Filed pursuant to Rule 424(b)(4)
Registration Nos. 333-281713 and 333-282082

PROSPECTUS

13,235,294 Shares

Common Stock

This is an initial public offering of shares of common stock of Zenas BioPharma, Inc.

We are offering 13,235,294 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price is $17.00 per share.

Our common stock has been approved for listing on the Nasdaq Global Select Market ("Nasdaq") under the symbol "ZBIO."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements in this prospectus and may elect to do so in future filings. Investing in our common stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 14.

PRICE $17.00 PER SHARE

	Price to Public	*Underwriting Discounts and Commissions(1)*	*Proceeds to Zenas BioPharma*
Per Share	*$ 17.00*	*$ 1.19*	*$ 15.81*
Total	*$ 224,999,998*	*$ 15,750,000*	*$ 209,249,998*

(1) See the section titled "Underwriters" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,985,294 shares of our common stock solely to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on September 16, 2024.

MORGAN STANLEY ***JEFFERIES*** ***CITIGROUP*** ***GUGGENHEIM SECURITIES***

September 12, 2024

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in the prospectus, before making any investment decision. Except where the context otherwise requires or where otherwise indicated, the terms "Zenas," "Zenas BioPharma," "we," "us," "our," "our company," "the company" and "our business" refer to Zenas BioPharma, Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies for patients in need. With the evolving understanding of the pathogenesis of autoimmune diseases, along with the expansion of promising immunology-based pharmacologic targets, we are building an immunology and inflammation ("I&I") focused biopharmaceutical company. Our core business strategy combines disciplined product candidate acquisition with strategic deployment of internal expertise and effective use of external resources. We leverage our experienced executive management team and our established networks throughout the biopharmaceutical industry to identify, acquire and develop product candidates that we believe can provide superior clinical benefits to patients living with autoimmune diseases.

Our lead I&I product candidate, obexelimab, is a bifunctional monoclonal antibody designed to bind both CD19 and Fcγ receptor IIb ("FcγRIIb"), which are broadly present across B cell lineage, in order to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. Based on existing clinical data generated to date, we believe that targeting B cell lineage via CD19 and FcγRIIb can inhibit B cells and has been shown to be well-tolerated. While anti-CD20 or other anti-CD19 targeting agents effectively deplete B cells in systemic circulation, these agents do not fully impact B cells in relevant tissue, and the intermittent dosing regimens of these agents may not provide optimal benefits for all patients. In addition, anti-CD20 and other anti-CD19 targeting agents may cause prolonged depletion of circulating B cells for six months or longer, placing patients at higher risk of opportunistic infections and potentially reducing their ability to respond to, and receive full benefit from, vaccines. We believe obexelimab's mechanism of action and chronic dosing regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease. Across five clinical trials, in which 198 subjects were dosed, obexelimab was well-tolerated and demonstrated clinical activity that we believe provides proof-of-concept ("POC") for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases and, together with its mechanism of action, positions obexelimab to be a potentially differentiated B cell therapy for the treatment of such patients. We are developing obexelimab as a potential I&I franchise for patients in several autoimmune diseases, representing substantial commercial opportunities individually and in the aggregate. The first four indications we are pursuing include immunoglobulin G4-related disease ("IgG4-RD") through an ongoing registration-directed Phase 3 trial; multiple sclerosis ("MS") and systemic lupus erythematosus ("SLE") through Phase 2, double-blind, randomized, placebo-controlled trials each of which we initiated in the third quarter of 2024; and warm autoimmune hemolytic anemia ("wAIHA") through an ongoing Phase 2/3 trial, currently in the Phase 2 open label portion.

IgG4-RD is a chronic fibro-inflammatory condition that can affect virtually all organ systems, including the pancreas, biliary tract, salivary and lacrimal glands, lungs and kidneys. IgG4-RD is a relatively recently described disease that incorporates groups of manifestations that were diagnosed as separate disease entities prior to 2003. We estimate that the currently diagnosed population of IgG4-RD patients in the United States is approximately 20,000, with comparable prevalence rates globally. MS is the most common immune- mediated, chronic inflammatory demyelinating disease of the central nervous system ("CNS"), affecting over two million people worldwide including as many as 1,000,000 in the United States. We estimate a diagnosed prevalence of approximately 650,000 patients in the United States with MS. SLE, the most common form of lupus, is a complex, chronic autoimmune disease characterized most notably by unpredictable flares in joints, skin, kidneys and other vital organs that cause progressive organ damage. According to the Lupus Foundation of America, at least 1.5 million Americans are afflicted by lupus and more than 16,000 new cases are reported

