to the named executive officer's continued service with Homology through each applicable vesting date and potential accelerated vesting as described under the heading "Employment Arrangements" below.

(2) Represents unvested restricted stock units granted pursuant to the 2018 Incentive Award Plan. Each restricted stock unit represents a contingent right to receive one share of Homology's common stock upon vesting. Unless otherwise provided below, restricted stock units vest annually in three equal installments on the first three anniversaries of the vesting commencement date, subject to the named executive officer's continued service with Homology through each applicable vesting date and potential accelerated or post-termination vesting as described under the heading "Employment Arrangements" below.

(3) Market value calculated using the closing price per share of Homology's common stock on December 29, 2023 of $0.6080.

(4) This option vests as to 25% on the first anniversary of the vesting commencement date and in 36 substantially equal monthly installments thereafter, subject to the named executive officer's continued service with Homology through each applicable vesting date and potential accelerated vesting as described under the heading "Employment Arrangements" below.
(5) These restricted stock units vest as to 50% on each of January 1, 2023 and January 1, 2024, subject to the named executive officer's continued service with Homology through each applicable vesting date and potential accelerated or post-termination vesting as described under the heading "Employment Arrangements" below.
(6) These restricted stock units vest and settle in full on January 1, 2024, subject to the named executive officer's continued service with Homology through the vesting date and potential accelerated or post-termination vesting as described under the heading "Employment Arrangements" below.
(7) These restricted stock units vest as to 1,056 shares on January 1, 2024 and 1,088 shares on January 1, 2025, subject to the named executive officer's continued service with Homology through each applicable vesting date and potential accelerated or post-termination vesting as described under the heading "Employment Arrangements" below.

Employment Arrangements

Homology entered into employment agreements with each of Dr. Seymour and Mr. Michaud and separation agreements with each of Drs. Alloway and Jordan and Mr. Smith. Additionally, Homology has entered into a consulting agreement with Mr. Smith.

Paul Alloway, Ph.D.

Under Dr. Alloway's amended and restated agreement, entered into on November 16, 2023, he is entitled to (a) an annual base salary of $462,425, (b) a payment equal to 50% of his target annual bonus for 2023, subject to his continued employment through the payment date (the "Alloway Annual Bonus") and (c) a lump sum cash payment in an amount equal to his base salary for the number of days elapsed from July 27, 2023 through the closing of the Merger, subject to his continued employment and a maximum of seven months of base salary (i.e., a maximum of $269,747.92) (the "Alloway Change in Control Bonus"). If Homology terminates Dr. Alloway without "cause" or he resigns for "good reason," subject to his timely executing a separation agreement, including a release of claims, and his continued compliance with restrictive covenants (including a non-competition covenant), he is entitled to receive (i) an amount in cash equal to his base salary, (ii) payment of the Alloway Annual Bonus if it is unpaid as of the date of termination, (iii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to 12 months, less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date, (iv) an extension of the post-termination exercise period for his vested and outstanding options until the first anniversary of his termination date, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger, (v) accelerated vesting of a prorated portion of the number of his unvested service-vesting restricted stock units that are scheduled to vest on the first annual vesting date of the applicable award following the date of termination, with the proration determined by reference to the portion of the vesting year that has elapsed since the last annual vesting date of the applicable award (or since the grant date if no vesting has occurred) rounded down to the nearest whole restricted stock unit, (vi) if the termination is before the Merger closes, a lump sum cash payment of $115,606.25 (the "Partial Alloway Change in Control Bonus"), (vii) if the termination is before the Merger closes, the Merger closes on or before August 16, 2024 and he provides transition services from his termination until closing of the Merger to the reasonable satisfaction of Homology, the excess of the Alloway Change in Control Bonus (determined disregarding the continued service requirement) over the Partial Alloway Change in Control Bonus, and (viii) if the termination is on or during the 12 months following the date the Merger closes, (A) accelerated vesting of all unvested service-vesting equity or equity-based awards and (B) an extension of the post-termination exercise period for his options that vest upon the closing of the Merger until the first anniversary of his termination date; provided that no options will remain

outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger.

Charles Michaud, Jr.

Under Mr. Michaud's employment agreement, entered into on November 16, 2023, he is entitled to (a) an annual base salary of $313,308, (b) a payment equal to 50% of his target annual bonus for 2023, subject to his continued employment through the payment date (the "Michaud Annual Bonus"), and (c) a lump sum cash payment in an amount equal to his base salary for the number of days elapsed from July 27, 2023 through the closing of the Merger, subject to his continued employment and a maximum of seven months of salary (i.e., a maximum of $182,763) (the "Michaud Change in Control Bonus"). If Homology terminates Mr. Michaud without "cause" or he resigns for "good reason," subject to his timely execution of a separation agreement, including a release of claims, and his compliance with restrictive covenants (including a non-competition covenant), he is entitled to receive (i) an amount in cash equal to nine months of his base salary, (ii) payment of the Michaud Annual Bonus if it is unpaid as of the date of termination, (iii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to 9 months, less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date, (iv) an extension of the post-termination exercise period for his vested and outstanding options until the first anniversary of his termination date, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger, (v) accelerated vesting of a prorated portion of the number of his unvested service-vesting restricted stock units that are scheduled to vest on the first annual vesting date of the applicable award following the date of termination, with the proration determined by reference to the portion of the vesting year that has elapsed since the last annual vesting date of the applicable award (or since the grant date if no vesting has occurred) rounded down to the nearest whole restricted stock unit, (vi) if the termination is before the Merger closes, a lump sum cash payment of $78,327.00 (the "Partial Michaud Change in Control Bonus"), (vii) if the termination is before the Merger closes, the Merger closes on or before August 16, 2024 and he provides transition services from his termination until closing of the Merger to the reasonable satisfaction of Homology, the excess of the Michaud Change in Control Bonus (determined disregarding the continued service requirement) over the Partial Michaud Change in Control Bonus, and (viii) if the termination is on or during the 12 months following the date the Merger closes, (A) accelerated vesting of all unvested service-vesting equity or equity-based awards and (B) an extension of the post-termination exercise period for his options that vest upon the closing of the Merger until the first anniversary of his termination date, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger.

Albert Seymour, Ph.D.

Homology's board of directors terminated the employment of Dr. Seymour, effective as of November 17, 2023. Under the terms of his separation agreement, subject to his continued compliance with restrictive covenants (including a non-competition covenant), Dr. Seymour is entitled to receive (i) base salary continuation for a period of 12 months, (ii) payment of all bonuses earned but unpaid as of the date of termination, (iii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to 12 months, less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date, (iv) a lump-sum cash payment equal to $85,759.88, (v) a lump-sum cash payment equal to 50% of his target annual bonus for 2023, (vi) an extension of the post-termination exercise period for his vested options until the first anniversary of his termination date, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger, and (vii) accelerated vesting of a prorated portion of the number of his service-vesting restricted stock units that were scheduled to vest on the first annual vesting date of the applicable award following the date of termination, with the proration determined by reference to the portion of the vesting year that has elapsed since the last annual vesting date of the applicable

award (or since the grant date if no vesting has occurred), rounded down to the nearest whole restricted stock unit. If the Merger closes on or before August 16, 2024, then, in addition to the foregoing severance benefits, Dr. Seymour is entitled to receive (a) an amount in cash equal to 0.5 times his base salary, (b) an amount in cash equal to 25% of his target annual bonus for the year of termination, (c) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to 6 months, less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date, (d) accelerated vesting of all unvested options and restricted stock units that vest solely based on the passage of time, with any such awards that vest based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement, (e) if he provides transition services from his termination until closing of the Merger to the reasonable satisfaction of Homology, a lump sum cash payment of $85,759.88, and (f) an extension until the first anniversary of his termination date of the post-termination exercise period for options that vest upon closing of the Merger, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger.

W. Bradford Smith

Homology's board of directors terminated the employment of Mr. Smith, effective as of November 17, 2023. Under the terms of his separation agreement, subject to his continued compliance with restrictive covenants (including a non-competition covenant), Mr. Smith is entitled to receive (i) base salary continuation for a period of 12 months, (ii) payment of all bonuses earned but unpaid as of the date of termination, (iii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to 12 months, less the amount he would have had to pay to receive such coverage as an active employee based on the cost sharing levels in effect on his termination date, (iv) a lump-sum cash payment equal to $69,345.14, (v) a lump-sum cash payment equal to 50% of his target annual bonus for 2023; (vi) an extension of the post-termination exercise period for his vested options until the first anniversary of his termination date, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger, and (vii) accelerated vesting of a prorated portion of the number of his service-vesting restricted stock units that were scheduled to vest on the first annual vesting date of the applicable award following the date of termination, with the proration determined by reference to the portion of the vesting year that has elapsed since the last annual vesting date of the applicable award (or since the grant date if no vesting has occurred), rounded down to the nearest whole restricted stock unit. If the Merger closes on or before August 16, 2024, then, in addition to the foregoing severance benefits, Mr. Smith is entitled to receive (a) accelerated vesting of all unvested options and restricted stock units that vest solely based on the passage of time, with any such awards that vest based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement, (b) if he provides transition services from his termination until closing of the Merger to the reasonable satisfaction of Homology, a lump sum cash payment of $69,345.14, and (c) an extension until the first anniversary of his termination date of the post-termination exercise period for options that vest upon closing of the Merger, provided that no options will remain outstanding past the expiration date of the award and each option will be subject to early termination in connection with a corporate transaction, including the Merger.

Mr. Smith also entered into a consulting agreement with Homology following his termination of employment on November 17, 2023 under which he will provide consulting services related to his former duties with Homology in exchange for a monthly consulting fee of $4,564.50. The consulting agreement will expire on March 29, 2024 unless earlier terminated as provided in the agreement.

Each of Homology's named executive officers has agreed to refrain from competing with Homology or soliciting its employees, in each case, while employed and following his termination of employment for any reason for a period of 12 months.

For purposes of the employment agreements, "cause" generally means the named executive officer's refusal to substantially perform the duties associated with his position with Homology or to carry out the reasonable and lawful instructions of Homology's Board of Directors concerning duties or actions consistent with his position, his breach of a material provision of the employment agreement which remains uncured (to the extent capable of cure) for a period of 30 days following written notice from Homology, his conviction, plea of no contest or nolo contendere or imposition of unadjudicated probation for any felony or crime involving moral turpitude, his unlawful use (including being under the influence) or possession of illegal drugs on Homology's premises or while performing his duties and responsibilities under the employment agreement, or his commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against Homology.

For purposes of the employment agreements, "good reason" generally means, subject to certain cure rights, the named executive officer's termination of employment due to a reduction in salary or target bonus, a material decrease in authority or areas of responsibility, Homology's breach of any one or more of the material provisions of the employment agreement, or a relocation by Homology of the named executive officer's primary office to a location more than 25 miles from the named executive officer's primary office on the date of the agreement.

Julie Jordan, M.D.

Dr. Jordan's employment with Homology terminated on August 3, 2023. Under the terms of her separation agreement, subject to her continued compliance with restrictive covenants (other than the non-competition covenant, which was waived by the Company), Dr. Jordan is entitled to receive (i) base salary continuation for a period of 52 weeks, (ii) a lump-sum cash payment equal to 50% of her target annual bonus for 2023, (iii) payment of the employer portion of premiums for continued medical, dental or vision coverage pursuant to COBRA for up to 12 months, (iv) an extension of the post-termination exercise period for her vested options until the first anniversary of her termination date (subject to early termination on the original expiration date of the award or in connection with a corporate transaction), and (v) accelerated vesting of a prorated portion of the number of her service-vesting restricted stock units that were scheduled to vest on the first annual vesting date of the applicable award following the date of termination.

Homology Non-Employee Director Compensation

The following table sets forth in summary form information concerning the compensation that was earned by or paid to each of Homology's non-employee directors during the year ended December 31, 2023. Dr. Seymour served as a member of Homology's Board through November 17, 2023. He was compensated as an employee for service as Homology's Chief Executive Officer and did not receive additional compensation for his service as a member of Homology's Board of Directors. See "Homology Executive Compensation—2023 Summary Compensation Table" above for information regarding Dr. Seymour's compensation and "Homology Executive Compensation—Outstanding Equity Awards at 2023 Fiscal Year-End" for option and restricted stock unit awards held by Dr. Seymour.

2023 Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Arthur Tzianabos, Ph.D.	75,000	14,916(2)	89,916
Steven Gillis, Ph.D.	48,000	14,916(2)	62,916
Richard J. Gregory, Ph.D. (3)	20,522		20,522
Matthew R. Patterson	47,500	14,916(2)	62,416
Jeffrey V. Poulton	67,500	14,916(2)	82,416
Alise S. Reicin, M.D.	54,000	14,916(2)	68,916
Mary Thistle	57,720	14,916(2)	72,636

(1) Amounts reflect the grant date fair value of stock options granted during the applicable year computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual.

Homology provides information regarding the assumptions used to calculate the value of all option awards in Note 14 to its consolidated financial statements included elsewhere in this prospectus. Consistent with its non-employee director compensation program described below, each non-employee director who continued serving on the Board was granted an option to purchase 23,000 shares of Homology common stock granted to each then-current non-employee director on June 14, 2023 with an exercise price of $1.03 per share.

The table below shows the aggregate numbers of shares of Homology common stock subject to option awards and stock awards held as of December 31, 2023 by each non-employee director. Other than referenced above with respect to Dr. Seymour, none of Homology's non-employee directors held any other outstanding equity awards as of December 31, 2023.

Name	Total Options Outstanding	Total Restricted Stock Units Outstanding
Arthur Tzianabos, Ph.D.	2,257,164	53,140
Steven Gillis, Ph.D.	123,740	—
Richard J. Gregory, Ph.D.(1)	—	—
Matthew R. Patterson	124,690	—
Jeffrey V. Poulton	95,000	—
Alise S. Reicin, M.D.	108,160	—
Mary Thistle	123,740	—

(1) Dr. Gregory's service on Homology's Board of Directors ended on June 14, 2023, upon the expiration of his term.

Homology maintained a compensation program for its non-employee directors under which each non-employee director received the following amounts for their service on Homology's Board of Directors. As amended effective June 14, 2023, Homology's non-employee director compensation program provided for the following:

- an option to purchase 46,000 shares of Homology's common stock upon the director's initial election or appointment to Homology's Board of Directors (the "Initial Award"),
- if the director has served on Homology's Board of Directors for at least six months as of the date of an annual meeting of stockholders, an option to purchase 23,000 shares of Homology's common stock on the date of the annual meeting (the "Annual Award"),
- an annual director fee of $40,000, and
- if the director serves on a committee of Homology's Board of Directors or in the other capacities stated below, an additional annual fee as follows:
  - chairman of the board, $35,000,
  - lead independent director, $35,000,
  - non-employee director service as lead director, $20,000,
  - chairman of the audit committee, $15,000,
  - audit committee member other than the chairman, $7,500,
  - chairman of the compensation committee, $10,000,
  - compensation committee member other than the chairman, $5,000,
  - chairman of the nominating and corporate governance committee, $8,000, and
  - nominating and corporate governance committee member other than the chairman, $4,000.

Stock options granted to Homology's non-employee directors under the program have an exercise price equal to the fair market value of Homology's common stock on the date of grant and expire not later than ten years after

the date of grant. Stock options granted upon a director's initial election or appointment vest in three equal installments on each of the first three anniversaries of the date of grant. Stock options granted annually to directors vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options vest in full upon the occurrence of a change in control.

Director fees under the program are payable in arrears in four equal quarterly installments not later than the fifteenth (15th) day following the final day of each calendar quarter, provided that the amount of each payment is prorated for any portion of a quarter that a director is not serving on Homology's Board of Directors.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, with the Company and the Company's directors and executive officers in the section titled "Legacy Q32 Executive and Director Compensation" elsewhere in this prospectus, the following is a description of each transaction involving Legacy Q32 or the Company since January 1, 2021 and each currently proposed transaction in which:

- either Legacy Q32 or the Company were or is to be a participant;
- the amounts involved exceeds the lesser of $120,000 and 1% of the average of Legacy Q32 or the Company's total assets at year-end for the last three completed fiscal years, as applicable; and
- any of the Company or Legacy Q32's directors or executive officers who became executive officers or directors of the Company, or holders of more than 5% of Legacy Q32's capital stock who became holders of more than 5% of the Company's capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Private Placements of Securities

Series B Convertible Preferred Stock Financing – Second Closing

In November and December 2021, Legacy Q32 sold an aggregate of 18,229,873 shares of Series B preferred stock at a purchase price of $1.0971 per share for aggregate gross proceeds of approximately $19.9 million in the second closing of Series B preferred stock, or the Second Series B Closing. The following table summarizes purchases of Legacy Q32's Series B preferred stock by related persons in the Second Series B Closing:

Participant	Shares of Series B Preferred Stock	Total Cash Purchase Price ($)
Abingworth Bioventures VII LP (1)	1,671,072	1,833,333
Acorn Bioventures, L.P. (2)	3,465,975	3,999,999
Atlas Venture Opportunity Fund I, L.P. (3)	3,494,060	3,833,333
OrbiMed Private Investments VII, LP (4)	4,557,469	4,999,999

(1) Abingworth Bioventures VII LP, or ABV VII, may be deemed to beneficially own more than 5% of our outstanding capital stock.
(2) Acorn Bioventures, L.P., or Acorn, beneficially owns more than 5% of our outstanding capital stock. Isaac Manke is a General Partner at Acorn and a member of our Board.
(3) Atlas Venture Opportunity Fund I, L.P., or Atlas Opportunity I, and entities affiliated with Atlas Opportunity I, beneficially own more than 5% of our outstanding capital stock. David Grayzel is a Partner at Atlas Venture Life Science Advisors, LLC and a member of our Board.
(4) OrbiMed Private Investments VII, LP may be deemed to beneficially own more than 5% of our outstanding capital stock. These shares are held by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or GP VII, is the general partner of OPI VII. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VII. By virtue of such relationships, GP VII and OrbiMed Advisors may be deemed to have beneficial ownership over such shares. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. Diyong Xu, a member of our Board, is an employee of OrbiMed Advisors. Each of Dr. Gordon and Messrs. Borho, Neild, and Xu disclaim beneficial ownership of the shares held by OPI VII.

Legacy Q32 Convertible Note Financing

In May 2022, Legacy Q32 entered into a note purchase agreement with certain existing investors to purchase up to an aggregate of $30.0 million in convertible notes, or the Convertible Notes, through December 31, 2022. The

Convertible Notes bear interest at 5.0% per annum. The Convertible Notes become due on demand of the holders of the Convertible notes one year from the date of issuance. In May, August and December 2022, Legacy Q32 received $8.3 million, $5.0 million, and $16.7 million, respectively, in exchange for issuance of the Convertible Notes.

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 Legacy Q32's common stock or preferred stock, as applicable, (i) upon an initial public offering of the Legacy Q32's common stock, (ii) upon Legacy Q32's issuance and sale of shares of a new series of preferred stock to one or more investors in a private transaction provided, in each case, Legacy Q32 receives aggregate gross proceeds of at least $25.0 million, or, (i) and (ii) collectively, a mandatory conversion event. The value of the Convertible Notes plus accrued interest, if any, convert into shares of Legacy Q32's common stock or preferred stock, as applicable, at 90% of the purchase price of the per share purchase price of common stock or preferred stock, as applicable, in a mandatory conversion event.

If the mandatory conversion events do not occur and if the Convertible Notes have not been repaid by the maturity date for the Convertible Notes, the holders of the Convertible Notes may request the Convertible Notes plus accrued interest, if any, to be converted into Series B preferred stock at the Series B preferred stock convertible price of $1.0971.

In August 2022, Legacy Q32 entered into an amendment to the note purchase agreement with an aggregate principal amount of $5,000,001 Convertible Notes sold to Bristol-Myers Squibb Company, or BMS. In June 2023, Legacy Q32 entered into an amendment to the Convertible Notes extending the maturity date of the Convertible Notes to December 23, 2023. Immediately prior to the Effective Time, Legacy Q32 caused the outstanding principal and accrued but unpaid interest on Legacy Q32 Convertible Notes to be converted into the applicable number of shares of Legacy Q32 common stock provided for under the terms of such Legacy Q32 Convertible Note, or the Convertible Notes Conversion. All Legacy Q32 Convertible Notes converted into shares of Legacy Q32 common stock and as a result are no longer outstanding and ceased to exist, and each holder of Legacy Q32 Convertible Notes thereafter ceased to have any rights with respect to Legacy Q32 Convertible Notes. Immediately following the Convertible Notes Conversion, at the Effective Time and by virtue of the Merger, all shares of Legacy Q32 common stock issued in the Convertible Notes Conversion were canceled and converted into the right to receive our common stock pursuant to the Merger Agreement.

The following table summarizes the aggregate amount of Convertible Notes purchased by related persons.