annually. It is estimated that five million people throughout the world suffer from some form of lupus, of which 70% suffer from the most common form, SLE. We estimate a diagnosed prevalence of approximately 245,000 patients in the United States having lupus, with approximately 172,000 having SLE. Autoimmune hemolytic anemia ("AIHA") is an acquired disorder in which autoantibodies directed against a patient's own red blood cell ("RBC") membrane antigens lead to their accelerated destruction, and the rate of production of new cells in the bone marrow can no longer compensate for their loss. We estimate that the currently diagnosed population of wAIHA patients in the United States is approximately 40,000, with similar prevalence rates in other countries. We estimate that the commercial opportunity across these four indications is approximately $50 billion in the aggregate in the U.S. alone.

To date, we have no product candidates approved for commercial sale in any country and have not generated any revenue from product sales.

Our Pipeline

We are developing obexelimab for the treatment of several I&I diseases summarized in the pipeline figure below:

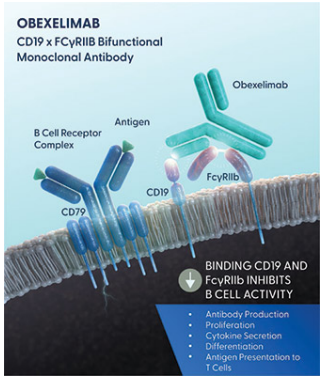
Other Pipeline Programs

Beyond our lead product candidate, obexelimab, we are advancing a pipeline of clinical programs for the potential treatment of other I&I indications that we may continue to develop and ultimately commercialize with partners. Our pipeline includes two global programs, ZB002 (an anti-TNFα monoclonal antibody) and ZB004 (a Cytotoxic T-Lymphocyte-Associated Antigen 4-Immunoglobulin ("CTLA-4-Ig fusion")), and two regional programs, ZB001 (also known as VRDN-001, an anti-insulin-like growth factor-1 receptor ("IGF-1R") monoclonal antibody) and related programs, and ZB005 (also known as DNTH103, an anti-active complement component 1s ("C1s") monoclonal antibody), both of which we hold the development and commercialization rights for in China, Hong Kong, Macau and Taiwan (collectively, "greater China"). Based on the ongoing clinical studies and clinical data generated to date, we intend to determine future potential indications in which to pursue further clinical development of these programs and ultimately, if approved, commercialization with one or more partners.

Our Obexelimab Program

Our lead product candidate, obexelimab, was engineered to mimic the natural antigen-antibody complex for the inhibition of B cells. By targeting CD19, obexelimab is designed to inhibit a broad B cell population, including plasmablasts and the subpopulation of CD19 expressing plasma cells, each of which produces high amounts of auto-antibodies. Co-engagement of CD19 and FcγRIIb by obexelimab has been shown to inhibit B cell activity, including antibody production, proliferation, cytokine secretion, B cell differentiation and antigen presentation to T cells. In addition, obexelimab is designed to inhibit rather than destroy or deplete B cell lineage. Accordingly, we believe that obexelimab's mechanism of action and chronic dosing regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease and has the potential to show greater clinical benefits, including over a longer course of maintenance treatment.

Mechanism of Action of Obexelimab



The inhibitory mechanism of obexelimab is believed to reduce the number of B cells in systemic circulation through margination of B cells to other tissues such as the lymph nodes and the spleen, rather than through depletion. We believe the rapid return in B cell activity following the cessation or pause in obexelimab dosing could allow the patient's immune system to more quickly return to baseline to protect against infections and allow a patient to receive vaccinations within as few as six weeks of his or her last dose, rather than potentially waiting six months or longer following treatment with an anti-CD19 or anti-CD20 targeted depleting therapy.

Obexelimab has been evaluated in five completed clinical trials in which a total of 198 subjects have received obexelimab either as an intravenous ("IV") infusion at doses of up to 10 mg/kg (n=158) or as a subcutaneous ("SC") injection at doses up to 375 mg (n=40). Across these five trials obexelimab was well-tolerated and demonstrated clinical activity that we believe provides POC for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases. The only serious adverse events ("SAEs") considered by the investigator to be related to obexelimab across the five clinical studies completed to date were two IV infusion related reactions, one in each of two obexelimab treated patients. Our current ongoing and planned future trials of obexelimab utilize a fixed 250 mg, dosed weekly as a self-administered SC injection, rather than an IV infusion.