Participant	Aggregate Amount of Convertible Notes ($)
Abingworth Bioventures VII LP (1)	3,644,352
Acorn Bioventures, L.P. (2)	2,655,105
Atlas Venture Opportunity Fund II, L.P. (3)	6,913,845
Bristol-Myers Squibb Company (4)	5,000,001
OrbiMed Private Investments VII, LP (5)	7,445,508

(1) Abingworth Bioventures VII LP, or ABV VII, may be deemed to beneficially own more than 5% of Legacy Q32's outstanding capital stock.
(2) Acorn Bioventures, L.P., or Acorn, beneficially owns more than 5% of Legacy Q32's outstanding capital stock. Isaac Manke is a General Partner at Acorn and a member of our Board.
(3) Atlas Venture Opportunity Fund II, L.P., or Atlas Opportunity II, and entities affiliated with Atlas Opportunity II beneficially own more than 5% of Legacy Q32's outstanding capital stock. David Grayzel is a Partner at Atlas Venture Life Science Advisors, LLC and a member of our Board.
(4) BMS beneficially owns more than 5% of our outstanding capital stock

(5) OrbiMed Private Investments VII, LP may be deemed to beneficially own more than 5% of our outstanding capital stock. These convertible notes are held by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or GP VII, is the general partner of OPI VII. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VII. By virtue of such relationships, GP VII and OrbiMed Advisors may be deemed to have beneficial ownership over such shares. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. Diyong Xu, a member of our Board, is an employee of OrbiMed Advisors. Each of Dr. Gordon and Messrs. Borho, Neild, and Xu disclaim beneficial ownership of the convertible notes held by OPI VII.

Legacy Q32 Pre-Closing Financing

In connection with the Merger Agreement, Legacy Q32 entered into a Subscription Agreement in November 2023, or the Subscription Agreement, with certain investors to consummate the Pre-Closing Financing. Pursuant to the Subscription Agreement, the investors agreed to purchase an aggregate of 35,032,111 shares of Legacy Q32 common stock, at a price of $1.989 per share, for aggregate gross proceeds of approximately $42.0 million. The Pre-Closing Financing closed on March 25, 2024. The closing of the Pre-Closing Financing is conditioned upon the satisfaction or waiver of the conditions to the Merger as well as certain other conditions. Five of the investors or their affiliates are beneficial holders of more than 5% of Legacy Q32's capital stock, and the table below sets forth the number of shares of Legacy Q32 common stock expected to be purchased by such holders at the closing of the Pre-Closing Financing:

Participant	Shares of Legacy Q32 Common Stock	Total Purchase Price ($)
Abingworth Bioventures VII LP (1)	4,332,673	5,194,442
Acorn Bioventures, L.P. (2)	3,156,665	3,784,526
Atlas Venture Opportunity Fund II, L.P. (3)	8,219,904	9,854,843
Bristol-Myers Squibb Company (4)	4,170,490	5,000,000
OrbiMed Private Investments VII, LP (5)	8,852,000	10,612,663

(1) Abingworth Bioventures VII LP, or ABV VII, may be deemed to beneficially own more than 5% of our outstanding capital stock.
(2) Acorn Bioventures, L.P., or Acorn, beneficially owns more than 5% of our outstanding capital stock. Isaac Manke is a General Partner at Acorn and a member of our Board.
(3) Atlas Venture Opportunity Fund II, L.P., or Atlas Opportunity II, and entities affiliated with Atlas Opportunity II beneficially own more than 5% of our outstanding capital stock. David Grayzel is a Partner at Atlas Venture Life Science Advisors, LLC and a member of our Board.
(4) BMS beneficially owns more than 5% of our outstanding capital stock.
(5) OrbiMed Private Investments VII, LP may be deemed to beneficially own more than 5% of our outstanding capital stock. These shares will be held by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or GP VII, is the general partner of OPI VII. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VII. By virtue of such relationships, GP VII and OrbiMed Advisors may be deemed to have beneficial ownership over such shares. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. Diyong Xu, a member of our Board, is an employee of OrbiMed Advisors. Each of Dr. Gordon and Messrs. Borho, Neild, and Xu disclaim beneficial ownership of the shares to be held by OPI VII.

Upon the closing of the Merger, the shares of Legacy Q32 common stock purchased by the investors in the Pre-Closing Financing were converted into shares of our common stock.

Registration Rights Agreement

Pursuant to the Subscription Agreement, on March 25, 2024, we entered into a registration rights agreement (the "Registration Rights Agreement") with the investors in the Pre-Closing Financing . Under the Registration Rights Agreement, among other things, we agreed to register for resale certain shares of our common stock held by such investors from time to time, including shares of our common stock issued in the Merger in exchange for the shares of Legacy Q32 common stock issued in the Pre-Closing Financing.

Pursuant to the Registration Rights Agreement, we are obligated to prepare and file a shelf registration statement covering the resale of covered shares of our common stock within forty-five (45) calendar days following the closing of the Merger, subject to certain exceptions, pursuant to Rule 415 of the Securities Act. We also agreed to use our reasonable best efforts to keep such registration statement continuously effective under the Securities Act until the earlier of the date that all registrable securities covered by such registration statement (a) have been sold, thereunder or pursuant to Rule 144 of the Securities Act, or Rule 144, or (b) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for us to be in compliance with the current public information requirement under Rule 144. The registration rights agreement also provides that we will pay certain expenses of the securityholders and indemnify the applicable securityholders against certain liabilities.

Indemnification Agreements

We have entered into agreements to indemnify its directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding,

Policies for Approval of Related Party Transactions

Our Board has adopted a written Related Person Transaction Policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. Under the policy, our finance department is primarily responsible for developing and implementing processes and procedures to obtain information regarding related persons with respect to potential related person transactions and then determining, based on the facts and circumstances, whether such potential related person transactions do, in fact, constitute related person transactions requiring compliance with the policy. If our finance department determines that a transaction or relationship is a related person transaction requiring compliance with the policy, our Chief Financial Officer is required to present to the Audit Committee all relevant facts and circumstances relating to the related person transaction. Our Audit Committee must review the relevant facts and circumstances of each related person transaction, including if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the extent of the related person's interest in the transaction, take into account the conflicts of interest and corporate opportunity provisions of our Code of Conduct, and either approve or disapprove the related person transaction. If advance Audit Committee approval of a related person transaction requiring the Audit Committee's approval is not feasible, then the transaction may be preliminarily entered into by management upon prior approval of the transaction by the chair of the Audit Committee subject to ratification of the transaction by the audit committee at the audit committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. If a transaction was not initially recognized as a related person, then upon such recognition the transaction will be presented to the audit committee for ratification at the audit committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. Homology's management will update the audit committee as to any material changes to any approved or ratified related person transaction and will provide a status report at least annually of all then current related person transactions. No director may participate in approval of a related person transaction for which he or she is a related person.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS OF HOMOLOGY

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, with Homology Medicines, Inc., or Homology, and Homology's directors and executive officers in the section titled "Homology Executive and Director Compensation" elsewhere in this prospectus, the following is a description of each transaction involving Homology since January 1, 2021 and each currently proposed transaction in which:

- either Homology was or is to be a participant;
- the amounts involved exceeds the lesser of $120,000 and 1% of the average of Homology's total assets at year-end for the last three completed fiscal years, as applicable; and
- any of Homology's directors or executive officers, or holders of more than 5% of Homology's capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

The information in this "Certain Relationships and Related Party Transactions of Homology" section relates to Homology before the Merger and does not reflect the effects of the Merger or the Reverse Stock Split.

Stock Purchase Agreement with Pfizer

On November 9, 2020, Homology entered into a stock purchase agreement, or the Stock Purchase Agreement, with Pfizer Inc., or Pfizer, which holds approximately 8.7% of Homology's common stock as of March 1, 2023, pursuant to which Pfizer purchased 5,000,000 shares of Homology's common stock through a private placement transaction at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million. Under the Stock Purchase Agreement, Pfizer was granted an exclusive ROFR for a 30-month period beginning on the date of the closing of the private placement to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103. Pfizer may exercise its right of first refusal under the ROFR one time for each of HMI-102 and HMI-103 during the ROFR period. Additionally, Pfizer has designated a member to join Homology's Scientific Advisory Board to participate in matters related to the development of these programs. For more information regarding Pfizer and its equity holdings, see the section in this proxy statement/prospectus entitled "*Principal Stockholders of Homology*."

Employment Agreements

Homology has entered into employment agreements with its named executive officers.

Indemnification Agreements

Homology has entered into indemnification agreements with each of its directors and executive officers. These agreements, among other things, require Homology or will require Homology to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of Homology, arising out of the person's services as a director or executive officer.

Policies and Procedures for Related Person Transactions

Homology's board of directors had adopted a written Related Person Transaction Policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. Under the policy, Homology's finance department is primarily responsible for developing and implementing processes and procedures to obtain information regarding related persons with respect to potential related person transactions and then determining, based on the facts and circumstances, whether such potential related person transactions do, in fact, constitute related person transactions requiring compliance with the policy. If Homology's finance

department determines that a transaction or relationship is a related person transaction requiring compliance with the policy, its Chief Financial Officer is required to present to the audit committee all relevant facts and circumstances relating to the related person transaction. Homology's audit committee must review the relevant facts and circumstances of each related person transaction, including if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the extent of the related person's interest in the transaction, take into account the conflicts of interest and corporate opportunity provisions of Homology's code of business conduct and ethics, and either approve or disapprove the related person transaction. If advance audit committee approval of a related person transaction requiring the audit committee's approval is not feasible, then the transaction may be preliminarily entered into by management upon prior approval of the transaction by the chair of the audit committee subject to ratification of the transaction by the audit committee at the audit committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. If a transaction was not initially recognized as a related person, then upon such recognition the transaction will be presented to the audit committee for ratification at the audit committee's next regularly scheduled meeting; provided, that if ratification is not forthcoming, management will make all reasonable efforts to cancel or annul the transaction. Homology's management will update the audit committee as to any material changes to any approved or ratified related person transaction and will provide a status report at least annually of all then current related person transactions. No director may participate in approval of a related person transaction for which he or she is a related person.

PRINCIPAL SECURITYHOLDERS

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 25, 2024 and reflects the 1-for-18 Reverse Stock Split of our common stock effected March 25, 2024.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power with respect to the securities as well as any shares of common stock that the individual or entity has the right to acquire within 60 days of March 25, 2024 the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to them, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The table lists applicable percentage ownership based on 11,929,528 shares of common stock outstanding as of March 25, 2024. The number of shares beneficially owned includes shares of common stock that each person has the right to acquire within 60 days, including upon the exercise of stock options and the vesting of restricted stock units. These stock options and restricted stock units shall be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of our common stock expected to be owned by such person but shall not be deemed to be outstanding for the purpose of computing the percentage of outstanding shares of the combined organization's common stock expected to be owned by any other person.

	Beneficial Ownership Prior to the Merger	
Name of Beneficial Owner	**Number**	**Percent**
5% or Greater Stockholders:		
OrbiMed Private Investments VII, LP (1)	2,252,987	18.89%
Entities affiliated with Atlas Venture (2)	2,092,106	17.54%
Abingworth Bioventures VII LP (3)	1,102,741	9.24%
Acorn Bioventures, L.P. (4)	803,425	6.73%
Bristol-Myers Squibb Company (5)	759,145	6.36%
Directors and Named Executive Officers:		
Jason A. Campagna (6)	76,649	*
Jodie Morrison (7)	123,352	1.02%
Shelia M. Violette (8)	106,307	*
Mary Thistle (9)	5,596	*
Arthur Tzianabos (10)	120,820	1.00%
Bill Lundberg (11)	11,793	*
Kathleen LaPorte (12)	8,563	*
Mark Iwicki (13)	34,527	*
David Grayzel (14)	2,092,106	17.54%
Isaac Manke	—	—
Diyong Xu (15)	2,252,987	18.89 %
All executive officers and directors as a group (12 persons)(16)	4,849,601	39.16 %

* Represents beneficial ownership of less than 1%.

(1) Consists of 2,252,987 shares of our common stock held by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or GP VII, is the general partner of OPI VII. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VII. By virtue of such relationships, GP VII and OrbiMed Advisors may be deemed to have beneficial ownership over such shares. OrbiMed Advisors

exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. Diyong Xu, a member of our Board, is an employee of OrbiMed Advisors. Each of Dr. Gordon and Messrs. Borho, Neild, and Xu disclaim beneficial ownership of the shares held by OPI VII. The address for the OrbiMed entities is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(2) Consists of (i) 864,261 shares of our common stock held by Atlas Venture Fund X, L.P., or Atlas X, (ii) 503,296 shares of our common stock held by Atlas Venture Opportunity Fund I, L.P., or Atlas Opportunity I, and (iii) 724,549 shares of our common stock held by Atlas Venture Opportunity Fund II, L.P., or Atlas Opportunity II. The general partner of Atlas X is Atlas Venture Associates X, L.P., or AVA X, and the general partner of AVA X is Atlas Ventures Associates X, LLC, or AVA X LLC. The general partner of Atlas Opportunity I is Atlas Venture Associates Opportunity I, L.P., or AVAO I, and the general partner of AVAO I is Atlas Venture Associates Opportunity I, LLC, or AVAO I LLC. The general partner of Atlas Opportunity II is Atlas Venture Associates Opportunity II, L.P., or AVAO II, and the general partner of AVAO II is Atlas Venture Associates Opportunity II, LLC, or AVAO II LLC. David Grayzel is a member of AVA X LLC, AVAO I LLC, and AVAO II LLC, and is a member of our Board. Each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, and Mr. Grayzel may be deemed to beneficially own the shares held by Atlas X, Atlas Opportunity I, and Atlas Opportunity II. Each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, and Mr. Grayzel expressly disclaim beneficial ownership of the securities owned by Atlas X, Atlas Opportunity I, and Atlas Opportunity II, except to the extent of its pecuniary interest therein, if any. The address for Atlas X, AVA X, AVA X LLC, Atlas Opportunity I, AVAO I, AVAO I LLC, Atlas Opportunity II, AVAO II, AVAO II LLC is 300 Technology Sq., 8th Floor, Cambridge, MA 02139.

(3) Consists of 1,102,741 shares of our common stock held by Abingworth Bioventures VII LP, or ABV VII. The Carlyle Group Inc., which is a publicly traded entity listed on Nasdaq, is the sole shareholder of Carlyle Holdings I GP Inc., which is the sole member of Carlyle Holdings I GP Sub L.L.C., which is the general partner of Carlyle Holdings I L.P., which, with respect to the securities reported herein, is the managing member of CG Subsidiary Holdings L.L.C., which is the managing member of TC Group, L.L.C., which is the managing member of Carlyle Investment Management, L.L.C., which is the sole member of Carlyle Genesis UK LLC. Carlyle Genesis UK LLC is the principal member of Abingworth LLP. ABV VII has delegated to Abingworth LLP all investment and dispositive power over the securities held of record by ABV VII. As a result, each of the foregoing entities may be deemed to share beneficial ownership of the securities held of record by ABV VII, but each disclaims such beneficial ownership. Voting and investment determinations with respect to the securities held by ABV VII are made by an investment committee of Abingworth LLP, which is comprised of Timothy Haines, Kurt von Emster, Bali Muralidhar and Andrew Sinclair. Each member of the investment committee disclaims beneficial ownership of the securities beneficially held by ABV VII.

(4) Consists of 803,425 shares of our common stock held by Acorn Bioventures, L.P., or Acorn. The general partner of Acorn is Acorn Capital Advisors GP, LLC. Isaac Manke is a General Partner at Acorn and a member of Q32's board of directors. The address for Acorn and Acorn Capital Advisors GP, LLC is 410 Lexington Ave, Suite 2626, New York, NY 10170.

(5) Consists of 759,145 shares of our common stock held by Bristol-Myers Squibb Company, or BMS. The address for BMS is Route 206 & Province Line Road, Princeton, NJ 08543-4000.

(6) Consists of 76,649 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.

(7) Consists of 123,352 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.

(8) Consists of (i) 36,277 shares of our common stock held by Violette Holdings LLC, or Violette Holdings, and (ii) 70,030 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024. The address of Violette Holdings is c/o Shelia Violette, 91 Simonds Road, Lexington, MA 02420.

(9) Consists of 5,596 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.

(10) Consists of (i) 7,154 shares of our common stock held by Dr. Tzianabos, and (ii) 113,666 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.
(11) Consists of (i) 1,200 shares of our common stock held by Mr. Lundberg, and (ii) 10,593 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.
(12) Consists of (i) 5,431 shares of our common stock held by The Kathleen D. LaPorte Revocable Trust, or the LaPorte Trust, and (ii) 3,132 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024. The address of the LaPorte Trust is c/o Kathleen D. LaPorte 30 Quail Ct, Portola Valley, CA 94028.
(13) Consists of 34,527 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.
(14) Consists of (i) 864,261 shares of our common stock held by Atlas Venture Fund X, L.P., or Atlas X, (ii) 503,296 shares of our common stock held by Atlas Venture Opportunity Fund I, L.P., or Atlas Opportunity I, and (iii) 724,549 shares of our common stock held by Atlas Venture Opportunity Fund II, L.P., or Atlas Opportunity II. The general partner of Atlas X is Atlas Venture Associates X, L.P., or AVA X, and the general partner of AVA X is Atlas Ventures Associates X, LLC, or AVA X LLC. The general partner of Atlas Opportunity I is Atlas Venture Associates Opportunity I, L.P., or AVAO I, and the general partner of AVAO I is Atlas Venture Associates Opportunity I, LLC, or AVAO I LLC. The general partner of Atlas Opportunity II is Atlas Venture Associates Opportunity II, L.P., or AVAO II, and the general partner of AVAO II is Atlas Venture Associates Opportunity II, LLC, or AVAO II LLC. David Grayzel is a member of AVA X LLC, AVAO I LLC, and AVAO II LLC, and is a member of our Board. Each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, and Mr. Grayzel may be deemed to beneficially own the shares held by Atlas X, Atlas Opportunity I, and Atlas Opportunity II. Each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, and Mr. Grayzel expressly disclaim beneficial ownership of the securities owned by Atlas X, Atlas Opportunity I, and Atlas Opportunity II, except to the extent of its pecuniary interest therein, if any. The address for Atlas X, AVA X, AVA X LLC, Atlas Opportunity I, AVAO I, AVAO I LLC, Atlas Opportunity II, AVAO II, AVAO II LLC is 300 Technology Sq., 8th Floor, Cambridge, MA 02139.
(15) Consists of 2,252,987 shares of our common stock held by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or GP VII, is the general partner of OPI VII. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VII. By virtue of such relationships, GP VII and OrbiMed Advisors may be deemed to have beneficial ownership over such shares. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. Diyong Xu, a member of our Board, is an employee of OrbiMed Advisors. Each of Dr. Gordon and Messrs. Borho, Neild, and Xu disclaim beneficial ownership of the shares held by OPI VII. The address for the OrbiMed entities is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.
(16) Consists of (i) 4,849,601 shares of our common stock and (ii) 454,446 shares of our common stock underlying options which are exercisable or will become exercisable within 60 days of March 25, 2024.

SELLING SECURITYHOLDERS

The selling stockholders acquired shares of common stock from us in the Merger upon exchange of shares of Legacy Q32 acquired from Legacy Q32 immediately prior to the Merger pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act. Under the registration rights agreement that we assumed in the Merger, we agreed to file a registration statement with the SEC for the purposes of registering for resale from time to time the shares of common stock.

Except for the ownership of shares of common stock received in the Merger, the selling stockholders have not had any material relationship with our company within the past three years.

The table below lists the selling stockholders and other information regarding their ownership of the shares of common stock offered hereby. The second column lists the number of shares of common stock beneficially owned by the selling stockholders as of March 25, 2024 immediately following consummation of the Merger. The selling stockholders may have sold or transferred some or all of the common stock indicated below and may in the future sell or transfer some or all of the common stock indicated below in transactions exempt from the registration requirements of the Securities Act rather than under this prospectus. The third column lists the shares of common stock being offered by this prospectus by the selling stockholders. The fourth column assumes the sale of all of the shares of common stock offered by the selling stockholders pursuant to this prospectus. The selling stockholders may sell all, some or none of their shares of common stock in this offering. See "*Plan of Distribution*."

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the selling stockholders have sole voting and investment power with respect to all shares of common stock that they own, subject to applicable community property laws. Beneficial ownership for the purposes of the table below is determined in accordance with the rules and regulations of the SEC. These rules generally provide that a person is the beneficial owner of securities if such person has or shares the power to vote or direct the voting thereof, or to dispose or direct the disposition thereof or has the right to acquire such powers within 60 days. Percentage of beneficial ownership is based on 11,929,528 shares of common stock outstanding as of March 25, 2024 immediately following consummation of the Merger.

Name and Address of Selling Stockholders	Number of Shares Beneficially Owned Before the Offering	Number of Shares that May Be Offered Hereby(11)	Shares Beneficially Owned After the Offering	
			Number	Percentage
Abingworth Bioventures VII LP (1)	1,102,741	208,031	894,710	7.50%
Acorn Bioventures, L.P. (2)	803,425	151,565	651,860	5.46%
Entities Affiliated Atlas (3)	2,092,106	394,674	1,697,432	14.23%
Aventis Inc. (4)	244,083	46,046	198,037	1.66%
Bristol-Myers Squibb Company (5)	759,145	200,244	558,901	4.69%
CU Healthcare Innovation Fund, L.P. (6)	139,550	50,061	89,489	*
OrbiMed Private Investments VII, LP (7)	2,252,987	425,024	1,827,963	15.32%
Osage University Partners III, LP (8)	539,171	101,043	438,128	3.64%
The Trustees of Columbia University in the City of New York (9)	133,903	25,260	108,643	*
Agent Capital Fund III LP (10)	80,097	80,097	—	—

* Less than 1%

(1) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of (i) 1,102,741 shares of our common stock held by Abingworth Bioventures VII LP. Securities are held of record by Abingworth VII LP, or ABV VII. The Carlyle Group Inc., which is a publicly traded entity listed on Nasdaq, is the shareholder of Carlyle Holdings I GP Inc., which is the general partner of Carlyle Holdings I

L.P., which, with respect to the securities reported herein, is the managing member of GG Subsidiary Holdings L.L.C., which is the managing member of TC Group, L.L.C., which is the managing member of Carlyle Investment Management, L.L.C., which is the sole member of Carlyle Genesis UK LLC. Carlyle Genesis UK LLC is the principal member of Abingworth LLP. ABV VII has delegated to Abingworth LLP all investment and dispositive power over the securities held of record by ABV VII. Voting and investment determinations with respect to the securities held by ABV VII are made by an investment committee of Abingworth LLP, which is comprised of Timothy Haines, Kurt von Emster, Bali Muralidhar and Andrew Sinclair. Each member of the investment committee disclaims beneficial ownership of the securities beneficially held by ABV VII. The address for each of the Carlyle entities is c/o The Carlyle Group, 1001 Pennsylvania Ave. NW, Suite 220 South, Washington, DC 20004-2505. The address for each of Abingworth LLP and ABV VII is c/o Abingworth LLP, 38 Jermyn Street, London, England SW1Y 6DN.

(2) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of (i) 803,425 shares held by Acorn Bioventures, L.P. The general partner of Acorn is Acorn Capital Advisors GP, LLC. Isaac Manke is a General Partner at Acorn and a member of Q32's board of directors. The address for Acorn and Acorn Capital Advisors GP, LLC is 410 Lexington Ave, Suite 2626, New York, NY 10170.

(3) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of (i) 864,261 shares of our common stock held by Atlas Venture Fund X, L.P., or Atlas X, (ii) 503,296 shares of our common stock held by Atlas Venture Opportunity Fund I, L.P., or Atlas Opportunity I, and (iii) 724,549 shares of our common stock held by Atlas Venture Opportunity Fund II, L.P., or Atlas Opportunity II. The general partner of Atlas X is Atlas Venture Associates X, L.P., or AVA X, and the general partner of AVA X is Atlas Ventures Associates X, LLC, or AVA X LLC. The general partner of Atlas Opportunity I is Atlas Venture Associates Opportunity I, L.P., or AVAO I, and the general partner of AVAO I is Atlas Venture Associates Opportunity I, LLC, or AVAO I LLC. The general partner of Atlas Opportunity II is Atlas Venture Associates Opportunity II, L.P., or AVAO II, and the general partner of AVAO II is Atlas Venture Associates Opportunity II, LLC, or AVAO II LLC. David Grayzel is a member of AVA X LLC, AVAO I LLC, and AVAO II LLC, and is a member of Q32's board of directors. Each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, and Mr. Grayzel may be deemed to beneficially own the shares held by Atlas X, Atlas Opportunity I, and Atlas Opportunity II. Each of AVA X, AVA X LLC, AVAO I, AVAO I LLC, AVAO II, AVAO II LLC, and Mr. Grayzel expressly disclaim beneficial ownership of the securities owned by Atlas X, Atlas Opportunity I, and Atlas Opportunity II, except to the extent of its pecuniary interest therein, if any. The address for Atlas X, AVA X, AVA X LLC, Atlas Opportunity I, AVAO I, AVAO I LLC, Atlas Opportunity II, AVAO II, AVAO II LLC is 300 Technology Sq., 8th Floor, Cambridge, MA 02139.

(4) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 244,083 shares held by Aventis, Inc, or Aventis. The natural person that has power to vote or dispose of the shares is Debora C. Pellicano who disclaims beneficial ownership of the shares held by Aventis. The address for Aventis is 55 Corporate Drive, Bridgewater, NJ 08807.

(5) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 759,145 shares of our common stock held by Bristol-Myers Squibb Company, or BMS. The address for BMS is Route 206 & Province Line Road, Princeton, NJ 08543-4000.

(6) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 139,550 shares held by CU Healthcare Innovation Fund L.P., or CU Healthcare. The natural persons that have power to vote or dispose of the shares are Steven Lindseth, Kimberly Muller and Steve VanNurden, each of whom disclaim beneficial ownership of the shares held by CU Healthcare. The address for CU Healthcare is 12635 East Montview Blvd., Suite 100, Aurora, Colorado 80045.

(7) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 2,252,987 shares held by OrbiMed Private Investments VII, LP. Securities are held of record by OrbiMed Private Investments VII, LP, or OPI VII. OrbiMed Capital GP VII LLC, or GP VII, is the general partner of OPI VII, and OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP VII. By virtue of such relationships, GP VII and Advisors may be deemed to have voting power and investment power over the securities held by OPI VII and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of

Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the shares held by OPI VII. Diyong Xu, a member of Q32's board of directors, is an employee of OrbiMed Advisors. The address for the OrbiMed entities is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022 .

(8) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 539,171 shares held by Osage University Partners III, LP. Osage University GP III, LLC ("OUP GP III") is the general partner of Osage University Partners III, LP ("OUP III"). Robert Adelson, William Harrington and Marc Singer (the "OUP Managers") are the managers of OUP GP III. OUP GP III and each OUP Manager may be deemed to share voting, investment and dispositive power over the shares held by OUP III and as a result may be deemed to have beneficial ownership over such securities. OUP GP III and each OUP Manager disclaims beneficial ownership over the securities held by OUP III, except to the extent of their respective pecuniary interests therein. The address of the principal business office of Osage University Partners III, L.P. is 50 Monument Road, Suite 201, Bala Cynwyd, PA 19004.

(9) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 133,903 shares held by the Trustees of Columbia University in the City of New York. The Trustees of Columbia University in the City of New York may be deemed to have voting and dispositive power over the securities held by the selling securityholder. The address for the selling securityholder is 405 Lexington Avenue, 63rd Floor, New York, New York 10174.

(10) Shares listed under "Number of Shares Beneficially Owned Before Offering" consists of 80,097 shares held by Agent Capital Fund III LP. Agent Capital Fund III LP is a Delaware limited partnership whose general partner is Agent Capital Fund III GP, LLC, or Agent GP, a Delaware limited liability company. Geeta Vemuri is the managing member of Agent Capital Fund III LP and exercises voting and investment power with respect to the shares owned by Agent Capital Fund III LP. Agent GP and Ms. Vemuri disclaim beneficial ownership of all shares held by Agent Capital Fund III LP, except to the extent of their respective pecuniary interests therein. The principal business address of Agent Capital Fund III LP is 1400 Main Street, Floor 1, Waltham MA 02451.

(11) No other shares of common stock, including, without limitation, shares of common stock acquired in the open market are being offered under this prospectus.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes some of the terms of our restated certificate of incorporation and amended and restated bylaws and of the Delaware General Corporation Law. This description is summarized from, and qualified in its entirety by reference to, our restated certificate of incorporation and amended and restated bylaws, each of which has been publicly filed with the SEC.

Our authorized capital stock consists of:

- 400,000,000 shares of common stock, par value $0.0001 per share; and
- 10,000,000 shares of preferred stock, par value $0.0001 per share

Common Stock

Our common stock is listed on the Nasdaq Global Market under the symbol "QTTB."

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. See below under *"—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions*."

Rights Upon Liquidation. In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Other Rights. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Transfer Agent

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Dividend

Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock. We have never declared or paid any cash dividends on our common stock. We do not intend to declare or pay cash dividends for the foreseeable future. We currently expect to retain all future earnings, if any, for use in the development, operation and expansion of our business. Any determination to pay cash dividends in the future will depend upon, among other things, our results of operations, plans for expansion, tax considerations, available net profits and reserves, limitations under law, financial condition, capital requirements and other factors that our board of directors considers to be relevant.

Preferred Stock

Under the terms of our restated certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors have the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing the board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of Homology's outstanding voting stock.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of the Delaware law, our restated certificate of incorporation and amended and restated bylaws could make the following transactions more difficult: an acquisition by means of a tender offer; an acquisition by means of a proxy contest or otherwise; or the removal incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure Homology outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of it. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of our company, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our restated certificate of incorporation and amended and restated bylaws provide that, subject to the rights of holders of any series of preferred stock, no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote in the election of directors. Subject to the rights of holders of any series of preferred stock, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of directors then in office, unless our board of directors determines by resolution that any such vacancy or newly created directorship shall be filled by our stockholders.

Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against it arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation or amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

In addition, our amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, and any person or entity purchasing or otherwise acquiring or holding any interest in our shares of capital stock shall be deemed to have notice of and consented to this choice of forum provision.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

Material U.S. Federal Income Tax Consequences for Holders of Common Stock

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common stock, which we refer to as our securities. This discussion applies only to securities that are held as capital assets for U.S. federal income tax purposes and is applicable only to holders who are receiving our securities in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors (such as the effects of Section 451 of the Code), including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own 5% or more of our voting shares;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to the securities;
- persons holding the securities as part of a "straddle," hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities; and
- tax-exempt entities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and will not seek, a ruling from the Internal Revenue Service, or the IRS, as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our securities through such entities. If a partnership (or other entity or arrangement classified as a partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of our securities, the U.S. federal income tax treatment of a partner or member in the partnership or other pass-through

entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our securities, we urge you to consult your tax advisor.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR SECURITIES IS URGED TO CONSULT ITS TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY UNITED STATES FEDERAL NON-INCOME, STATE AND LOCAL, AND NON-U.S. TAX LAWS.

Material U.S. Federal Income Tax Consequences for U.S. Holders

For purposes of this discussion, a "U.S. Holder" is any beneficial owner of our common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder's adjusted tax basis in common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under "*U.S. Holders-Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock*" below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock. Upon a sale or other taxable disposition of common stock, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the common stock so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of the shares would be subject to short-term capital gain

treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its common stock so disposed of. A U.S. holder's adjusted tax basis in its common stock generally will equal the U.S. holder's acquisition cost for the common stock or less, in the case of a share of common stock, any prior distributions treated as a return of capital. In the case of any shares of common stock originally acquired as part of an investment unit, the acquisition cost for the share of common stock that were part of such unit would equal an allocable portion of the acquisition cost of the unit based on the relative fair market values of the components of the unit at the time of acquisition.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our shares of common stock, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Material U.S. Federal Income Tax Consequences for Non-U.S. Holders

This section applies to you if you are a "Non-U.S. holder." As used herein, the term "Non-U.S. holder" means a beneficial owner of common stock who or that is for U.S. federal income tax purposes:

- a non-resident alien individual (other than certain former citizens and residents of the U.S. subject to U.S. tax as expatriates);
- a foreign corporation or
- an estate or trust that is not a U.S. holder;

but generally does not include an individual who is present in the United States for 183 days or more in the taxable year of disposition. If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership or sale or other disposition of our securities.

Taxation of Distributions. In general, any distributions we make to a Non-U.S. holder of shares of common stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder's adjusted tax basis in its shares of common stock and, to the extent such distribution exceeds the Non-U.S. holder's adjusted tax basis, as gain realized from the sale or other disposition of the common stock, which will be treated as described under "*Non-U.S. Holders-Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock*" below.

The withholding tax does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S.

income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A Non-U.S. corporation receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock. A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of common stock, unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder); or
- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held common stock, and, in the case where shares of common stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of common stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder's holding period for the shares of common stock. There can be no assurance that common stock will be treated as regularly traded on an established securities market for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower treaty rate).

If the second bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of common stock will be subject to tax at generally applicable U.S. federal income tax rates.

Information Reporting and Backup Withholding. Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of our shares of common stock. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid the backup withholding as well. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes. Provisions commonly referred to as "FATCA" impose withholding of 30% on payments of dividends (including constructive dividends) on common stock to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other Non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied by, or an exemption applies to, the payee (typically certified as to by the delivery of a properly completed IRS Form W-8BEN-E). Pursuant to proposed Treasury Regulations, the U.S. Treasury Department has indicated its intent to eliminate the requirement under FATCA of withholding on gross proceeds from the sale or other disposition of property of a type which can produce U.S. source dividends or interest. The U.S. Treasury Department has indicated that taxpayers may rely on these proposed Treasury Regulations pending their finalization. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under certain circumstances, a Non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a Non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits. Prospective investors should consult their tax advisers regarding the effects of FATCA on their investment in our securities.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees, donees, transferees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their securities covered hereby on the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, or the New York Stock Exchange or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities that require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders also may transfer the securities in other circumstances, in which case the transferees, pledgees, donees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales (it being understood that the selling stockholders shall not be deemed to be underwriters solely as a result of their

participation in this offering). In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of the date that the securities (i) have been sold, pursuant to this prospectus or pursuant to Rule 144, or (ii) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, and without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from sales of any shares of common stock by the selling stockholders.

We cannot assure you that the selling stockholders will sell all or any portion of the shares of common stock offered hereby. We are registering the resale of shares of our common stock to provide the selling stockholders with freely tradable securities, but the registration of such shares does not necessarily mean that any of such shares will be offered or sold by the selling stockholders pursuant to this prospectus or at all.

To the extent required, this prospectus may be amended and/or supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

The validity of the common stock being offered by this prospectus has been passed upon for us by Goodwin Procter LLP, Boston, Massachusetts.

EXPERTS

The financial statements of Homology Medicines, Inc. as of December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, included in this registration statement, have been audited by Deloitte & Touche LLP, or Deloitte, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

The consolidated financial statements of Q32 Bio Operations, Inc. (formerly Q32 Bio, Inc.) at December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

CHANGE IN CERTIFYING ACCOUNTANT

(a) Dismissal of Independent Registered Public Accounting Firm

Deloitte & Touche LLP, or Deloitte, served as our independent registered public accounting firm prior to completion of the Merger. On March 25, 2024, following the completion of the Merger, Deloitte was dismissed as our independent registered public accounting firm. The decision to dismiss Deloitte was approved by the Audit Committee of the Board.

The reports of Deloitte on our consolidated financial statements for the fiscal years ended December 31, 2023 and 2022 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles, or other similar opinion as defined in Item 304(a)(1)(ii) of Regulation S-K (17 CFR § 229.304(a)(1)(ii) except for an explanatory paragraph regarding existence of substantial doubt about the Company's ability to continue as a going concern in the report for the year ended December 31, 2023.

During our two most recent fiscal years and the subsequent period from January 1, 2024 to March 25, 2024, there were (i) no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) with Deloitte on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of Deloitte, would have caused it to make reference to the subject matter of the disagreement in connection with its report and (ii) no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

We provided Deloitte with a copy of the disclosures made above and requested Deloitte to furnish us with a letter addressed to the SEC stating whether it agrees with the statements made by us and, if not, stating the respects in which it does not agree. A copy of Deloitte's letter to the SEC dated March 26, 2024 regarding these statements is filed as Exhibit 16.1 hereto.

(b) Engagement of New Independent Registered Public Accounting Firm

Ernst & Young LLP, or E&Y, served as the independent registered public accounting firm of Legacy Q32 prior to the completion of the Merger. On March 25, 2024, following the completion of the Merger, the Audit Committee of the Board approved the appointment of E&Y as our independent registered public accounting firm.

During our two most recent fiscal years and the subsequent period from January 1, 2024 to March 25, 2024, we did not consult with E&Y regarding any of the matters or events set forth in Item 304(a)(2)(i) and (ii) of Regulation S-K.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains our filings as well as reports, proxy and information statements, and other information issuers file electronically with the SEC at www.sec.gov.

We also make available free of charge on or through our website at www.q32bio.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnishes it to the SEC. The website addresses are inactive textual references and except as specifically incorporated by reference into this prospectus, information on those websites is not part of this prospectus.

This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement or documents incorporated by reference in the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement through the SEC's website, as provided above.

If you would like to request documents, please send a request in writing or by telephone to the following address:

Q32 Bio Inc.
830 Winter Street
Waltham, MA 02451
Attn: Investor Relations
(781) 999-0232
Email: IR@q32bio.com

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Q32 Bio Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Years ended December 31, 2023 and 2022

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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 Matter

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

	Accrued and Prepaid Research and Development Expenses
Description of the Matter	The Company's accrued external research and development expenses totaled $3.6 million at December 31, 2023. In addition, the Company's current and noncurrent prepaid external research and

development expenses were $1.8 million and $0.7 million, respectively. 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 and pre-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 and pre-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 discussed the progress of research and development activities 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 reviewed information received by the Company directly from certain vendors, which indicated the vendors' estimate of costs incurred to date. We also analyzed fluctuations in prepaids and accruals by vendor and by trial throughout the period subject to audit and tested subsequent invoices received from vendors.

/s/ Ernst & Young LLP

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

Boston, Massachusetts
March 26, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	**$ 25,617**	$ 43,893
Prepaid expenses and other current assets	**3,099**	2,960
Total current assets	**28,716**	46,853
Property and equipment, net	**1,782**	2,276
Right-of-use asset, operating leases	**6,301**	6,890
Restricted cash and restricted cash equivalents	**5,647**	5,647
Other noncurrent assets	**4,611**	108
Total assets	**$ 47,057**	$ 61,774
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	**$ 3,468**	$ 1,435
Accrued expenses and other current liabilities	**9,763**	9,497
Venture debt, current portion	**878**	—
Convertible notes	**—**	32,402
Deferred revenue, current portion	**—**	14,531
Total current liabilities	**14,109**	57,865
Deferred revenue, net of current portion	**—**	11,318
Lease liability, net of current portion	**6,248**	6,786
Venture debt, net of current portion	**4,581**	5,072
Convertible notes	**38,595**	—
Other noncurrent liabilities	**55,000**	—
Total liabilities	**118,533**	81,041
Commitments and contingencies (Note 7)		
Series A convertible preferred stock, $0.0001 par value, 47,628,788 shares authorized, issued and outstanding as of December 31, 2023 and 2022 (liquidation preference of $47,629 at December 31, 2023)	**47,458**	47,458
Series A-1 convertible preferred stock, $0.0001 par value, 6,500,000 shares authorized, issued and outstanding at December 31, 2023 and 2022 (liquidation preference of $5,753 as of December 31, 2023)	**4,132**	4,132
Series B convertible preferred stock, $0.0001 par value, 54,689,627 shares authorized, issued and outstanding at December 31, 2023 and 2022 (liquidation preference of $60,000 as of December 31, 2023)	**59,855**	59,855
Total convertible preferred stock	**111,445**	111,445
Stockholders' deficit:		
Common stock, $0.0001 par value; 225,000,000 and 141,900,000 shares authorized, 7,472,835 and 7,139,216 shares issued and outstanding at December 31, 2023 and 2022, respectively	**1**	1
Additional paid-in capital	**4,159**	2,625
Accumulated deficit	**(187,081)**	(133,338)
Total stockholders' deficit	**(182,921)**	(130,712)
Total liabilities, convertible preferred stock and stockholders' deficit	**$ 47,057**	$ 61,774

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

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

	Year Ended December 31,	
	2023	**2022**
Collaboration arrangement revenue	**$ (6,651)**	$ 6,651
Operating expenses:		
Research and development	**31,729**	35,814
General and administrative	**9,875**	10,062
Total operating expenses	**41,604**	45,876
Loss from operations	**(48,255)**	(39,225)
Change in fair value of convertible notes	**(6,193)**	(2,402)
Other income (expense), net	**1,023**	(1,120)
Total other income (expense), net	**(5,170)**	(3,522)
Loss before provision for income taxes	**(53,425)**	(42,747)
Provision for income taxes	**(318)**	(62)
Net loss and comprehensive loss	**$ (53,743)**	$ (42,809)
Net loss attributable to common stockholders—basic and diluted	**(53,743)**	(42,809)
Weighted-average common shares—basic and diluted	**7,253,978**	7,025,420
Net loss per share attributable to common stockholders—basic and diluted	**$ (7.41)**	$ (6.09)

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

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

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock			Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount			
Balance as of December 31, 2021	47,628,788	$47,458	6,500,000	$ 4,132	54,689,627		$59,855	6,828,125	$ 1	$ 1,318	$ (90,529)	$ (89,210)
Exercise of stock options	—	—	—	—	—		—	307,859	—	69	—	69
Vesting of restricted stock	—	—	—	—	—		—	3,232	—	—	—	—
Stock-based compensation expense	—	—	—	—	—		—	—	—	1,238	—	1,238
Net loss	—	—	—	—	—		—	—	—	—	(42,809)	(42,809)
Balance as of December 31, 2022	47,628,788	47,458	6,500,000	4,132	54,689,627		59,855	7,139,216	1	2,625	(133,338)	(130,712)
Exercise of stock options	—	—	—	—	—		—	**333,619**	—	**106**	—	**106**
Stock-based compensation expense	—	—	—	—	—		—	—	—	**1,428**	—	**1,428**
Net loss	—	—	—	—	—		—	—	—	—	**(53,743)**	**(53,743)**
Balance as of December 31, 2023	**47,628,788**	**$47,458**	**6,500,000**	**$ 4,132**	**54,689,627**		**$59,855**	**7,472,835**	**$ 1**	**$ 4,159**	**$ (187,081)**	**$ (182,921)**

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

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

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	**$ (53,743)**	$ (42,809)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and issuance costs	**87**	100
Depreciation expense	**499**	370
Loss on disposal of property and equipment	**—**	23
Stock-based compensation expense	**1,428**	1,238
Non-cash lease expense	**544**	776
Change in fair value of convertible notes	**6,193**	2,402
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	**(94)**	(1,209)
Other noncurrent assets	**(4,503)**	195
Accounts payable	**2,033**	(1,241)
Operating lease liability	**(471)**	(409)
Accrued expenses and other current liabilities	**199**	3,758
Contingent liability	**55,000**	—
Deferred revenue	**(25,849)**	25,849
Net cash used in operating activities	**(18,677)**	(10,957)
Cash flows from investing activities:		
Purchases of property and equipment	**(5)**	(2,485)
Proceeds from sale of property and equipment	**—**	19
Net cash used in investing activities	**(5)**	(2,466)
Cash flows from financing activities:		
Proceeds from borrowings under loan and security agreement, net	**5,500**	—
Payments on borrowings under loan and security agreement, net	**(5,200)**	—
Proceeds from exercise of common stock options	**106**	69
Proceeds from issuance of convertible debt	**—**	30,000
Net cash provided by financing activities	**406**	30,069
Net increase (decrease) in cash, cash equivalents, restricted cash and restricted cash equivalents	**(18,276)**	16,646
Cash, cash equivalents, restricted cash and restricted cash equivalents at beginning of period	**49,540**	32,894
Cash, cash equivalents, restricted cash and restricted cash equivalents at end of period	**$ 31,264**	$ 49,540
Supplemental disclosure of non-cash operating, investing and financing activities:		
Interest payments on venture debt	**$ 422**	$ 229
Right-of-use asset obtained in exchange for new operating lease liability	**$ —**	$ 7,666

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. (the Q32 or Company) was formed on April 10, 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. The Company aims to bring safer, more efficacious therapeutics to patients suffering from a wide range of devastating autoimmune and inflammatory diseases, starting with those rooted in the complement system and interleukin-7 (IL-7) signaling pathways.