We believe obexelimab holds the potential to provide meaningful clinical benefit for patients in multiple I&I indications. We are currently pursuing a registration-directed trial in patients with IgG4-RD, planning Phase 2, double-blind, randomized, placebo-controlled, clinical trials of obexelimab in patients with MS and SLE, each of which we initiated in the third quarter of 2024, and an ongoing Phase 2/3 trial, currently in the Phase 2 open label portion, in patients with wAIHA.

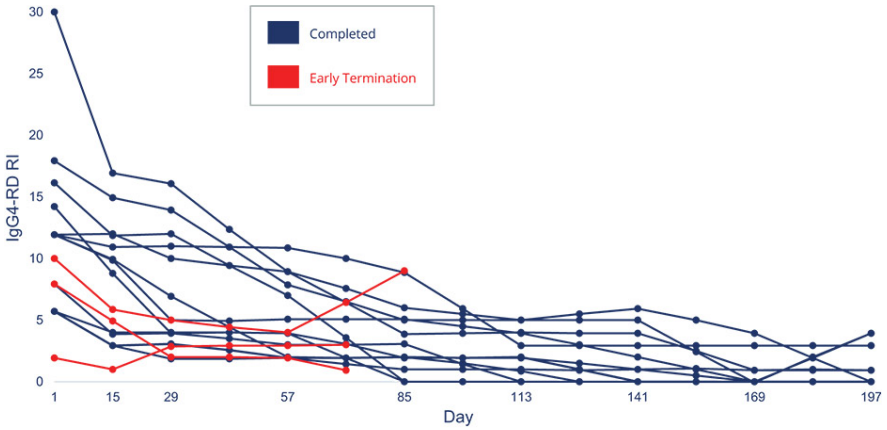
Obexelimab for the Treatment of IgG4-RD

We believe obexelimab's differentiated mechanism of action as an inhibitor of B cell lineage supports its potential to play an important role in the treatment of IgG4-RD. The reported evidence for the role of B cells in the pathogenesis of IgG4-RD, the observed effects of B cell targeting agents in previous trials in IgG4-RD, and the data from our Phase 2 IgG4-RD trials with obexelimab support the continued development of obexelimab in patients with IgG4-RD.

In August 2023, the results of the Phase 2, open-label, single-arm trial of obexelimab for the treatment of patients with IgG4-RD were published in The Lancet Rheumatology. In the primary efficacy analysis, as shown below, the median decrease in the IgG4-RD responder index ("RI") score was 11.5 points (interquartile range ("IQR") 7.5-14.5). The IgG4-RD RI score at day 169 had decreased by two or more points from baseline in 12 (80%) patients, eight (67%) of whom had a score of zero (complete remission). These patients included four (80%) of five patients who had achieved remission on previous therapies. Fourteen (93%) patients

achieved an improvement on the RI of two or more points, and further evaluation found that the one patient who failed to achieve that reduction had atypical disease activity in only the larynx. Twelve (80%) patients achieved a combined (secondary) endpoint of a decrease on the RI of two or more points at day 169, with no steroid use after day 57, and no disease flares. All primary responders had sustained responses through the end of the trial.

Rapid and Sustained IgG4-RD RI Responses from Phase 2 Trial



The one (7%) patient who did not meet clinical response criteria had a RI score of two at baseline and a score of one before withdrawing from the trial after the Day 71 dose due to lack of efficacy (an IgG4-RD RI score reduction of less than two). Two responders also did not complete the trial: one discontinued after experiencing a disease relapse and one discontinued after an infusion-related hypersensitivity reaction during the fifth infusion.

Furthermore, circulating B cell counts decreased by approximately 60% throughout the treatment period. However, among seven patients with post-treatment follow-up data, four (57%) demonstrated recovery of circulating B cells to at least 75% of baseline within 42 days of the final obexelimab dose. Circulating plasmablasts also decreased quickly, by approximately 70 to 80%, and began returning following cessation of obexelimab. Obexelimab inhibited B cell receptor ("BCR") linked signaling pathways but did not induce B cell depletion. Both reductions in circulating B cells without evidence of depletion during obexelimab treatment and their rapid rebound after treatment discontinuation suggest that obexelimab might lead to B cell sequestration (margination) in lymphoid organs or the bone marrow.