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 and its collaboration arrangement.

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.

Merger with Homology

On November 16, 2023, the Company entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement) with Homology and Kenobi Merger Sub, Inc., a wholly owned subsidiary of Homology (Merger Sub). The Merger was completed on March 25, 2024. Pursuant to the Merger Agreement, Merger Sub merged with and into the Company, with the Company continuing as the surviving company and as a wholly owned subsidiary of Homology (the Merger). Homology changed its name to Q32 Bio, Inc., and the Company which remains as a wholly-owned subsidiary of Q32, changed its name to Q32 Bio Operations, Inc. On March 26, 2024, the combined company's common stock began trading on the Nasdaq Global Market under the ticker symbol "QTTB". The business of the Company will continue 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 the Company to purchase shares of the Company's common stock for an aggregate purchase price of $42.0 million (the Pre-Closing Financing).

On March 25, 2024 (the Closing Date), following approval by the stockholders of the Company and Homology, the Pre-Closing Financing closed immediately prior to the consummation of the Merger. Shares of the Company'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 of its then outstanding common stock. Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "Effective Time") which was March 25, 2024, all issued and

outstanding shares of the Company's common stock (including common stock issued upon the conversion of all the Company's Series A, Series A-1 and Series B preferred stock, conversion of 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 calculated in accordance with the Exchange Ratio at the Effective Time. Lastly, each option to purchase the Company's shares that was outstanding and unexercised immediately prior to the Effective Time was converted into an option to purchase shares of Homology based on the Exchange Ratio. Immediately following the merger, stockholders of the Company owned approximately 74.4% of the outstanding common stock of the combined company.

The Merger will be accounted for as a reverse recapitalization in accordance with U.S. GAAP. For accounting purposes, the Company is the accounting acquirer and Homology is the acquired company based on the terms of the Merger agreement and other factors, including: (i) the Company's shareholders own a majority of the voting rights in the combined company; (ii) the Company designated a majority (seven of nine) of the initial members of the board of directors of the combined company; (iii) the Company's executive management team became the management 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 (the in-process research and development assets potentially remaining as of the combination are de minimis value); and (v) the combined company was named Q32 Bio, Inc. and is headquartered in the Company's office in Waltham, Massachusetts. Accordingly, the merger was treated as the equivalent of the Company's issuing stock to acquire the net assets of Homology. As a result of the merger, the net assets of Homology will be recorded at their acquisition-date fair value in the financial statements of the combined company and the reported operating results prior to the merger will be those of the Company.

At the Effective Time, each person who as of immediately prior to the Effective Time was a stockholder of record of Homology or had the right to receive Homology's common stock will be entitled to receive a contractual contingent value right (CVR) issued by Homology subject to and in accordance with the terms and conditions of a Contingent Value Rights Agreement between Homology and the rights agent (the CVR Agreement), representing the contractual right to receive cash payments from the combined company upon the receipt of certain proceeds from a disposition of Homology's pre-merger assets, calculated in accordance with the CVR Agreement.

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.

The Company has incurred recurring losses since its inception, including a net loss of $53.7 million for the year ended December 31, 2023. In addition, as of December 31, 2023, the Company had an accumulated deficit of $187.1 million. To date, the Company has funded its net losses principally through the sale of preferred stock, convertible notes, debt, and proceeds from a collaboration arrangement. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future.

The Company expects that its cash and cash equivalents as of December 31, 2023 of $25.6 million, together with the proceeds from the issuance of additional shares of common stock in the Pre-Closing Financing for aggregate proceeds of $42.0 million and Homology's net cash and cash equivalents of $61.3 million on the closing date 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 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 consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Update (ASU) of the FASB.

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 consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these 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 valuation of common stock awards, the valuation of convertible notes, the accruals of research and development expenses, the identification of material rights and estimation of standalone selling price for the identified performance obligations in the collaboration agreement and the inputs and assumptions to the over-time recognition of revenue under the collaboration agreement. 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, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer (CEO). The Company and the CEO view the Company's operations and manage its business as one operating segment. All material long-lived assets of the Company reside in the United States.

Foreign Currency Transactions

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

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 organization (CROs) which provide services related to the research and development activities in its programs.

Off-Balance Sheet Risk

As of December 31, 2023 and 2022, the Company had no off-balance-sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

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.

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 the 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.

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. The Company maintains its cash in bank deposits accounts that are FDIC insured up the $250,000. At times, the Company's bank accounts may exceed the federal insurance limits. 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,	
	2023	2022
Cash and cash equivalents	**$25,617**	$ 43,893
Restricted cash and cash equivalents	**5,647**	5,647
Total cash, cash equivalents, restricted cash and restricted cash equivalents	**$31,264**	$ 49,540

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.

Convertible notes

During 2022, the Company recognized a liability as a result of the issuance of convertible promissory notes (the Convertible Notes). The Company accounts for all Convertible Notes issued under the fair value option election of ASC 825, *Financial Instruments* (ASC 825). The financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value adjustment is recognized within other income (expense) 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.

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.

Convertible Preferred Stock

The Company records all convertible preferred stock upon issuance at its respective fair value or original issuance price less issuance costs, as stipulated by its terms. The Company classifies its convertible preferred stock outside of stockholders' deficit as the redemption of such shares is outside the Company's control in certain circumstances, including upon liquidation or sale, as holders of the convertible preferred shares could cause redemption of the shares in these situations. The Company does not adjust the carrying value of the convertible preferred stock to redemption value until the contingent events that could give rise to redemption are considered probable of occurring.

Revenue Recognition

Under ASC Topic 606, *Revenue from Contracts with Customers* (Topic 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 Topic 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 Topic 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.

Collaboration Arrangement

The Company analyzes first its collaboration arrangement to assess whether it is within the scope of FASB ASC Topic 808, Collaborative Arrangements (ASC 808) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company assesses whether aspects of the arrangement between the Company and its collaboration partner are within the scope of other accounting literature, including ASC 606. If it is concluded that some or all aspects of the arrangement represent a transaction with a customer, the Company will account for those aspects of the arrangement within the scope of ASC 606. ASC 808 provides guidance for the presentation and disclosure of transactions in collaborative arrangements, but it does not provide recognition or measurement guidance.

Therefore, if the Company concludes a counterparty to a transaction is not a customer or otherwise not within the scope of ASC 606, the Company considers the guidance in other accounting literature, including the guidance in ASC 606, as applicable or by analogy to account for such transaction. The classification of transactions under the Company's arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

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.

Research and Development Tax Incentive

The Company is eligible under the AusIndustry Research and Tax Development Tax Incentive Program to obtain a cash amount from the Australian Taxation Office (ATO). The tax incentive is available to the Company on the basis of specific criteria with which the Company must comply related to research and development expenditures in Australia. The Company adopted on January 1, 2022, ASU No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*. The Company applied a grant accounting model by analogy to IAS 20. The Company recognizes the Research and Development Tax Incentive (grant) as it incurs costs eligible for reimbursement under the AusIndustry Research and Tax Development Tax Incentive Program when it is reasonably assured that the grant funding will be received, as evidenced through enrollment in the program and when the applicable conditions under the program have been met. During the years ended December 31, 2023 and 2022, respectively, the Company recorded zero million and $0.4 million of research and development tax incentives as contra-research and development expense over the periods in which the Company recognized the eligible research and development activities taking place in Australia.

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.

Stock-Based Compensation

The Company accounts for stock-based awards in accordance with 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. The Company uses the value of its common stock to determine the fair value of its stock-based awards. 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 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.

Determination of Fair Value of Common Stock on Grant Dates

The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company's common stock, expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends (see Note 11). The Company has been a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies. The expected term of options was calculated using the simplified method, which represents the average of the contractual term of the option and the weighted-average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term. The expected term of options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Due to the absence of an active market for the Company's common stock, the Company and the board of directors were required to determine the fair value of the Company's common stock at the time of each grant of a stock-based award. The Company estimated the fair value of its common stock utilizing methodologies 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*. In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including prices paid for the Company's convertible preferred stock and the rights, preferences, and privileges of the Company's Preferred Stock and common stock; the Company's stage of development and status of technological developments within the Company's research; the illiquid nature of securities in a private company; the prospects of a liquidity event; and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date. The Company's common stock valuations were prepared using an option pricing method, or OPM. The OPM treats common stock and 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 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. There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. 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, 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 classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

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 have been 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.

Comprehensive Income (Loss)

Comprehensive 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. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying financial statements.

Net Loss per Share Attributable to Common Stockholders

Net loss per share attributable to common stockholders is determined using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. In periods of income, the convertible preferred stock would be considered participating securities because the shares include rights to participate in dividends with the common stock; however, the convertible preferred stock is not considered a participating security in periods of loss as they do not have an obligation to share in the Company's net losses and are not included in the calculation of net loss per share in the periods in which a net loss is recorded. Net loss attributable to common stockholders is equal to the net loss for the period.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the treasury stock method and if-converted method. The Company allocates earnings first to preferred stockholders based on dividend rights and then to common and preferred stockholders based on ownership interests. The weighted-

average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and preferred stock. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

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 and comprehensive loss. As of December 31, 2023, the Company had capitalized deferred transaction costs of $3.9 million in other noncurrent assets related to the merger with Homology.

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 March 26, 2024, the date of these consolidated financial statements were available to be issued. See Note 17.

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 June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326) – Measurement of Credit Losses on Financial Instruments,* which has been subsequently amended by ASU No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11 and ASU No. 2020-03 (ASU 2016-13). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 was effective for the Company on January 1, 2023. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* (ASU 2020-06), which reduces the number of accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU 2020-06 is effective for the Company on January 1, 2024, with early adoption permitted. The Company early adopted on January 1, 2022. The early adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards Not Yet Adopted

In November 2023, the FASB issued Accounting Standards Update 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 will adopt this standard as of January 1, 2024. The Company has determined that the effects of adopting the amendments in ASU 2023-07 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.

On December 14, 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures*. ASU No. 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. 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, 2023 (see Note 8) approximated fair value based on interest rates currently available to the Company.

The tables below presents information about the Company's assets and liabilities that are regularly measured and carried at fair value on a recurring basis at December 31, 2023 and 2022 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, 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**	**$24,100**	**$ —**	**$ —**
Restricted cash equivalents:				
Money market funds	**5,000**	**5,000**	**—**	**—**
Total	**$ 29,100**	**$29,100**	**$ —**	**$ —**
Liabilities				
Convertible Notes	**$ 38,595**	**$ —**	**$ —**	**$ 38,595**
Total	**$ 38,595**	**$ —**	**$ —**	**$ 38,595**

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 are summarized as follows (in thousands):

Description	Balance as of December 31, 2022	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	$ 42,496	$42,496	$ —	$ —
Restricted cash equivalents:				
Money market funds	5,000	5,000	—	—
Total	$ 47,496	$47,496	$ —	$ —
Liabilities				
Convertible Notes	$ 32,402	$ —	$ —	$ 32,402
Total	$ 32,402	$ —	$ —	$ 32,402

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. During the years ended December 31, 2023 and 2022, there were no transfers between Level 1, Level 2 and Level 3. There have been no impairments of the Company's assets measured and carried at fair value during the years ended December 31, 2023 and 2022.

The Company issued convertible notes (Convertible Notes) totaling $30,000,000 during the year ended December 31, 2022. The Company concluded that the Convertible Notes and its related features are within the scope of ASC 825, *Financial Instruments*, as a combined financial instrument, and the Company elected the fair value option where changes in fair value of the Convertible Notes are measured through the accompanying consolidated statement of operations and comprehensive loss 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 ending December 31, 2023	Scenario 1	Scenario 2	Scenario 3
Probability of each scenario	80.0%	15.0%	5.0%
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.

4. Property and Equipment, Net

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

	December 31,	
	2023	2022
Lab equipment	**$1,382**	$1,382
Furniture and fixtures	**341**	341
Computer equipment	**85**	85
Leasehold improvements	**940**	935
Total property and equipment	**2,748**	2,743
Less accumulated depreciation	**(966)**	(467)
Property and equipment, net	**$1,782**	$2,276

Depreciation expense for the years ended December 31, 2023 and 2022 was $499 thousand and $370 thousand, respectively. No impairment losses occurred in 2023 and 2022. The Company had a loss on disposal of fixed assets of $23 thousand for the year ended December 31, 2022.

5. 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,	
	2023	2022
Payroll tax credit	**$ 755**	$ 948
Prepaid external research and development	**1,834**	1,329
Research credit receivable	**—**	116
Prepaid expenses	**427**	421
Other	**83**	146
Total prepaid expenses and other current assets	**$3,099**	$2,960

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

	December 31,	
	2023	2022
Deferred transaction costs	**$3,912**	$—
Prepaid external research and development—long term	**676**	—
Other	**23**	108
Total other noncurrent assets	**$4,611**	$108

6. Accrued Expenses and Other Current Liabilities

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

	December 31, 2023	2022
Accrued external research and development	**$3,578**	$4,077
Accrued compensation and related expenses	**3,003**	2,791
Accrued taxes payable	**316**	570
Operating lease liability, current	**538**	471
Accrued professional services and other	**2,328**	1,588
Total accrued expenses and other current liabilities	**$9,763**	$9,497

7. Commitments and Contingencies

As of December 31, 2023, the Company has several ongoing clinical studies in various clinical trial stages. Its most significant contracts relate to agreements with clinical research organizations (CROs) for clinical trials and preclinical studies and contract development and manufacturing organizations (CMOs), which the Company enters into in the normal course of business. The contracts with CROs and CMOs 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. The lease for the Company's corporate headquarters provides approximately 15,000 rentable square feet for general office use and research lab facilities. The lease commencement date began on 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 $970 thousand 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 $647 thousand 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, 2023, the Company's operating lease had a weighted-average remaining lease term of eight 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, 2023 and 2022 were as follows (in thousands):

	December 31, 2023	2022
Assets:		
Operating lease right-of-use assets	**$6,301**	$6,890
Total operating lease right-of-use assets	**$6,301**	$6,890
Liabilities:		
Current:		
Operating lease liabilities	**$ 538**	$ 471
Noncurrent:		
Operating lease liabilities, net of current portion	**6,248**	6,786
Total operating lease liabilities	**$6,786**	$7,257

The following table summarizes operating lease costs for the years ended December 31, 2023 and 2022 (in thousands):

	December 31, 2023	2022
Fixed lease costs	**$ 999**	$1,232
Variable lease costs	**73**	103
Total lease costs	**$1,072**	$1,335

Variable lease costs were primarily related to operating expenses, taxes and insurances associated with the operating leases, 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 and comprehensive loss. Future minimum lease payments under non-cancelable lease agreement as of December 31, 2023 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
2024	$ 1,029
2025	1,060
2026	1,092
2027	1,124
2028	1,158
Thereafter	3,687
Total minimum lease payments	9,150
Less imputed interest	(2,364)
Total lease liability	$ 6,786
Lease liability, current portion	$ 538
Lease liability, net of current portion	6,248
Total	$ 6,786

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, 2023 and 2022, the Company recorded research and development expense of zero and $50 thousand, respectively for milestone related to the Colorado License Agreement. The financial statements as of December 31, 2023 and 2022 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

During the year ended December 31, 2019, the Company recorded in-process-research and development expense of $14.6 million in the statement of operations related to the BMS License Agreement comprised of $8.0 million of cash consideration and $6.6 million of Series A preferred shares issued to BMS.

As of December 31, 2023, no events have occurred that would require payment of the milestones, royalties or sublicense fees.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of FASB ASC Topic 450, *Contingencies*. The Company expenses as incurred the costs related to its legal proceedings.

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.

8. 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 $91 thousand 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, 2023.

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. The loan matures on December 31, 2024. The amendment increases the final payment from 2.0% to 4.0% of the advanced payment and modifies 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. The loan matures on 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 extends 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%. Pursuant to this amendment, specifically the interest-only period through June 30, 2024, the Company classified the principal of its venture debt as noncurrent on the consolidated balance sheet as of December 31, 2022.

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 extends the time the Company has to receive the net proceeds to March 31, 2024.

In conjunction with the Loan Agreement, the Company issued warrants to purchase 166,371 shares of common stock to the lender at a per share price of $0.33 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 211,528 shares of common stock to the lender at a per share price of $0.36 with a maximum contractual term of 10 years. The warrants are issued in two separate tranches of 105,764 based upon certain milestone events. The warrants had a de minimis total relative fair value at the time of issuance.

Pursuant to ASC Topic 480, *Distinguishing Liabilities from Equity* and 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 $531 thousand and $327 thousand for the years ended December 31, 2023 and 2022, respectively. The effective rate on the Loan Agreement, including the amortization of the debt discount and issuance costs was 10.42% and 9.49% at December 31, 2023 and 2022, respectively. The components of the long-term debt balance are as follows (in thousands):

	December 31,	
	2023	**2022**
Principal amount of term loans	**$5,500**	$5,000
Unamortized debt discount and issuance costs	**(41)**	72
Carrying amount	**5,459**	5,072
Less current portion	**(878)**	—
Long-term debt, net	**$4,581**	$5,072

Convertible Notes

On May 20, 2022, the Company entered into an agreement with the existing investors of the Company to purchase up to an aggregate of $30.0 million in convertible notes (the Convertible Notes). 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 $1.5 million and $376 thousand for the year ended December 31, 2023 and 2022, respectively.

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 common shares 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 has 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 and comprehensive loss until settlement. As the Convertible Notes are due on demand. the Company recorded the Convertible Notes at fair value totaling $32.4 million within current liabilities on its consolidated balance sheet as of December 31, 2022. Subsequent to December 31, 2023 and per the Merger further discussed in Note 1, the Convertibles Notes converted into 29,853,711 shares of common stock. As the Convertible Notes were settled with equity securities subsequent to the balance sheet date but prior to the issuance of the financial statements, per ASC 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 an 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.

9. Convertible Preferred Stock

In July 2018, the Company entered into a Series A and A-1 Preferred Stock Purchase Agreement and issued 10,000,000 shares of Series A preferred stock at a price of $1.00 per share less issuance costs of $100 thousand for total net proceeds of $9.9 million. The Company also issued 6,500,000 shares of Series A1 preferred stock for the conversion of financial instruments that had been previously issued during the years ended December 31, 2018 and 2017.

In connection with the initial issuance of the Series A preferred stock, the holders received the right to purchase, and the Company the obligation to sell, an additional 31,000,000 shares of Series A preferred stock at the same purchase price as the initial closing upon achieving certain milestones. The specified milestones could be waived upon written consent of the holders of a majority of the shares of Series A preferred stock. The Company determined that the tranche rights did not meet the definition of a freestanding financial instrument because they are not legally detachable. Further, the Company determined that the tranche rights do not meet the definition of an embedded derivative that require bifurcation from the equity instrument.

In August 2019, the Company issued 3,000,000 shares of Series A preferred stock at a price of $1.00 per share less issuance costs of $30 thousand for net proceeds of $2.97 million upon the achievement of specified milestones. In September 2019, the Company issued 28,000,000 shares of Series A preferred stock at a price of $1.00 per share less issuance costs of $40 thousand for net proceeds of $27.96 million upon the receipt of a waiver of the final milestones being met.

In September 2019, the Company issued 6,628,788 Series A preferred shares in association with the purchase of a license agreement with BMS as further described in Note 7.

On August 31, 2020, the Company entered into a Series B Preferred Stock Purchase Agreement and issued 34,636,767 shares of Series B preferred stock at a price of $1.0971 per share less issuance costs of $100 thousand for total net proceeds of $37.9 million.

In connection with the initial issuance of the Series B preferred stock, the holders received the right to purchase, and the Company the obligation to sell, an additional 17,318,383 shares of Series B preferred stock at the same purchase price as the initial closing upon achieving certain milestones. The specified milestones could be waived upon written consent of the holders of a majority of the shares of Series B preferred stock. The Company also had the right to issue additional shares of Series B preferred stock to new investors if the agreement was reached before December 31, 2020, a portion of which would be issued immediately and a portion upon achieving the specified milestones. The Company determined that the tranche rights did not meet the definition of a freestanding financial instrument because they are not legally detachable. Further, the Company determined that the tranche rights do not meet the definition of an embedded derivative that require bifurcation from the equity instrument.

On October 15, 2020, the Company issued an additional 1,822,987 shares of Series B preferred stock to new investors at a purchase price of $1.0971 per share for total net proceeds of $2.0 million.

In November and December of 2021, the Company issued 18,229,873 shares of Series B preferred stock at a purchase price of $1.0971 per share less issuance cost of $10 thousand for total net proceeds of $20.0 million upon the achievement of the specified milestones.

The Series A preferred stock, the Series A-1 preferred stock and the Series B preferred stock, (together the Preferred Stock) have the following rights and preferences:

Voting Rights

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of shares of common stock into which the shares of Preferred Stock held by such holder are convertible at the time of such vote.

Except as provided by law or by the other provisions of the Company's Second Amended and Restated Certificate of Incorporation, holders of Preferred Stock vote together with the holders of common stock as a single class and on an as-converted to Common Stock basis.

The holders of record of the shares of Series B preferred stock, exclusively and as a separate class, are entitled to elect two directors of the Company (the Series B Preferred Directors); the holders of record of the shares of Series A preferred stock, exclusively and as a separate class, are entitled to elect three directors of the Company (the Series A Preferred Directors and together with the Series B Directors, the Preferred Directors).

Conversion

Each share of Preferred Stock is convertible, at the option of the holder, at any time, and without the payment of additional consideration, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the Applicable Preferred Stock Original Issue Price (as defined below) by the Applicable Preferred Stock Conversion Price (as defined below) in effect at the time of conversion.

The Applicable Preferred Stock Original Issue Price is $1.00 per Series A share, $0.885 per Series A1 share and $1.0971 per Series B share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization with respect to the Preferred Stock. The Applicable Preferred Stock Conversion Price is initially $1.00 for Series A, $0.885 for Series A1 and $1.0971 for Series B, subject to appropriate adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization and other adjustments, as set forth in the Company's Second Amended and Restated Certificate of Incorporation.

Each share of Preferred Stock will automatically convert into shares of common stock at the then effective conversion ratio (i) upon an initial public offering of the Company's common stock, provided that such offering results in at least $50 million of gross proceeds, after deducting the underwriting discount and commissions, to the Company or (ii) upon the vote or written consent of the holders of a majority of the outstanding shares of Preferred Stock.

On March 25, 2024, immediately prior to completing the Merger, all classes of convertible Preferred Stock of Q32 were converted to Q32 common stock. The Series A convertible preferred stock converted to 47,628,788 shares of Q32 common stock, the Series A-1 convertible preferred stock converted to 6,500,000 shares of Q32 common stock and the Series B convertible preferred stock converted to 54,689,627 shares of Q32 common stock. The conversion of the Q32 preferred stock into shares of Q32 common stock results in an increase of $11 thousand to Common stock and an increase of $111.4 million to additional paid-in-capital immediately prior to completing the Merger.

Dividends

The Company may not declare, pay or set aside any dividends on any other class or series of stock of the Company, other than dividends on common stock payable in common stock, unless the holders of the Preferred Stock first receive, or simultaneously receive, a dividend on each outstanding Preferred Stock of an amount equal to six percent (6%) of the applicable preferred stock original issue price (as defined below) per share of such series of Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such series of Preferred Stock). Dividends are non-cumulative. No cash dividends were declared or paid during the years ended December 31, 2023 or 2022.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), the holders of shares of Preferred Stock then outstanding shall be entitled, on a pari passu basis, to be paid out of the assets of the Company available for distribution to its stockholders before any payment will be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to with respect to the Series A, A1 and B preferred stock, one times the original issue price, plus any dividends declared but unpaid. If upon any such liquidation, dissolution or winding up of the Company or Deemed Liquidation Event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Preferred Stock the full amount to which they shall be entitled, the holders of the shares of Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

After the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Company available for distribution to its stockholders will be distributed among the holders of the shares of Series A, A1 and B preferred stock, and common stock, pro rata based on the number of shares held by each such holder, treating for the purpose all such securities as if they had been converted to common stock. Unless the holders of a majority of the Preferred Stock, voting together as a single class, elect otherwise, a Deemed Liquidation Event shall include (i) a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or (ii) a sale, lease, transfer, exclusive license, or other disposition of substantially all of the assets of the Company.

Redemption

The Preferred Stock is not redeemable at the option of the holders thereof. However, the Preferred Stock is redeemable upon the occurrence of certain contingent events, unless otherwise determined by the holders.

As it relates to the payment upon the occurrence of a contingent event, the Company evaluated the Preferred Stock in accordance with the guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, and determined that the payment upon the occurrence of a contingent event is not solely within its control and accordingly classified the Preferred Stock in temporary equity. The Preferred Stock is not currently redeemable, nor is it currently probable that the instruments will become redeemable, and therefore the instruments are not accreted to redemption value.

10. Common Stock

As of December 31, 2023 the Company's Second Amended and Restated Certificate of Incorporation authorized the Company to issue 225,000,000 shares of common stock, $0.0001 par value per share, respectively. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above. Each share

of common stock entitles the holder to one vote, together with the holders of the Preferred Stock, on all matters submitted to the stockholders for a vote. On May 20, 2022, December 8, 2022 and November 16, 2023, the Company amended and restated the Certificate of Incorporation to increase the authorized common stock by 5,000,000, 6,900,000 and 83,100,000 respectively to 225,000,000.

Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any, subject to the preferential dividend rights of the Preferred Stock. No dividends have been declared or paid during the years ended December 31, 2023 and 2022.

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

	As of December 31,	
	2023	2022
Shares reserved upon the conversion of authorized Series A preferred stock	**47,628,788**	47,628,788
Shares reserved upon the conversion of authorized Series A1 preferred stock	**6,500,000**	6,500,000
Shares reserved upon the conversion of authorized Series B preferred stock	**54,689,627**	54,689,627
Shares reserved for future issuance under the 2017 Stock Incentive Plan	**1,167,685**	1,669,058
Shares reserved upon the conversion of the convertible notes	**29,853,711**	—
Shares reserved for stock option exercises	**23,165,393**	22,997,639
Shares reserved for warrants	**377,899**	166,371
	163,383,103	133,651,483

11. Stock-Based Compensation

Grants under the 2017 Plan

The Company adopted the 2017 Stock Option and Grant Plan and subsequent amendments (the Plan) with 25,956,535 shares of common stock reserved for issuance to employees, directors, and consultants. The Plan allows for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock awards. Recipients of stock options are eligible to purchase shares of the Company's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant. The maximum contractual term of options granted under the Plan is ten years, and the awards vest under such terms prescribed by the Company's board of directors.

Since inception, the Company has granted restricted stock awards, non-qualified stock options and incentive stock options. As of December 31, 2023, 1,167,685 shares remain available for future grant under the Plan.

Restricted Stock

For the restricted stock awards, the purchase price equaled the estimated fair value of the common stock as determined by the board of directors on the date of grant. The Company has the right, but not the obligation to repurchase unvested shares at the original purchase price if employees or non-employees are terminated or cease their employment or service relationship with the Company. The vesting period is generally contingent upon continued employment or consulting services being provided to the Company. The shares typically vest over a two-year or four-year period. The unvested shares of restricted stock are not considered outstanding shares for accounting purposes until the shares vest.

The aggregate fair value of restricted stock awards that vested during the year ended December 31, 2023 was zero. No restricted stock awards were issued during the years ended December 31, 2023 and 2022. As of December 31, 2023, no shares remained subject to a repurchase right by the Company.

As of December 31, 2023, there was no unrecognized compensation cost related to the unvested restricted stock awards.

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 under the 2017 Plan during the year ended December 31, 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	22,997,639	$ 0.34	7.94	$ 362
Granted	3,221,672	0.52	—	
Exercised	(333,619)	0.32	—	
Cancelled	(2,720,299)	0.35	—	
Outstanding at December 31, 2023	23,165,393	$ 0.36	6.87	$ 10,712
Exercisable at December 31, 2023	12,899,524	$ 0.33	5.36	$ 6,299

The weighted-average grant date fair value per share of options granted in the period ended December 31, 2023 was $0.40. The total fair value of options vested during 2023 was $1.4 million. As of December 31, 2023, total unrecognized compensation costs to the unvested stock options were approximately $3.0 million, which is expected to be recognized over a weighted-average period of 2.5 years. The total intrinsic value of options exercised during the year ended December 31, 2023 was $0.1 million.

Stock-Based Compensation Expense

For purposes 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, 2023 and 2022 were as follows:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate range	3.59% – 4.67%	1.74% – 3.90%
Expected dividend rate	—	—
Expected term (years) range	5.08 – 6.12	5.94 – 6.11
Expected stock price volatility range	88.9% – 94.0%	85.9% – 88.9%

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 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 – As there has been no public market for the Company's common stock to date, the estimated fair value of its common stock has been 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, 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.

Stock-Based Compensation Expense

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

	Year Ended December 31,	
	2023	**2022**
Research and development	**$ 500**	$ 447
General and administrative	**929**	791
Total stock-based compensation expense	**$ 1,429**	$ 1,238

12. Agreements with Horizon

The Company entered into a Collaboration and Option Agreement (the Horizon Collaboration Agreement) and an Asset Purchase Agreement (the Purchase Agreement, collectively with the Horizon Collaboration Agreement, the Horizon Agreements) with Horizon Therapeutics Ireland DAC (Horizon) on August 12, 2022. Prior to the execution of the Horizon Agreements, the Company had completed a Phase 1 study for bempikibart (formerlyADX-914, a fully humanized, high affinity anti-inerleukin-7 receptor antagonist antibody) and was preparing to initiate two separate Phase 2 clinical trials. Under the terms of the Horizon Agreements, the Company was required to complete the two planned Phase 2 clinical trials as well as certain other development work agreed to by the parties. Horizon had the option to purchase bempikibart at any time up until the option termination date, which would have been shortly after the receipt of a data package from the second Phase 2 clinical trial. If Horizon had elected to exercise the option to acquire bempikibart, Horizon would have received all tangible and non-tangible assets related to bempikibart, including the assignment of the license the Company obtained from BMS (see Note 7) when it initially acquired the technology, and would have assumed liabilities associated with bempikibart, including payment obligations under the BMS license.

Per the terms of the Horizon Collaboration Agreement, the Company received a total of $55.0 million for initiation of certain development activities associated with the planned clinical trials and related activities. If

Horizon had exercised its option, the Company would have received a prespecified fee pursuant to the Purchase Agreement. The Company would also have been entitled to receive additional payment from Horizon based on the achievement of future development and regulatory milestones as well as royalty payments on annual net sales.

Horizon Termination Agreement

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 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.

Accounting Analysis

Prior to the termination agreement, the Company concluded the arrangement was within the scope of Topic 606. Specifically, the Company concluded that the research services required to be performed as part of the Horizon Collaboration Arrangement represented an output of the Company's ordinary activities, and this represents a contract with a customer. At the commencement of the collaboration arrangement with Horizon, the Company identified two performance obligations related to the development activities of bempikibart, one of each of the specified clinical trials, with each composing the services related to the clinical trial and other related development activities. The Company 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 Topic 606. The Company 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.

The following table summarizes the allocation of the transaction price allocated to each performance obligation (in thousands):

	Transaction Price
AD phase 2 research services	$ 25,417
AA phase 2 research services	18,265
Material right for the purchase of ADX-914	11,318
Total	$ 55,000

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. As of December 31, 2022, the Company had received $32.5 million of the $55.0 million transaction price from Horizon. The Company recognized $6.7 million of collaboration agreement revenue for the year ended December 31, 2022. As of December 31, 2023, the Company had received the full $55.0 million, which the 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, 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 the customer are not in exchange for a distinct good or service; therefore, the Company accounts for consideration payable to a customer 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 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 is not probable that the respective milestones will be achieved at this time.

13. Related Party Transactions

The Company has consulting and advisory agreements with certain investors and board members which are considered to be related party transactions. For the years ended December 31, 2023 and 2022, the Company recorded expense of zero and $87 thousand, respectively, related to services provided by these investors.

No amounts were due to related parties at December 31, 2023 or 2022.

14. 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.

15. Income Taxes

For the years ended December 31, 2023 and 2022, the Company recorded current and deferred income tax expense of $0.3 million and $62 thousand, respectively. The Company's effective tax rate of 0.6% differs from the U.S. statutory tax rate of 21.0% 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):

	Year Ended December 31,	
	2023	**2022**
Pretax loss:		
United States	**$ (53,430)**	$ (42,722)
Foreign	**5**	(25)
Loss before income taxes	**$ (53,425)**	$ (42,747)

The components of our provision for income taxes during the two years ended December 31, 2023, consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Current:		
Federal	**$316**	$—
State	**1**	—
Foreign	**1**	62
Total current	**318**	62
Deferred:		
Federal	**$—**	$—
State	—	—
Foreign	—	—
Total deferred	—	—
Total income tax provision	**$318**	$ 62

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:

	Year Ended December 31,	
	2023	2022
Federal income tax expense at statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	5.9	6.9
Permanent differences	(1.2)	(0.4)
Convertible note revaluation	(1.8)	0.0
Research and development tax credits	3.1	4.1
Change in valuation allowance	(27.6)	(31.6)
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):

	2023	2022
Deferred tax assets:		
Federal net operating loss carryforwards	**$ 13,412**	$ 19,135
State net operating loss carryforwards	**3,500**	5,401
Contingent liability	**14,876**	—
Accruals and Reserves	**818**	659
Capitalized intangible assets	**2,828**	3,089
Tax credit carryforwards	**5,762**	4,745
Capitalized R&D expenditures	**13,546**	7,378
Lease liability	**1,835**	1,962
Stock compensation and other	**544**	318
Total gross deferred tax assets before valuation allowance	57,121	42,687
Less: Valuation allowance	(55,078)	(40,342)
Net deferred tax assets	2,043	2,345
Deferred tax liabilities:		
Fixed assets	**(339)**	(483)
Right of use asset	**(1,704)**	(1,862)
Net deferred tax assets	**$ —**	$ —

The Company had gross deferred tax assets before valuation allowances of $57.1 million and $42.7 million as of December 31, 2023 and 2022, 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 $14.7 million during the year ended December 31, 2023 due primarily to the contingent liability related to the termination of Horizon agreements which was recorded in 2023.

As of December 31, 2023, the Company has $63.9 million of federal net operating loss carryforwards which can be carried forward indefinitely, and $55.4 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, 2023, the Company had federal and state research and development tax credit carryforwards of $4.3 million and $1.8 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. As a result of ownership changes in the Company from its inception through December 31, 2023, the Company's NOL and tax credit carryforwards allocable to the periods preceding each such ownership change could be subject to limitations under IRC Section 382, however the Company has not yet completed an IRC Section 382 study.

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 2020, although carryforward attributes that were generated prior to tax year 2020 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, 2023, 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, 2023, the Company had no gross unrecognized tax benefits. During 2022 the Company amended its prior year tax filings and settled the $1.4 million unrecognized tax benefit that was previously recognized in the December 31, 2021 reporting period. 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, 2023, the Company has not accrued penalties and provisions for interest.

16. Net Loss per Share

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding.

The Company's potentially dilutive securities, which include convertible preferred stock, convertible notes, and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2023	2022
Series A convertible preferred stock	47,628,788	47,628,788
Series A-1 convertible preferred stock	6,500,000	6,500,000
Series B convertible preferred stock:	54,689,627	54,689,627
Options to purchase common stock	23,165,393	22,997,639
Warrants to purchase common stock	377,899	166,371

In addition, during the year ended December 31, 2022, the Company issued convertible notes with a principal balance of $30.0 million. These convertible notes and any accrued interest may convert into either a variable number of common shares 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.

17. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the date the financial statements are available to be issued for potential recognition or disclosure in the financial statements. The Company has completed an evaluation of all subsequent events after the audited balance sheet date of December 31, 2023 through March 26, 2024, the date the financial statements were issued, to ensure that these financial statements include appropriate disclosure of events both recognized in the financial statements as of December 31, 2023 and events which occurred subsequently but were not recognized in the financial statements.

Amendment to Loan Agreement

On March 21, 2024, an eighth amendment to the Loan Agreement was entered into with the lender. The eighth amendment extends the time the Company has to receive the net proceeds to May 31, 2024 and also extends the time to Company can 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 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.

Merger with Homology

On March 25, 2024 the Company completed the Merger with Homology. See Note 1 for further discussion of the Merger.

Stock Option Grants

In March 2024, the Company granted under the 2024 Stock Option Plan, 0.9 million stock options to the officers, directors and other key members of management. Stock options were issued with an exercise price on the close of business on March 25, 2024. The stock option awards vest in accordance with terms typically grants under the 2024 Stock Option Plan.

Homology Medicines, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Homology Medicines, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Homology Medicines, Inc. and its subsidiary (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations incurred since inception, the expectation of continuing losses for the foreseeable future, and discontinuation of all clinical trials and research activities, as well as the Company's workforce reduction plan, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Matter

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

Equity method investment - Refer to Notes 1 and 6 to the financial statements

Critical Audit Matter Description

The Company uses the equity method of accounting to account for its investment in Oxford Biomedica (US) LLC, or OXB (US) LLC. The Company's proportionate share of the net income or loss of OXB (US) LLC is included in consolidated net loss within the caption, loss from equity method investment. During the year-ended December 31, 2023, OXB (US) LLC recorded an impairment of certain long-lived assets, resulting in the Company recording an incremental $14.0 million loss from equity method investment and reducing the balance of the equity method investment to $0 as of December 31, 2023, which required significant estimates and assumptions related to future revenue projections and the selection of a revenue multiplier used in the market approach model.