We believe these results are promising and support the continued development of obexelimab for the treatment of IgG4-RD and potentially other B cell-mediated I&I conditions. We are enrolling patients in our INDIGO Trial, a global Phase 3 registration-directed, double-blind, placebo-controlled trial to evaluate the safety and efficacy of obexelimab in patients with active IgG4-RD in a randomized controlled period ("RCP") followed by an optional open-label extension period. We expect to enroll up to approximately 200 patients in the RCP and all patients from the RCP will be eligible for the open-label extension ("OLE") period. We expect to conduct the trial at approximately 100 sites in 20 countries and to complete enrollment in 2024. The RCP consists of a screening period (Day -28 to Day -1) and a 52-week treatment period, during which 250 mg of obexelimab or placebo will be administered as an SC injection every seven days. Following the 52-week RCP, eligible patients will have the opportunity to continue in an OLE period where all patients will receive obexelimab. We expect to report topline data from our INDIGO Trial by the end of 2025 and, subject to the data, submit a Biologics License Application ("BLA") in 2026.

Obexelimab for the Treatment of MS

We believe obexelimab's differentiated mechanism of action as an inhibitor of B cell lineage supports its potential for the treatment of MS. The role of B cells in the pathogenesis of MS has been demonstrated

through the successful clinical development, approval and clinical use of anti-CD20 B cell targeting therapies of other companies, including OCREVUS (ocrelizumab) and KESIMPTA (ofatumumab), which selectively deplete peripheral CD20-expressing B cells. B cells are thought to play a central role in MS pathology and its concomitant neurodegeneration via multiple mechanisms. In addition to antibody secretion by plasmablasts and plasma cells, B cell functions implicated in MS pathogenesis include antigen presentation to T cells and production of pro-inflammation cytokines. We believe this activity observed from B cells may contribute to both MS relapses as well as the underlying disease progression. Given the clinical activity observed with B cell depleting agents, we initiated the MoonStone Trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with relapsing MS ("RMS"), in the third quarter of 2024.

The MoonStone Trial is a randomized, placebo-controlled trial in patients with relapsing active forms of MS in order to assess the safety and efficacy of a 250 mg weekly SC dose of obexelimab, utilizing various MRI detection techniques and biomarkers to assess its impact in both the active and chronic aspects of the disease. The primary objective of this trial will be to assess the change from baseline in the cumulative number of gadolinium ("Gd") enhancing lesions identified on T1-weighted MRI over the course of three months. Upon completion of the three-month period, patients on placebo will receive obexelimab treatment for at least three months, and patients initially randomized to obexelimab will continue on treatment. Important secondary endpoints will include changes in various other MRI assessments. We expect to report data from the MoonStone Trial on the primary endpoint at 12 weeks in mid-2025 and additional data at 24 weeks in the fourth quarter of 2025.

Obexelimab for the Treatment of SLE

The crucial role of B cells in SLE pathogenesis is well recognized, from producing autoantibodies to abnormal regulation of immune responses. Moreover, SLE is an autoimmune disease characterized by B cell dysfunction, the production of autoantibodies toward cellular and nuclear components, and multiorgan damage caused by immune complex deposition and inflammation within affected tissues. Current treatments are limited in number and are modestly effective with improvement over placebo in clinical trials of nine to seventeen percentage points. Obexelimab has demonstrated clinical activity as a B cell-directed agent due to its inhibitory effect on B cell lineage via its binding to CD19 and FcγRIIb. We believe a prior Phase 2 double-blind, randomized trial demonstrated POC in the overall trial population and increased response in patients who maintain higher systemic exposure to obexelimab in biomarker-defined subpopulations, and coupled with the safety data obtained to date, provide support for further clinical trials and the use of a SC obexelimab formulation in patients with SLE.

In the completed Phase 2 double-blind, randomized trial of obexelimab in SLE, the primary endpoint (the proportion of patients without loss of improvement in SLE disease activity) in the Efficacy Evaluable ("EE") population did not achieve statistical significance. However, analysis of the intent-to-treat ("ITT") population revealed a larger absolute treatment difference of 17.3% (40.4% versus 23.1%) in the obexelimab-treated group versus the placebo-treated group. Based on that observed clinical activity, strong signals of activity in patients who had higher blood levels of obexelimab and biomarker-defined subpopulations and safety data to date, in the third quarter of 2024 we initiated the SunStone Trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab when used to reduce disease activity in patients with SLE. We expect to enroll approximately 190 patients and to conduct the trial at multiple sites worldwide. Patients will be randomized 1:1 to obexelimab 250 mg or placebo SC injection every seven days over 24 weeks. The primary endpoint will be the percentage of responders, defined by BILAG-based Composite Lupus Assessment, with a reduction of SLE disease activity at week 24. We expect to complete enrollment of the SunStone Trial in 2025 and report data on the primary endpoint at 24 weeks in the first half of 2026.