We identified the estimation of future revenue projections and the use of a revenue multiplier associated with the valuation of the related asset group of OXB (US) LLC as a critical audit matter due to the significant judgments required in both the estimation of future revenue and the selection of the revenue multiplier used in the market approach model. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of the estimates and assumptions related to the forecasts of future revenues and selection of revenue multipliers.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the estimates and assumptions utilized in the market approach model used for the impairment analysis included the following, among others:

- We (1) evaluated the reasonableness of the forecasts of future revenues by comparing those estimates to historical results and internal communications to management and the Board of Directors and (2) evaluated the reasonableness of the valuation methodology utilized in the fair value estimate.
- We read the audited financial statements of OXB (US) LLC as of and for the year ended December 31, 2023, audited in accordance with auditing standards generally accepted in the United States of America.
- We considered whether other information obtained during the course of our audit represented contradictory evidence in relation to selection of the revenue multiplier in the valuation model or the estimated revenue projections utilized in the model.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 12, 2024

We have served as the Company's auditor since 2017

HOMOLOGY MEDICINES, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 39,266	$ 33,986
Short-term investments	43,387	141,040
Assets held for sale	260	—
Prepaid expenses and other current assets	1,001	5,989
Total current assets	83,914	181,015
Equity method investment	—	25,814
Property and equipment, net	—	1,078
Right-of-use assets	650	20,563
Total assets	$ 84,564	$ 228,470
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,234	$ 1,144
Accrued expenses and other liabilities	7,021	18,715
Operating lease liabilities	1,318	1,561
Deferred revenue	—	1,156
Total current liabilities	11,573	22,576
Non-current liabilities:		
Operating lease liabilities, net of current portion	—	27,916
Total liabilities	11,573	50,492
Commitments and contingencies (Note 10)		—
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 58,017,412 and 57,483,910 shares issued and outstanding as of December 31, 2023 and 2022, respectively	6	6
Additional paid-in capital	615,088	607,513
Accumulated other comprehensive loss	(5)	(404)
Accumulated deficit	(542,098)	(429,137)
Total stockholders' equity	72,991	177,978
Total liabilities and stockholders' equity	$ 84,564	$ 228,470

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	For the Year ended December 31,	
	2023	2022
Collaboration revenue	$ 1,156	$ 3,208
Operating expenses:		
Research and development	62,002	98,351
General and administrative	31,256	38,138
Restructuring and other charges	9,327	—
Total operating expenses	102,585	136,489
Loss from operations	(101,429)	(133,281)
Other income:		
Gain on sale of business	—	131,249
Gain on lease termination	8,767	—
Interest income	5,582	3,230
Total other income	14,349	134,479
Income (loss) before income taxes	(87,080)	1,198
Provision for income taxes	—	(715)
Loss from equity method investment	(25,881)	(5,488)
Net loss	$ (112,961)	$ (5,005)
Net loss per share-basic and diluted	$ (1.95)	$ (0.09)
Weighted-average common shares outstanding-basic and diluted	57,834,819	57,399,762

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	For the Year ended December 31,	
	2023	2022
Net loss	$(112,961)	$(5,005)
Other comprehensive gain (loss):		
Change in unrealized gain (loss) on available for sale securities, net	399	(397)
Total other comprehensive gain (loss)	399	(397)
Comprehensive loss	$(112,562)	$(5,402)

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share amounts)

	Common Stock $0.0001 Par Value		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2022	57,150,274	$ 6	$593,784	$ (7)	$ (424,132)	$ 169,651
Issuance of common stock from RSU vesting	106,890	—	—	—	—	—
Issuance of common stock from option exercises	293	—	1	—	—	1
Issuance of common stock pursuant to employee stock purchase plan	226,453	—	595	—	—	595
Stock-based compensation	—	—	13,054	—	—	13,054
Stock-based compensation for equity method investee	—	—	79	—	—	79
Other comprehensive loss	—	—	—	(397)	—	(397)
Net loss	—	—	—	—	(5,005)	(5,005)
Balance at December 31, 2022	57,483,910	$ 6	$607,513	$ (404)	$ (429,137)	$ 177,978
Issuance of common stock from RSU vesting	373,519	—	—	—	—	—
Issuance of common stock from option exercises	26,166	—	16	—	—	16
Issuance of common stock pursuant to employee stock purchase plan	133,817	—	168	—	—	168
Stock-based compensation	—	—	7,324	—	—	7,324
Stock-based compensation for equity method investee	—	—	67	—	—	67
Other comprehensive gain	—	—	—	399	—	399
Net loss	—	—	—	—	(112,961)	(112,961)
Balance at December 31, 2023	58,017,412	$ 6	$615,088	$ (5)	$ (542,098)	$ 72,991

See notes to consolidated financial statements

HOMOLOGY MEDICINES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$(112,961)	$ (5,005)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	578	1,293
Noncash lease expense	2,065	1,306
Loss from equity method investment	25,881	5,488
Stock-based compensation expense	7,324	13,054
Accretion of discount on short-term investments	(2,948)	(1,947)
Non-cash gain on lease termination	(8,866)	—
(Gain) loss on disposal of property and equipment	(94)	49
Gain on sale of business	—	(131,249)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	4,988	840
Accounts payable	2,090	(981)
Accrued expenses and other liabilities	(11,686)	7,418
Deferred revenue	(1,156)	(3,208)
Operating lease liabilities	(1,445)	(719)
Net cash used in operating activities	(96,230)	(113,661)
Cash flows from investing activities:		
Purchases of short-term investments	(73,240)	(157,460)
Maturities of short-term investments	174,240	65,461
Proceeds from sale of business	—	130,000
Proceeds from sale of property and equipment	554	—
Purchases of property and equipment	(228)	(1,285)
Net cash provided by investing activities	101,326	36,716
Cash flows from financing activities:		
Proceeds from issuance of common stock pursuant to employee stock purchase plan	168	595
Proceeds from issuance of common stock from option exercises	16	1
Net cash provided by financing activities	184	596
Net change in cash, cash equivalents and restricted cash	5,280	(76,349)
Cash, cash equivalents and restricted cash, beginning of period	33,986	110,335
Cash, cash equivalents and restricted cash, end of period	$ 39,266	$ 33,986
Supplemental disclosures of noncash investing and financing activities:		
Lease liability settled through termination of lease	$ 28,338	$ —
Lease liability obtained in exchange for right-of-use asset	$ 1,625	$ —
Cash paid for income taxes	$ —	$ 720
Unrealized gain (loss) on available for sale securities, net	$ 399	$ (397)
Property and equipment additions included in accrued expenses and other liabilities	$ —	$ 8

See notes to consolidated financial statements.

HOMOLOGY MEDICINES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share amounts)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business-Homology Medicines, Inc. (the "Company" or "Homology") is a clinical-stage genetic medicines company historically focused on transforming the lives of patients suffering from rare diseases by addressing the underlying cause of the disease with one-time gene therapy and gene editing treatments. The Company was founded in March 2015 as a Delaware corporation. Its principal offices are in Bedford, Massachusetts.

On July 27, 2023, the Company announced that it had completed a review of its business and the Company's Board of Directors had approved a plan to explore, review and evaluate a range of potential strategic options available to the Company, including, without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. Based on the financing environment and the Company's anticipated clinical development timeline for its lead program, HMI-103, the Company also announced that it was stopping further development of its programs and reduced its workforce by 86% in an effort to significantly reduce its ongoing operating costs as it evaluated strategic alternatives. The workforce reduction was substantially completed in the third quarter of 2023 (see Note 9).

Agreement and Plan of Merger

After a comprehensive review of strategic alternatives, on November 16, 2023, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), with Q32 Bio Inc., a Delaware corporation ("Q32"), and Kenobi Merger Sub, Inc., a Delaware corporation and the Company's direct, wholly owned subsidiary ("Merger Sub"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Q32, with Q32 continuing as the Company's wholly owned subsidiary and the surviving corporation of the merger (the "Merger"). The Company's future operations are highly dependent on the success of the Merger and there can be no assurance that the Merger will be successfully consummated. If the Merger is completed, the business of Q32 will continue as the business of the combined company.

Merger Consideration

Subject to the terms and conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger (the "Effective Time"), all Q32 preferred stock will be converted into Q32 common stock pursuant to the organizational documents of Q32 (the "Q32 Preferred Stock Conversion"), and (ii) at the Effective Time, (a) each outstanding share of Q32 common stock (excluding Q32 common stock issued in the Concurrent Financing, as described below) will be converted into the right to receive a number of shares of the Company's common stock ("Company Common Stock"), calculated in accordance with the Merger Agreement, (b) each outstanding Q32 stock option and warrant that has not previously been exercised prior to the closing of the Merger will be assumed by the Company and become an option or warrant, as applicable, to purchase a number of shares of Company Common Stock and (c) the Q32 common stock issued in the Concurrent Financing will be converted into the right to receive a number of shares of the Company's Common Stock calculated in accordance with the Merger Agreement. The shares of Company Common Stock that will be issued to stockholders of Q32 will be calculated using a formula in the Merger Agreement based on the equity value of each of Q32 and the Company. Q32 has been ascribed an aggregate equity value of $195 million and the Company's equity value is expected to be approximately $80 million subject to adjustment based on the amount of net cash of the Company at closing of the Merger.

Concurrent Financing

Pursuant to the Merger Agreement, immediately prior to the Effective Time, Q32 will consummate a financing through the sale of its common stock for aggregate gross proceeds of $42 million based on the same aggregate

equity value of Q32 used in the Merger (the "Concurrent Financing"). On November 16, 2023, Q32 entered into subscription agreements with certain accredited investors (the "Investors") for the Concurrent Financing with expected gross proceeds to Q32 of $42 million. In connection with the Concurrent Financing, at the closing of the Merger, Q32 will enter into a registration rights agreement with the Investors providing for the registration under the Securities Act of 1933, as amended (the "Securities Act") of the shares of common stock sold in the Concurrent Financing. The consummation of the transactions contemplated by the subscription agreements is conditioned on the satisfaction or waiver of the conditions set forth in the Merger Agreement and in the subscription agreements. Shares of Q32 common stock issued pursuant to the Concurrent Financing will be converted into shares of Company Common Stock in the Merger in accordance with the Merger Agreement.

Contingent Value Rights Agreement

At the Effective Time, if any Legacy Assets (as defined below) have not been disposed of in a Legacy Asset Disposition (as defined below) or if additional consideration may be payable for the Legacy Assets (as defined below) after closing of the Merger, the Company and Equiniti Trust Company, LLC, a New York limited liability company, as the initial rights agent ("Rights Agent"), will enter into a Contingent Value Rights Agreement (the "CVR Agreement"), pursuant to which the Company's common stockholders of record as of the close of business on the last business day prior to the day on which the Effective Time occurs will receive one contingent value right (each, a "CVR") for each outstanding share of Company Common Stock held by such stockholder on such date.

Each CVR will represent 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 Company's HMI-103, HMI-204, Capsids and AAVHSC Platform, including any equity interests held directly or indirectly by the Company in Oxford Biomedica Solutions, LLC or its affiliates ("OXB Solutions") pursuant to that certain Equity Securities Purchase Agreement, dated as of January 28, 2022, by and between the Company and OXB Solutions (the "Legacy Assets" and such disposition, a "Legacy Asset Disposition"), net of certain tax, transaction costs and certain other expenses.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the holders of the CVRs. There can be no assurance that any holders of CVRs will receive payments with respect thereto. The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and will not be transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs will not be evidenced by a certificate or any other instrument and will not be registered with the Securities and Exchange Commission (the "SEC"). The CVRs will not have any voting or dividend rights and will not represent any equity or ownership interest in the Company or any of its affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

Other Recent Developments

On March 9, 2023, the Company filed a Registration Statement on Form S-3 (File No. 333-270414) (the "Shelf") with the SEC in relation to the registration of up to an aggregate of $250.0 million of its common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for a period up to three years from the date of the filing. The Shelf became effective on March 17, 2023. The Company also simultaneously entered into a sales agreement with Cowen and Company, LLC ("Cowen"), as sales agent, providing for the offering, issuance and sale by the Company of up to an aggregate of $75.0 million of its common stock from time to time in "at-the-market" offerings under the Shelf (the "ATM"). The Company did not sell any shares of common stock under the ATM during the year ended December 31, 2023. As of December 31, 2023, there remained $75.0 million of common stock available for sale under the ATM.

On March 10, 2022, the Company closed a transaction with Oxford Biomedica (US) LLC ("OXB (US)"), to establish a new adeno-associated virus ("AAV") vector manufacturing company, Oxford Biomedica (US) LLC ("OXB (US) LLC") that provides AAV vector process development and manufacturing services to biotechnology

companies. Under the terms of the agreement, the Company contributed its manufacturing team of 125 employees, manufacturing facility and equipment, manufacturing-related intellectual property and know-how and certain other assets. Oxford paid the Company $130.0 million of upfront cash and invested $50.0 million of cash to fund OXB (US) LLC in exchange for an 80 percent ownership interest, while Homology retained a 20 percent ownership interest in the new company and received a put option on this ownership position (see Note 6).

Since its inception and until recently, the Company has devoted substantially all of its resources to recruiting personnel, developing its technology platform and advancing its pipeline of product candidates through discovery, preclinical and clinical trials, developing and implementing manufacturing processes, building out manufacturing and research and development space, and maintaining and building its intellectual property portfolio. The Company is subject to a number of risks similar to those of other companies conducting high-risk, early-stage research and development of product candidates. Principal among these risks are dependency on key individuals and intellectual property, competition from other products and companies, and the technical and regulatory risks associated with the successful research, development and manufacturing of its product candidates.

To date, the Company has not generated any revenue from product sales and does not expect to generate any revenue from the sale of product in the foreseeable future. Through December 31, 2023, the Company has financed its operations primarily through public offerings of its common stock, the issuance of convertible preferred stock, and with proceeds from its transaction with Oxford (see Note 6), its collaboration and license agreement with a former collaboration partner and its private placement with Pfizer (see Note 17). During the year ended December 31, 2023, the Company incurred a loss from operations of $101.4 million and as of December 31, 2023, had $542.1 million in accumulated deficit.

The Company has incurred and expects to continue to incur costs and expenditures in connection with the process of evaluating strategic alternatives. Though the Company has executed the Merger Agreement with Q32 effective November 16, 2023, there can be no assurance that the Company will be able to successfully consummate the Merger or any other strategic transaction. The process of evaluating strategic options has been and may continue to be costly, time-consuming and complex and the Company may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges.

Based on current projections, management believes that the Company's cash and cash equivalents and short-term investments as of December 31, 2023 will enable the Company to continue its operations for at least one year from the date of this filing. However, due to the consideration of certain qualitative factors, including the discontinuation of all clinical trials and research activities, as well as the Company's workforce reduction of all but a few custodial employees, management has concluded there is substantial doubt regarding the Company's ability to continue as a going concern for more than twelve months from the date that the consolidated financial statements included in this Annual Report on Form 10-K have been issued. These financial statements do not include any adjustments that might result from the outcome of this uncertainty. Should the Company resume the development of product candidates, it would need to obtain substantial additional funding in connection with continuing operations, particularly if the Company were to resume its preclinical activities and clinical trials for its product candidates. There can be no assurance that the Company will be able to obtain sufficient capital to cover its costs on acceptable terms, if at all.

Basis of Presentation-The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation-The Company's consolidated financial statements include the accounts of the Company and its subsidiary, Homology Medicines Securities Corporation, a wholly owned Massachusetts

corporation, for the sole purpose of buying, selling, and holding securities on the Company's behalf. All intercompany balances and transactions have been eliminated in the consolidated financial statements.

Use of Estimates-The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, and expenses, and the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, accrued research and development expenses and the valuation of the Company's equity method investment. The Company assesses estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Comprehensive Loss -Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale investments.

Cash and Cash Equivalents and Restricted Cash-Cash and cash equivalents consist of standard checking accounts, money market accounts and certain investments. The Company considers all highly liquid investments with original or remaining maturities at the time of purchase of 90 days or less to be cash equivalents.

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

Concentrations of Credit Risk-Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. The Company believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses on these deposits. The Company regularly invest excess cash with major financial institutions in money market funds, U.S. government and corporate debt securities and commercial paper, all of which can be readily purchased and sold using established markets. As of December 31, 2023, the Company's cash and cash equivalents were held with two financial institutions. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated based on the fact that many of these securities are either government-backed or of high credit rating.

Equity Method Investment-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 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.

At December 31, 2023, the Company accounted for its investment in OXB (US) LLC using the equity method of accounting (see Note 6).

Offering Costs-The Company capitalizes incremental legal, professional accounting and other third-party fees that are directly associated with equity financings as other current assets until the transactions are completed. After equity financings are complete, these costs are recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering.

Leases- The Company determines if an arrangement is a lease at contract inception. The Company's contracts are determined to contain a lease when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company's lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis. The expected lease term includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option. Variable lease cost is recognized as incurred. Right-of-use assets are periodically evaluated for impairment.

The Company subleases a portion of its headquarters that is now occupied by OXB (US) LLC (see Note 18). Homology assigned all of its right, title and interest in, to and under this lease to OXB (US) LLC and effective October 1, 2023, the Company was released from being the primary obligor under such lease. Therefore, the related right-of-use asset and operating lease liability were derecognized as of October 1, 2023 and a new right-of-use asset and operating lease liability representing the present value of the future sublease payments to be made to OXB (US) LLC was recorded (see Note 10).

Guarantees and Indemnifications-As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2023, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related liabilities have been established.

Property and Equipment-Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred. When assets are retired or disposed of, the assets and related accumulated depreciation are derecognized from the accounts, and any resulting gain or loss is included in the determination of net loss. Depreciation is provided using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.

Computer equipment and software	3 years
Laboratory equipment and office furniture	5 years
Manufacturing equipment	5 - 7 years
Leasehold improvements	Shorter of the lease term or estimated useful life

Assets Held for Sale-The Company classifies assets as held for sale when the following conditions are met: (1) management has committed to a plan to sell, (2) the assets are available for immediate sale in their present condition, (3) the Company has initiated an active program to identify a buyer, (4) it is probable that a sale will occur within one year, (5) the assets are actively marketed for sale at a reasonable price in relation to their current fair value, and (6) there is a low likelihood of significant changes to the plan or that the plan will be withdrawn. If all of the criteria are met as of the balance sheet date, the assets are presented separately in the consolidated balance sheet as held for sale at the lower of the carrying amount or fair value less costs to sell. The assets are then no longer depreciated or amortized while classified as held for sale.

Impairment of Long-Lived Assets-The Company evaluates its long-lived assets, which consist primarily of property and equipment and right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. To date, no impairments have been recognized for these assets.

Research and Development Costs-Research and development costs are charged to expense as incurred. Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical and clinical expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses.

Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expense or accrued research and development expense.

Income Taxes-The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the year in which the differences are expected to

reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. Since inception, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the net deferred tax assets has not been determined to be more likely than not.

Segment Information-Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's President and Chief Operating Officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is dedicated to translating proprietary gene editing and gene therapy technology into novel treatments for patients with rare genetic diseases. All of the Company's tangible assets are held in the United States.

Revenue Recognition- Revenue is recognized in accordance with FASB Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements would likely consist of a license, rights to the Company's intellectual property or research, development and manufacturing services. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of consideration to which the Company expects to be entitled to. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts may include development and regulatory milestone payments that are assessed under the most likely amount method and constrained until it is probable that a significant revenue reversal would not occur. Milestone payments that are not within the Company's control, such as regulatory approvals, are not

considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and regulatory milestones and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from the Company's collaboration arrangement.

The Company allocates the transaction price based on the estimated standalone selling price of each performance obligation. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress for its over-time arrangements at each reporting period and, if necessary, updates the measure of progress and revenue recognized.

Stock-based Compensation-The Company recognizes compensation expense for awards to employees and non-employees based on the grant date fair value of stock-based awards on a straight-line basis over the period during which an award holder provides service in exchange for the award. The fair value of options on the date of grant is calculated using the Black-Scholes option pricing model based on key assumptions such as stock price, expected volatility and expected term. The Company's estimates of these assumptions are primarily based on the trading price of the Company's stock, historical data, peer company data and judgment regarding future trends and factors. The Company recognizes forfeitures as they occur.

The purchase price of common stock under the Company's employee stock purchase plan ("ESPP") is equal to 85% of the lesser of (i) the fair market value per share of the common stock on the first business day of an offering period and (ii) the fair market value per share of the common stock on the purchase date. The fair value of the look-back provision under the ESPP is calculated using the Black-Scholes option pricing model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the 180-day purchase period.

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

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

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

Net Loss per Share-Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, restricted stock units and unvested shares of common stock.

Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recent Accounting Pronouncements-The Jumpstart Our Business Startups Act of 2012 permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company ceased to qualify as an emerging growth company effective December 31, 2023.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13") to improve financial reporting by requiring more timely recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. ASU 2016-13 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help investors and other financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization's portfolio. The Company adopted ASU 2016-13 on January 1, 2023. The adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements and related disclosures.

3. CASH AND CASH EQUIVALENTS

From time to time, the Company may have cash balances in financial institutions in excess of federal deposit insurance limits. The Company has never experienced any losses related to these balances. The Company considers only those investments that are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents.

The following table summarizes the Company's cash and cash equivalents:

	December 31,	
	2023	2022
	(in thousands)	
Cash	$ 749	$ 19
Money market funds	38,517	33,967
Total cash and cash equivalents	$ 39,266	$ 33,986

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 following table summarizes the Company's short-term investments as of December 31, 2023 and December 31, 2022:

As of December 31, 2023	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
US Treasury securities	$ 31,817	$ 6	$ (5)	$ 31,818
Corporate debt securities	11,575	—	(6)	11,569
Total	$ 43,392	$ 6	$ (11)	$ 43,387

As of December 31, 2022	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
Commercial paper	$ 57,138	$ —	$ —	$ 57,138
US Treasury securities	65,160	—	(335)	64,825
Corporate debt securities	19,146	—	(69)	19,077
Total	$141,444	$ —	$ (404)	$141,040

The Company utilizes the specific identification method in computing realized gains and losses. The Company had no realized gains and losses on its available-for-sale securities for the years ended December 31, 2023 and 2022. The contractual maturity dates of all of the Company's investments are less than one year.

5. FAIR VALUE MEASUREMENTS

The Company's financial instruments consist of cash and cash equivalents, short-term investments, restricted cash and accounts payable. The carrying amount of cash, restricted cash and accounts payable are each considered a reasonable estimate of fair value due to the short-term maturity.

Assets measured at fair value on a recurring basis were as follows:

Description	December 31, 2023	Quoted Prices (Unadjusted) in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Cash equivalents:				
Money market mutual funds	$ 38,517	$ 38,517	$ —	$ —
Total cash equivalents	$ 38,517	$ 38,517	$ —	$ —
Short-term investments:				
US Treasury securities	31,818	—	31,818	—
Corporate debt securities	11,569	—	11,569	—
Total short-term investments	$ 43,387	$ —	$ 43,387	$ —
Total financial assets	$ 81,904	$ 38,517	$ 43,387	$ —

Description	December 31, 2022	Quoted Prices (Unadjusted) in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Cash equivalents:				
Money market mutual funds	$ 33,967	$ 33,967	$ —	$ —
Total cash equivalents	$ 33,967	$ 33,967	$ —	$ —
Short-term investments:				
Commercial paper	$ 57,138	$ —	$ 57,138	$ —
US Treasury securities	64,825	—	64,825	—
Corporate debt securities	19,077	—	19,077	—
Total short-term investments	$ 141,040	$ —	$ 141,040	$ —
Total financial assets	$ 175,007	$ 33,967	$ 141,040	$ —

Short-term securities are valued using models or other valuation methodologies that use Level 2 inputs. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, default rates, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

There were no transfers between fair value measurement levels during the years ended December 31, 2023 and 2022.

6. EQUITY METHOD INVESTMENT

Summary of Transaction

On March 10, 2022, the Company closed a transaction with OXB (US) LLC, Oxford Biomedica (US), Inc., ("OXB"), and Oxford, pursuant to the Equity Securities Purchase Agreement (the "Purchase Agreement"), dated as of January 28, 2022, by and among Homology, OXB (US) LLC and Oxford, whereby, among other things, Homology and Oxford agreed to collaborate to operate OXB (US) LLC, which provides AAV vector process development and manufacturing services to pharmaceutical and biotechnology companies (the "OXB (US) LLC Transaction").

Pursuant to the terms of the Purchase Agreement and a contribution agreement (the "Contribution Agreement") entered into between Homology and OXB (US) LLC prior to the closing of the OXB (US) LLC Transaction (the "Closing"), Homology contributed its manufacturing team of 125 employees and assigned and transferred to OXB (US) LLC all of its assets that are primarily used in the manufacturing of AAV vectors for use in gene therapy and gene editing products, including its manufacturing facility and equipment and manufacturing-related intellectual property and know-how, but excluding certain assets related to manufacturing or testing of Homology's proprietary AAV vectors (collectively, the "Transferred Assets"), in exchange for 175,000 common equity units in OXB (US) LLC ("Units"), representing 100 percent (100%) of the ownership interest of OXB (US) LLC, and OXB (US) LLC assumed from the Company, and agreed to pay, perform and discharge when due, all of the Company's duties, obligations, liabilities, interests and commitments of any kind under, arising out of or relating to the Transferred Assets.

Effective as of the Closing, Homology sold to OXB, and OXB purchased from Homology, 130,000 Units, (the "Transferred Units") in exchange for $130.0 million of cash consideration. In connection with the Closing, OXB contributed $50.0 million in cash to OXB (US) LLC in exchange for an additional, newly issued 50,000 Units. Immediately following the Closing, (i) OXB owned 180,000 Units, representing 80 percent (80%) of the fully

diluted equity interests in OXB (US) LLC, and (ii) Homology owned 45,000 Units, representing 20 percent (20%) of the fully diluted equity interests in OXB (US) LLC.

Pursuant to the Amended and Restated Limited Liability Company Agreement of OXB (US) LLC (the "OXB (US) LLC Operating Agreement") which was executed in connection with the Closing, at any time following the three-year anniversary of the Closing, (i) OXB will have an option to cause Homology to sell and transfer to OXB, and (ii) Homology will have an option to cause OXB to purchase from Homology, in each case all of Homology's equity ownership interest in OXB (US) LLC at a price equal to 5.5 times the revenue for the immediately preceding 12-month period (together, the "Options"), subject to a maximum amount of $74.1 million. Pursuant to the terms of the OXB (US) LLC Operating Agreement, Homology is entitled to designate one director to the board of directors of OXB (US) LLC, currently Paul Alloway, Homology's President and Chief Operating Officer.

Pursuant to the OXB (US) LLC Transaction, the Company also assigned all of its right, title and interest in, to and under its facility lease to OXB (US) LLC, with Homology subleasing a portion of lab and office space back from OXB (US) LLC. Effective October 1, 2023, the Company was released from being primary obligor under such lease. Therefore, the related right-of-use asset and operating lease liability were derecognized as of October 1, 2023 and a new right-of-use asset and operating lease liability representing the present value of the future sublease payments to be made to OXB (US) LLC was recorded (see Note 10).

Equity Method of Accounting

The Company has significant influence over, but does not control, OXB (US) LLC through its noncontrolling representation on OXB's board of directors and the Company's equity interest in OXB (US) LLC. In addition, the Company and OXB (US) LLC have intra-entity transactions through a series of agreements entered into in conjunction with the OXB (US) LLC Transaction, OXB (US) LLC granted certain licenses to the Company, and the Company has representation on the joint steering committee which oversees the activities governed by the Supply Agreement. Accordingly, the Company does not consolidate the financial statements of OXB (US) LLC and accounts for its investment using the equity method of accounting.

The Company recorded its equity method investment in OXB (US) LLC at fair value upon deconsolidation of OXB (US) LLC as of the Closing. 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 using the consideration paid, including the Options, 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 common equity units 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. The valuation included certain subjective assumptions including discounts for lack of control and marketability given the consideration paid for OXB (US) LLC was for a controlling interest in the entity and the Company owns a noncontrolling interest.

As of March 10, 2022, the Closing, the fair value of the Company's investment in OXB (US) LLC was $31.2 million and the Company recorded a gain of $131.2 million on the sale of its manufacturing business in other income in the Company's consolidated statements of operations. The gain was computed as follows:

(in thousands)	March 10, 2022
Cash received	$ 130,000
Plus: Fair value of equity method investment	31,223
Less: Carrying value of transferred assets	(29,974)
Gain on sale of business	$ 131,249

During the year ended December 31, 2023, the Company determined that the fair value of its investment in OXB (US) LLC was negatively impacted due to a change in OXB (US) LLC' forecasted performance relative to expected performance when the Company initially invested in OXB (US) LLC. The Company determined that

the decline in value was deemed to be other than temporary and recorded an impairment charge of $3.8 million to reduce its equity method investment to fair value. The impairment charge is included in the loss on equity method investment in the Company's consolidated statements of operations.

In addition, the Company records its share of income or losses from OXB (US) LLC on a quarterly basis. For the year ended December 31, 2023, OXB (US) LLC recorded an impairment charge of $119.1 million which significantly increased OXB (US) LLC's net loss for the period. After recording its share of OXB (US) LLC's net loss, the carrying value of the Company's equity method investment was reduced to $0.0 million.

Summarized Financial Information

Summarized financial information for OXB (US) LLC is as follows:

	December 31,	
	2023	2022
Balance Sheet Data	(in thousands)	
Current assets	$10,763	$ 39,237
Noncurrent assets	$74,461	$228,745
Current liabilities	$ 6,151	$ 12,352
Noncurrent liabilities	$42,835	$ 37,718

	December 31,	
	2023	2022
Statement of Operations Data	(in thousands)	
Revenues	$ 30,699	$29,380
Net loss	$167,062	$29,036

See Note 18 for information regarding the Company's related party transactions with OXB (US) LLC.

7. PROPERTY AND EQUIPMENT

Property and equipment, net consists of the following:

	December 31,	
	2023	2022
	(in thousands)	
Laboratory equipment	$—	$ 6,025
Computers and purchased software	—	644
Furniture and fixtures	—	645
Property and equipment, at cost	—	7,314
Less: accumulated depreciation and amortization	—	(6,236)
Property and equipment, net	$—	$ 1,078

In August 2023, consistent with its decision to stop further development of its programs and explore, review and evaluate a range of potential strategic options available to the Company, the Company committed to a plan to sell its remaining property and equipment and therefore has classified the amount as assets held for sale on the consolidated balance sheet as of December 31, 2023. The assets held for sale were reported at the lower of the carrying amount or fair value with no depreciation expense taken after August 2023. The Company expects to dispose of all assets held for sale during the first quarter of 2024.

Depreciation expense for the years ended December 31, 2023 and 2022 was approximately $0.6 million and $1.3 million, respectively. The Company disposed of approximately $0.5 million and $0.1 million of property and equipment, net during each of the years ended December 31, 2023 and 2022, respectively.

8. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following:

	December 31,	
	2023	2022
	(in thousands)	
Accrued compensation and benefits	$5,755	$ 5,953
Accrued research and development expenses	—	9,447
Accrued professional fees	941	1,052
Accrued other	325	2,263
Total accrued expenses and other liabilities	$7,021	$18,715

Accrued compensation and benefits includes a restructuring accrual for severance and related costs of approximately $4.6 million (see Note 9).

9. RESTRUCTURING AND OTHER CHARGES

On July 25, 2023, the Company's Board of Directors approved a process to explore, review and evaluate a range of potential strategic options available to the Company, including, without limitation, an acquisition, merger, reverse merger, sale of assets, strategic partnerships or other transactions. Therefore, based on cost-reduction initiatives intended to reduce the Company's ongoing operating expenses and maximize shareholder value as the Company plans to pursue strategic options, the Company's Board of Directors approved a reduction in the Company's workforce by approximately 80 employees, or 86% of the Company's workforce as of July 2023. Simultaneous with the signing of the Merger Agreement, the Company terminated another 6 employees in November 2023.

In connection with the reduction in force, the Company recorded a restructuring charge for severance and related costs of $10.3 million in the Company's consolidated statements of operations during the year ended December 31, 2023. The Company's restructuring liability, which was included in accrued compensation and benefits, consisted of the following:

(in thousands)	Employee-Related Costs
Accrued restructuring balance at January 1, 2023	$ —
Expenses incurred	10,279
Payments	(5,666)
Accrued restructuring balance at December 31, 2023	$ 4,613

The Company had previously granted certain of the terminated employees restricted stock units ("RSUs") that vest in annual installments based on continued service to the Company, as well as options to purchase shares of the Company's common stock that typically vest over a period of four years. In connection with the reduction in workforce, the Company agreed to accelerate the vesting of a portion of the RSUs that were unvested as of the employees' termination dates, and also modify the stock options for terminated employees such that subject to the satisfaction of severance conditions, the terminated employees' vested options will remain outstanding and exercisable until the first anniversary of each employee's termination date. These equity modifications, described in detail in Note 14, resulted in a net reduction to stock based compensation expense of approximately $1.0 million reflected within restructuring and other charges in the Company's consolidated statements of operations during the year ended December 31, 2023.

10. COMMITMENTS AND CONTINGENCIES

Operating Leases-In December 2017, the Company entered into a noncancelable operating lease for approximately 67,000 square feet of research and development, manufacturing and general office space in

Bedford, Massachusetts. Prior to a subsequent amendment described below, the lease was set to expire in February 2027 with an option for an additional five-year term. Rent became due under the lease in two phases; rent on the first 46,000 square feet started in September 2018 and rent on the remaining 21,000 square feet started in March 2019. The initial annual base rent was $39.50 per square foot and increases by three percent annually. The Company is obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises. The lease agreement allowed for a tenant improvement allowance not to exceed $10.9 million, which the Company received in full, to be applied to the total cost of tenant improvements to the leased premises. The unamortized balance of the tenant improvement allowance was included in deferred rent incentives and recorded as a reduction to operating right-of-use asset upon adoption of the new leasing standards.

In November 2021, the Company entered into an amendment of its December 2017 lease agreement (the "Lease Amendment") for its corporate headquarters in Bedford, Massachusetts. The Lease Amendment increased the space under lease by approximately 23,011 square feet (the "Expansion Premises") and extended the expiration date of the existing premises under the lease from February 2027 to June 2030. The payment term with respect to the Expansion Premises commenced on May 1, 2022, and continues for a period of ten years and five months. The term of the Expansion Premises and the existing premises are not coterminous. Annual base rent for the existing premise under the Lease Amendment is approximately $4.7 million beginning on March 1, 2027, and increases by three percent annually; annual base rent for the Expansion Premises is approximately $1.4 million per year and increases by three percent annually. The Lease Amendment allows for tenant improvement allowances not to exceed $6.3 million in the aggregate. The Lease Amendment was accounted for as a lease modification and the right-of-use asset and operating lease liability for the existing premises were remeasured at the modification date, which resulted in an increase of $10.9 million to both the right-of-use asset and operating lease liabilities. In February 2022, the Company revised its assumption for when it expected to utilize the tenant improvement allowances. This change in assumption was accounted for as a lease modification and the right-of-use asset and operating lease liability for the existing premises were remeasured at the modification date, which resulted in an increase of $0.2 million to both the right-of-use asset and operating lease liabilities.

In March 2022, in accordance with its transaction with OXB (US) LLC, the Company assigned all of its right, title and interest in, to and under its corporate headquarters lease to OXB (US) LLC and entered into a sublease agreement whereby OXB (US) LLC subleased certain premises in its facility to Homology. However, as the Company remained jointly and severally liable for the payment of rent under this lease, the Company was not released from being the primary obligor and therefore the related right-of-use asset and lease liability were not derecognized and remained on the Company's balance sheet.

In September 2022, the Company concluded that 100% of the tenant improvement allowances would be utilized by OXB (US) LLC. This change in assumption was accounted for as a lease modification and the right-of-use asset and operating lease liability for the existing premises were remeasured at the modification date, which resulted in an increase of $6.1 million to both the right-of-use asset and operating lease liabilities.

On September 25, 2023, the Company signed and executed a release letter with its lessor related to its corporate headquarters lease. The lessor agreed to release the Company of all obligations under the lease effective October 1, 2023 (the "Release Date") in exchange for a $0.1 million cash payment. On October 1, 2023, the Company derecognized the right-of-use asset and operating lease liability and recorded the difference as a gain of $8.8 million within other income on the consolidated statements of operations. Because the Company's sublease agreement with OXB (US) LLC remains in effect after termination of the head lease, the Company recorded a new right-of-use asset and an operating lease liability of $1.6 million, which equals the present value of the future sublease payments owed to OXB (US) LLC for the remaining term of the sublease. The Company's sublease expires on December 31, 2024.

During the fourth quarter of fiscal year 2023, the Company significantly reduced active use of its corporate headquarters, with the plan to fully abandon the space in the first quarter of fiscal year 2024. Accordingly, the Company shortened the remaining useful of its right-of-use asset to equal the time remaining until the planned abandonment date. This had no impact on the operating lease liability.

Prior to being released from obligation under the lease, the Company was acting as sublessor to OXB (US) LLC for accounting purposes. For the years ended December 31, 2023 and 2022, the Company received $2.3 million and $2.0 million, respectively, in sublease payments from OXB (US) LLC, which was recorded as a reduction to lease cost.

The following table summarizes operating lease costs and variable lease costs, as well as sublease income:

	For the Year ended December 31,	
	2023	2022
	(in thousands)	
Operating lease costs	$ 4,273	$ 3,913
Variable lease costs	1,771	2,142
Sublease income	(2,312)	(1,979)
Net lease cost	$ 3,732	$ 4,076

The maturities of the Company's operating lease liabilities and minimum lease payments as of December 31, 2023 were as follows:

For the Years Ending December 31,	Amount (in thousands)
2024	$ 1,380
Total undiscounted lease payments	$ 1,380
Less: imputed interest	(62)
Present value of operating lease liabilities	$ 1,318

The following table summarizes the lease term and discount rate as of December 31, 2023:

	December 31, 2023
Weighted-average remaining lease term (years)	
Operating leases	1.0
Weighted-average discount rate	
Operating leases	10.5%

The following table summarizes the supplemental cash flow information related to the Company's operating leases:

	For the Year ended December 31,	
	2023	2022
	(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities	$3,653	$3,326
Increase in lease liabilities and right-of-use assets due to lease remeasurements	$ —	$6,262

Legal Proceedings-On March 25, 2022, the Company and certain of its executives were named as defendants in a putative securities class action lawsuit filed in the United States District Court for the Central District of California; Pizzuto v. Homology Medicines, Inc., No. 2:22-CV-01968 (C.D. Cal 2022). The complaint alleges that the Company failed to disclose certain information regarding efficacy and safety in connection with a Phase I/II HMI-102 clinical trial, and seeks damages in an unspecified amount. The case is in its early stages. The Company believes the claims alleged lack merit and has filed a motion to transfer venue (filed September 2, 2022) and a motion to dismiss (filed October 17, 2022). On April 18, 2023, the court granted the motion to transfer, finding that venue was not proper in the Central District of California and transferring the case to the District of Massachusetts. Following the transfer, the case number changed to 1:23-cv-10858-AK (D. Mass.). On May 9, 2023, the Massachusetts court issued an order permitting the parties to submit updated briefs in

connection with the motion to dismiss, which were submitted on June 8, 2023, July 13, 2023, and August 3, 2023. On March 4, 2024, the Massachusetts court held oral argument on the Company's motion to dismiss, which remains pending. As the outcome is not presently determinable, any loss is neither probable nor reasonably estimable.

On February 22, 2024, a purported stockholder of the Company, Kevin Welsh, filed a putative class action complaint against the Company and its directors related to the Company's proposed Merger with Q32, alleging violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, as amended. Welsh v. Homology Medicines, Inc., No. 1:24-cv-00242 (D. Del.). The complaint alleges that the Company and its directors filed a proxy statement containing material omissions regarding financial forecasts and their respective analysis, and seeks damages in an unspecified amount. The case is in its early stages. The Company believes the claims alleged lack merit. As the outcome is not presently determinable, any loss is neither probable nor reasonably estimable.

11. LICENSE AGREEMENTS

City of Hope

In April 2016, the Company entered into an exclusive license agreement with City of Hope, or COH, an academic research and medical center. COH granted the Company an exclusive, sublicensable, worldwide license, or the COH License, to certain AAV vector-related patents and know-how owned by COH to develop, manufacture, use and commercialize products and services covered by such patents and know-how in any and all fields.

The Company is required to pay an annual license fee of $25,000, reimburse COH for patent costs incurred, pay amounts up to $3.2 million upon the achievement of certain development and commercialization milestones for each product under the license, pay royalties on future sales in the low single-digits and royalties on sublicense revenue in the low double-digits, if any. Other than the annual license fee, there were no payments to COH in 2022. In January 2023, the Company paid $50,000 to COH upon dosing the first patient in the pheEDIT Phase 1 clinical trial.

On August 6, 2021, the Company received notice from COH that it did not accomplish at least one of the partnering milestones by the applicable deadline, as set forth in the COH License. This notice does not affect the Company's exclusive license in the field of mammalian therapeutics, including all human therapeutics, associated diagnostics, and target validation, or the Mammalian Therapeutic Field, where the Company retains exclusive rights. Instead, the notice served as written notice that the exclusive license granted pursuant to the COH License in all fields except the Mammalian Therapeutic Field converted from exclusive to non-exclusive effective as of September 20, 2021, which was forty-five days from the receipt of notice. In connection with the conversion, any royalty obligations and sublicensee fees relating to fields outside of the Mammalian Therapeutic Field shall be reduced by a certain percentage. This change to the Company's exclusive worldwide license with COH does not impact any of its product candidates, including HMI-102, HMI-103, HMI-104, HMI-203 and HMI-204.

12. INCOME TAXES

Provision for income taxes consists of the following:

	For the Year ended December 31,	
	2023	2022
	(in thousands)	
Federal tax provision:		
Current	$ —	$ 698
Deferred	—	—
Total federal tax provision	—	698
State tax provision:		
Current	—	17
Deferred	—	—
Total state tax provision	—	17
Total tax provision	$ —	$ 715

A reconciliation between the U.S. federal statutory tax and the Company's tax provision is summarized below.

	For the Year ended December 31,	
	2023	2022
	(in thousands)	
Federal statutory rate	$ (23,722)	$ (901)
Tax credits	(7,699)	(13,955)
State taxes, net of federal tax benefit	(8,496)	(2,994)
Non-deductible expenses	595	875
Other	(2,351)	1,410
Change in valuation allowance	41,673	16,280
Tax provision	$ —	$ 715

The principal components of the Company's deferred tax assets and liabilities consist of the following:

	For the Year ended December 31,	
	2023	2022
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 88,552	$ 76,735
R&D credits	79,094	66,761
Equity compensation	8,215	7,888
Operating lease liabilities	356	8,003
Accrued expense and other	9,351	1,479
Deferred revenue	—	314
Capitalized R&D costs	35,987	24,477
Total deferred tax assets	221,555	185,657
Deferred tax liabilities:		
Right-of-use assets	(176)	(5,583)
Depreciation	(54)	(171)
Other	—	(251)
Total deferred tax liabilities	(230)	(6,005)
Valuation allowance	(221,325)	(179,652)
Net deferred taxes	$ —	$ —

The Company recorded an income tax provision of $0.7 million for the year ended December 31, 2022. This prior year-to-date tax provision predominately resulted from the gain associated with the sale of the Company's manufacturing business due to the transaction with Oxford (see Note 6), offset by available federal and state net operating loss carryforwards and research and development tax credits which are subject to certain limitations as to their utilization. The Company did not record an income tax provision (benefit) for the year ended December 31, 2023.

At December 31, 2023, the Company had $326.2 million and $317.3 million of federal and state net operating loss carryforwards, respectively. Federal net operating loss carryforwards of $0.4 million, generated before 2018, will begin expiring in varying amounts through 2035 unless utilized. The remaining federal net operating loss carryforwards of $325.8 million, generated after 2017, will be carried forward indefinitely. The state net operating losses will begin expiring in varying amounts through 2043 unless utilized. At December 31, 2023, the Company had $65.5 million and $17.2 million of federal and state research and development credit carryforwards, respectively, that expire at various dates through 2043. Included in the $65.5 million of federal research and development credit carryforwards is $50.7 million of orphan drug credit carryforwards.

A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. A roll forward of the valuation allowance is as follows:

(in thousands)	Valuation Allowance
Balance at December 31, 2022	$(179,652)
Utilization of net operating losses against taxable income	—
Increase in net deferred taxes	(41,673)
Balance at December 31, 2023	$(221,325)

For all years through December 31, 2023, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards. Since a full valuation allowance has been provided against the Company's research and development credits, any reduction in the gross deferred tax asset established for the research and development credit carryforwards would not result in any net impact to the Company's consolidated financial statements.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards that could be used annually to offset future taxable income. The Company completed a study to assess ownership changes through December 31, 2021. Based on this analysis, the net operating losses are limited but the Company does not believe that any of its net operating losses or research and development credit carryforwards will expire unutilized due to Section 382 limitations.

The Company files tax returns in the United States, Massachusetts and several other states. All tax years since inception remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

As of December 31, 2023, the Company had no uncertain tax positions. The Company has elected to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2023 and 2022.

13. STOCKHOLDERS' EQUITY

Common Stock-Voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Voting-Each holder of outstanding shares of common stock are entitled to one vote in respect of each share. The holders of outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

Dividends-Subject to the payment in full of any preferential dividends to which the holders of preferred stock are entitled, the holders of common stock shall be entitled to receive dividends out of funds legally available therefore at such times and in such amounts as the Board of Directors may determine in its sole discretion.

Liquidation Rights-In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, after the payment or provision for payment of all debts and liabilities of the Company and any preferential amounts to which the holders of preferred stock are entitled with respect to the distribution of assets in liquidation, the holders of common stock shall be entitled to share ratably in the remaining assets of the Company available for distribution.

There were 58,017,412 and 57,483,910 shares of common stock outstanding at December 31, 2023 and 2022, respectively.

Preferred Stock-As of December 31, 2023 and 2022, there were no shares of preferred stock issued and outstanding.

14. STOCK INCENTIVE PLANS

2015 Stock Incentive Plan

In December 2015, the Company's Board of Directors adopted the 2015 Stock Incentive Plan (the "2015 Plan"), which provided for the grant of incentive stock options, nonqualified stock options and restricted stock awards to the Company's employees, officers, directors, advisors, and outside consultants. Stock options granted under the 2015 Plan generally vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the 2015 Plan. At December 31, 2023, there were no additional shares available for future grant under the 2015 Plan.

2018 Incentive Award Plan

In March 2018, the Company's Board of Directors adopted and the Company's stockholders approved the Homology Medicines, Inc. 2018 Incentive Award Plan (the "2018 Plan" and, together with the 2015 Plan, the "Plans"), which became effective on the day prior to the first public trading date of the Company's common stock. Upon effectiveness of the 2018 Plan, the Company ceased granting new awards under the 2015 Plan.

The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock or cash-based awards to employees and consultants of the Company and certain affiliates and directors of the Company. The number of shares of

common stock initially available for issuance under the 2018 Plan was 3,186,205 shares of common stock plus the number of shares subject to awards outstanding under the 2015 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company on or after the effective date of the 2018 Plan. In addition, the number of shares of common stock available for issuance under the 2018 Plan is subject to an annual increase on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028 equal to the lesser of (i) 4% of the Company's outstanding shares of common stock on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Company's Board of Directors, provided that not more than 20,887,347 shares of common stock may be issued under the 2018 Plan upon the exercise of incentive stock options. As of December 31, 2023, there were 4,978,083 shares available for future grant under the 2018 Plan. On January 1, 2024, an additional 2,320,696 shares were added to the 2018 Plan, representing 4% of total common shares outstanding at December 31, 2023.

2018 Employee Stock Purchase Plan

In March 2018, the Company's Board of Directors adopted, and the Company's stockholders approved, the Homology Medicines, Inc. 2018 Employee Stock Purchase Plan (the "2018 ESPP"). The 2018 ESPP allows employees to buy Company stock through after-tax payroll deductions at a discount from market value. The 2018 ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code. The number of shares of common stock initially available for issuance under the 2018 ESPP was 353,980 shares of common stock plus an annual increase on the first day of each calendar year beginning on January 1, 2019 and ending on and including January 1, 2028 equal to the lesser of (i) 1% of the Company's outstanding shares of common stock on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Company's Board of Directors, provided that not more than 4,778,738 shares of common stock may be issued under the 2018 ESPP. As of December 31, 2023, there were 2,693,911 shares available for future grant under the 2018 ESPP. On January 1, 2024, an additional 580,174 shares were added to the 2018 ESPP, representing 1% of total common shares outstanding at December 31, 2023.

Under the 2018 ESPP, employees may purchase common stock through after-tax payroll deductions at a price equal to 85% of the lower of the fair market value on the first trading day of an offering period or the last trading day of an offering period. The 2018 ESPP generally provides for offering periods of six months in duration that end on the final trading day of each February and August. In accordance with the Internal Revenue Code, no employee will be permitted to accrue the right to purchase stock under the 2018 ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of the Company's common stock as of the first day of the offering period).

During the year ended December 31, 2023, 133,817 shares were issued under the 2018 ESPP for aggregate proceeds to the Company of $0.2 million. During the year ended December 31, 2022, 226,453 shares were issued under the 2018 ESPP for aggregate proceeds to the Company of $0.6 million. Pursuant to the 2018 ESPP, the Company recorded stock-based compensation of less than $0.1 million for each of the years ended December 31, 2023 and 2022, respectively.

Stock Options

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model, with the assumptions noted in the table below. Expected volatility for the Company's common stock was determined based on an average of the historical volatility of a peer group of publicly traded companies that are similar to the Company. The expected term of options was calculated using the simplified method, which represents the average of the contractual term of the option and the weighted-average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free rate is based on

the U.S. Treasury yield curve in effect at the time of grant for periods commensurate with the expected term of the award. The Company recognizes forfeitures as they occur.

The assumptions used in the Black-Scholes option pricing model are as follows:

	For the Year ended December 31,	
	2023	2022
Expected volatility	69.2% - 69.7%	68.7% - 70.1%
Weighted-average risk-free interest rate	3.45% - 4.22%	1.46% - 4.16%
Expected dividend yield	— %	— %
Expected term (in years)	5.5 - 6.25	5.5 - 6.25
Underlying common stock fair value	$ 0.92-$1.60	$ 1.40-$4.17

The following table summarizes the Company's stock option activity during the year ended December 31, 2023:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2023	9,865,734	$ 10.96	7.2	$ 493
Granted	3,188,150	$ 1.53		
Exercised	(26,166)	$ 0.61		
Cancelled/Forfeited	(3,476,677)	$ 7.05		
Outstanding at December 31, 2023	9,551,041	$ 9.26	5.2	$ 66
Vested and expected to vest at December 31, 2023	9,551,041	$ 9.26	5.2	$ 66
Exercisable at December 31, 2023	7,061,128	$ 11.35	4.3	$ 66

The total intrinsic value of options exercised during the year ended December 31, 2023 and 2022 was insignificant for each period. The weighted-average grant date fair value of options granted during the years ended December 31, 2023 and 2022 was $1.01 and $1.68, respectively.

Stock Awards Modifications—Corporate Restructuring

In connection with the Company's reduction in force implemented in July and November of 2023 (see Note 9), the Company terminated approximately 86 employees and modified approximately 6.3 million existing stock options and approximately 1.0 million existing restricted stock units ("RSUs") granted to these terminated employees in prior periods. The modification of the vested stock options to permit terminated employees up to one year following their termination date to exercise their options, rather than the 90-day window for terminated employees, is accounted for as a modification under FASB ASC Topic 718, Compensation-Stock Compensation ("ASC 718"). Accordingly, the Company recognized incremental compensation cost on the modification date in an amount equal to the difference between the fair value of the awards before and after the modification. The fair value of the awards immediately before assumes an expected term equal to 90 days from the termination date, whereas the fair value immediately after assumes an expected term equal to one year from the termination date. Total incremental compensation cost recognized for the year ended December 31, 2023 related to awards that were vested prior to modification was less than $0.1 million. Certain terminated employees' unvested stock options were also modified such that the stock options will vest in full upon a change of control occurring within

45 days of termination. The remaining unvested stock options were forfeited upon termination and the Company reversed all compensation cost previously recorded on the forfeited awards. Total compensation cost reversed in the year ended December 31, 2023 was approximately $0.4 million.

The terminated employees' RSUs were modified to accelerate the vesting of a portion of the RSUs that were unvested as of the employees' termination dates. The accelerated vesting of certain RSUs is accounted for as a Type III (improbable to probable) modification under ASC 718. Accordingly, the Company reversed all compensation cost previously recorded on the awards that are not expected to vest under the original terms. Certain terminated employees' unvested RSUs were also modified such that the RSUs will vest in full upon a change of control occurring within 45 days of termination. Total compensation cost reversed in the year ended December 31, 2023 was approximately $0.5 million. Total compensation cost of approximately $0.2 million, equal to the modification date fair value, was recognized over the remaining service period, beginning on the modification date and ending on each employee's termination date.

Stock Awards Modifications—OXB (US) LLC Transaction

As part of the transaction with OXB (US) LLC (see Note 6), the Company transferred employees to OXB (US) LLC and modified approximately 1.6 million existing stock options and approximately 0.1 million existing restricted stock units granted to these transferred employees in prior periods in order to permit such individuals to continue vesting in their awards and exercise their vested options as long as they are employed by and provide services to OXB (US) LLC. The modification of the unvested stock awards to continue vesting was accounted for as a Type III (improbable to probable) modification under ASC 718. Accordingly, the Company reversed all compensation cost previously recorded on the awards that were not expected to vest under the original terms. Total compensation cost reversed in the year ended December 31, 2022 was less than $0.1 million. Total compensation cost of $0.8 million, equal to the modification date fair value, will be recognized over the remaining service period. A portion of this total compensation cost will be included as a component of the loss from equity method investment.

The modification of the vested stock awards to permit transferred employees to exercise their options over the remaining life of the award, rather than the 90-day window for terminated employees, was accounted for as a modification under ASC 718. Accordingly, the Company recognized incremental compensation cost on the modification date in an amount equal to the difference between the fair value of the awards before and after modification. The fair value of the awards immediately before modification assumed a 90-day expected term, whereas the fair value immediately after assumed an expected term equal to the remaining life of the modified options. Total incremental compensation cost recognized in the year ended December 31, 2022 related to awards that were vested as of the modification date was $0.4 million.

Restricted Stock Units

The fair value of RSUs is based on the fair market value of the Company's common stock on the date of grant. Each RSU represents a contingent right to receive one share of the Company's common stock upon vesting. In general, RSUs vest annually in two or three equal installments on January 1st of each year after the grant date. The following table summarizes the Company's RSU activity for the year ended December 31, 2023:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2023	543,179	$ 6.12
Granted	483,850	$ 1.60
Vested	(373,519)	$ 4.86
Forfeited	(312,171)	$ 2.59
Outstanding at December 31, 2023	341,339	$ 2.95

Stock-based Compensation Expense

The Company recognizes compensation expense for awards to employees based on the grant date fair value of stock-based awards on a straight-line basis over the period during which an award holder provides service in exchange for the award, which is generally the vesting period. The Company recorded stock-based compensation expense related to stock options, shares purchased under the 2018 ESPP, restricted stock units and stock award modifications as follows:

	For the Year ended December 31,	
	2023	2022
	(in thousands)	
General and administrative	$ 5,952	$ 7,867
Research and development	1,372	5,187
	$ 7,324	$ 13,054

As of December 31, 2023, there was $13.1 million of unrecognized compensation expense related to unvested employee and non-employee share-based compensation arrangements granted under the Plans. The unrecognized compensation expense is estimated to be recognized over a period of 2.0 years at December 31, 2023.

15. NET LOSS PER SHARE

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at December 31, 2023 and 2022, from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	December 31,	
	2023	2022
Stock options to purchase common stock	9,551,041	9,865,734
Restricted stock units	341,339	543,179
Total	9,892,380	10,408,913

16. DEFINED CONTRIBUTION PLAN

The Company has a 401(k) defined contribution plan (the "401(k) Plan") for all of its employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits, while the Company contributes to the plan at the discretion of the Board of Directors. The Company's discretionary match made under the 401(k) Plan for the years ended December 31, 2023 and 2022 was $0.4 million and $0.6 million, respectively.

17. PFIZER STOCK PURCHASE AGREEMENT

On November 9, 2020, the Company entered into a common stock purchase agreement (the "Stock Purchase Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which the Company agreed to issue and sell to Pfizer 5,000,000 shares of the Company's common stock through a private placement transaction (the "Private Placement") at a purchase price of $12.00 per share, for an aggregate purchase price of $60.0 million. The shares of common stock sold to Pfizer were subject to a one-year lock-up from closing, during which time Pfizer was prohibited from selling or otherwise disposing of such shares.

Under the Stock Purchase Agreement, Pfizer was granted an exclusive right of first refusal (the "ROFR") for a 30-month period (the "ROFR Period") beginning on the date of the closing of the Private Placement (collectively, the "ROFR Provision"), to negotiate a potential collaboration on the development and commercialization of HMI-102 and HMI-103. The ROFR Period expired on May 9, 2023. In addition to the ROFR, the Stock Purchase Agreement provided for an information sharing committee (the "Information Committee"), comprised of representatives of each company which will serve as a forum for sharing information regarding the development of HMI-102 and HMI-103 during the ROFR Period.

The Company recorded the issuance of common stock at its estimated fair value of $52.0 million, which reflected a discount for the lack of marketability of the shares. The remaining $8.0 million of aggregate purchase price was allocated to the other elements of the Stock Purchase Agreement, which represented a contract with a customer. The Company concluded that the Information Committee represented the only performance obligation under the contract. The ROFR did not provide Pfizer with a material right and was therefore not a performance obligation. As such, the Company allocated the $8.0 million to the Information Committee obligation.

The Company recognized revenue over time as the measure of progress which it believed best depicted the transfer of control to Pfizer. The Information Committee met regularly over the ROFR Period to share information which resulted in recognition of the transaction price over the 30-month ROFR Period.

The Company recognized collaboration revenue of $1.2 million and $3.2 million during the years ended December 31, 2023 and 2022, respectively. There was no deferred revenue related to the Company's obligation to Pfizer as of December 31, 2023. As of December 31, 2022, there was approximately $1.2 million of deferred revenue related to the Company's obligation to Pfizer.

18. RELATED PARTY TRANSACTIONS

Oxford Biomedica (US) LLC

As described in Note 6, the Company has significant influence over, but does not control, OXB (US) LLC through its noncontrolling representation on OXB Solution's board of directors and the Company's equity interest in OXB (US) LLC. In March 2022, concurrently with the closing of the transaction with OXB (US) LLC, the Company entered into certain ancillary agreements with OXB (US) LLC including a supply agreement, a lease assignment and assumption agreement, a sublease agreement and a transitional services agreement.

Supply Agreement

Pursuant to the terms of the Manufacturing and Supply Agreement with OXB (US) LLC entered into in March 2022 (the "Supply Agreement"), the Company agreed to purchase from OXB (US) LLC at least 50% of its clinical supply requirements of AAV-based products during the initial term of the supply agreement. The Supply Agreement provides for an initial term of three years, which may be extended for an additional one-year term. Under the Supply Agreement, the Company was committed to purchase a minimum number of batches of drug substance and drug product, as well as process development services, for a total commitment of approximately $29.7 million in 2023. As of December 31, 2023, the Company had no remaining purchase obligations to OXB (US) LLC pursuant to the Supply Agreement; there are no minimum purchase commitments in 2024 (year three) of the Supply Agreement. After the initial term, the Company will have the right to terminate the Supply Agreement for convenience or other reasons specified in the Supply Agreement upon prior written notice. Either party may terminate the Supply Agreement upon an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party.

During the years ended December 31, 2023 and 2022, the Company recorded purchases of drug substance from OXB (US) LLC related to the Supply Agreement of approximately $21.7 million and $13.9 million, respectively,

purchases of process development services of approximately $7.4 million and $12.5 million, respectively, and stability and other support of approximately $1.0 million and $1.8 million, respectively. These amounts are included within research and development expenses on the Company's consolidated statements of operations. The amounts due to OXB (US) LLC under the Supply Agreement were $3.1 million and $5.2 million as of December 31, 2023 and 2022, respectively, and were included in accounts payable and accrued expenses and other liabilities on the Company's consolidated balance sheets.

Lease Assignment and Sublease Agreement

As described in Note 10, the Company leases space for research and development, manufacturing and general office space in Bedford, Massachusetts. In March 2022, the Company and OXB (US) LLC entered into a lease assignment and assumption agreement pursuant to which Homology assigned all of its right, title and interest in, to and under this lease to OXB (US) LLC and a sublease agreement whereby OXB (US) LLC subleased certain premises in its facility to Homology. However, as the Company remained jointly and severally liable for the payment of rent under this lease, the Company was not released from being the primary obligor under such lease and therefore the related right-of-use asset and operating lease liability were not derecognized and the Company recorded sublease income from OXB (US) LLC as if it were subleasing the space to OXB (US) LLC. See Note 10 for details.

During the years ended December 31, 2023 and 2022, the Company recorded sublease income of $2.3 million and $2.0 million, respectively, related to the sublease agreement with OXB (US) LLC. This amount was recognized as a reduction to lease expense in the Company's consolidated statements of operations.

During 2023, OXB (US) LLC assumed responsibility for paying the landlord for invoices related to the leased property and, as such, the Company began making direct payments to OXB (US) LLC for amounts due to OXB (US) LLC under the sublease. Therefore, as of December 31, 2023, the amount of sublease income payable to OXB (US) LLC was $0.3 million and was included in accrued expenses on the Company's consolidated balance sheets. As of December 31, 2022, the amount of sublease income receivable from OXB (US) LLC was $0.5 million and was included in prepaid expenses and other current assets on the Company's consolidated balance sheets.

Transitional Services Agreement

Under the transitional services agreement with OXB (US) LLC (the "Services Agreement"), the Company is performing certain services for the benefit of OXB (US) LLC and OXB (US) LLC is performing certain services for the benefit of the Company. The term of the Services Agreement will not exceed eighteen months and lasts until the earlier of termination for convenience, termination for cause in the event of an uncured material breach, termination as a result of bankruptcy of either party, and expiration or termination of the only remaining outstanding service as set forth in the Services Agreement. Each company is fully reimbursing the other for these services. As of December 31, 2023, the Services Agreement was substantially complete.

Expenses incurred by the Company for services provided by OXB (US) LLC recognized under the Services Agreement totaled approximately $0.3 million and $0.7 million for the years ended December 31, 2023 and 2022, respectively, and are presented within research and development expenses in the consolidated statements of operations as the services related to facilities support within the Company's research and development labs. The Company did not have a payable balance to OXB (US) LLC under the Services Agreement as of December 31, 2023. As of December 31, 2022, the amount due to OXB (US) LLC under the Services Agreement was $0.1 million and was included in accrued expenses and other liabilities on the Company's consolidated balance sheets.

The Company provided finance, human resources, IT and legal services to OXB (US) LLC under the Services Agreement and recognized $0.5 million and $1.7 million for the years ended December 31, 2023 and 2022,

respectively, for amounts reimbursed by OXB (US) LLC as a reduction to general and administrative expense in the Company's consolidated statements of operations. The Company did not provide reimbursable services to OXB (US) LLC under the Services Agreement during the second half of 2023 and did not have a receivable balance from OXB (US) LLC as of December 31, 2023. As of December 31, 2022, the Company had a receivable balance of $0.3 million from OXB (US) LLC which was recorded as a component of prepaid expenses and other current assets in the Company's condensed consolidated balance sheets. Pursuant to the Services Agreement, the Company had been paying vendors on OXB (US) LLC's behalf; this process was fully transitioned to OXB (US) LLC in 2023. As of December 31, 2022, the amount receivable from OXB (US) LLC for amounts paid to vendors on their behalf was $1.1 million and was included in prepaid expenses and other current assets on the Company's consolidated balance sheets. In addition, as of December 31, 2022, the Company had an amount due to OXB (US) LLC of $2.0 million as a result of a year-end reconciliation between the two companies related to vendor invoicing.

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Up to 1,682,045 Shares of Common Stock

PROSPECTUS

April 29, 2024