Obexelimab for the Treatment of wAIHA

Immunoglobulin G ("IgG") autoantibodies are the key pathogenic factors involved in most forms of wAIHA. Accordingly, we believe that obexelimab's ability to inhibit or down-regulate B cell activity and its clinical activity and tolerability profile observed in previous clinical studies provide a strong rationale for its development in wAIHA.

In late 2023, we initiated our SApHiAre Trial, a global Phase 2/3, multicenter, randomized, double-blind, placebo-controlled trial, with an open-label safety and dose confirmation run-in period ("SRP") to evaluate the efficacy and safety of obexelimab in patients with wAIHA. We expect initial data from the SRP will be available in the fourth quarter of 2024 for patients enrolled prior to such date. After considering a number of factors, including whether the results of the SRP portion of the SApHiAre Trial are favorable, we may meet with the U.S. Food and Drug Administration ("FDA") to finalize the design, including the proposed endpoints, of the RCP. If we continue with the Phase 3 RCP of this trial, we expect that a total of approximately 134 patients would be enrolled in the trial, including the patients enrolled in the SRP, at approximately 90 sites in 18 countries. If we continue with the Phase 3 RCP portion of the SApHiAre Trial and if the results of the RCP portion are then favorable, we would intend to seek regulatory approval for the treatment of wAIHA.

Our Team and Investors

Our executive management team is comprised of seasoned executives and scientists with extensive experience in the biopharmaceutical industry leading drug development and commercialization and executing successful business development strategies. Our company is led by Leon (Lonnie) O. Moulder, Jr., our Founder, Chief Executive Officer and Chairman, and the Managing Member of Tellus BioVentures, LLC, an early-stage life sciences investment fund. Prior to founding Zenas, Mr. Moulder co-founded TESARO, an oncology-focused biopharmaceutical company, serving as Chief Executive Officer and Director until its acquisition by GlaxoSmithKline. He previously served as President and Chief Executive Officer of Abraxis BioScience and as Vice Chairman of Eisai Corporation of North America following Eisai's acquisition of MGI PHARMA, where he served as President and Chief Executive Officer. Mr. Moulder is joined by our team of veteran biopharmaceutical executives, including Joseph Farmer, Jennifer Fox and Orlando Oliveira, who together with the rest of the leadership team, bring exceptional track records and experiences across the biopharmaceutical industry at companies such as TESARO, GlaxoSmithKline, Amgen, Nuvation, Mirati and Cubist. Our leadership team has collectively been responsible for Investigational New Drug Application ("INDs"), New Drug Applications, BLAs and the associated commercial product launches of multiple successful pharmaceutical products.

Since our inception, we have raised $358.3 million from investors, including Enavate Sciences, SR One, Longitude Capital, Tellus BioVentures, Fairmount, New Enterprise Associates, Norwest Venture Partners and Bristol-Myers Squibb ("BMS"). Potential investors should not consider investments made by our existing investors as a factor when making a decision to purchase shares in this offering since our existing investors may have had different risk tolerances and paid less per share than the price at which the shares are being offered in this offering.

Our Strategy

Our vision is to become a global leader in delivering transformative I&I therapeutics to patients in need by leveraging the experience and capabilities of our executive management team and our established networks throughout the biopharmaceutical industry to identify, acquire, develop and, if approved, commercialize product candidates that we believe can offer enhanced efficacy, safety and/or convenience over existing therapies and thereby provide superior clinical benefits to patients. We intend to achieve our goals by implementing the following strategies:

- Develop and commercialize our obexelimab franchise across multiple I&I indications.
- Build our operational capabilities to develop and potentially commercialize our products in key regions.
- Advance the clinical development and ultimately, if approved, commercialization of, our pipeline programs, ZB002, ZB004, ZB001 and ZB005, with partners.
- Utilize our business development experience and expertise to continue to build a deep and balanced portfolio of products and product candidates.
- Leverage success in initial indications to expand into broader I&I opportunities.
- Evaluate other strategic collaborations as appropriate.

Risk Factors Summary

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- We are a clinical-stage biopharma company with a limited operating history and no products approved for commercial sale; we have incurred substantial losses since our inception, and we anticipate incurring substantial and increasing losses for the foreseeable future;
- Even if this offering is successful, we will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, would cause us to delay, limit, reduce or terminate our product development efforts;
- Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, imposing restrictions on our operations or require us to relinquish rights to our product candidates;
- Clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our current product candidates or any future product candidates;
- Delays or difficulties in the enrollment and dosing of patients in clinical trials delay or prevent receipt of necessary regulatory approvals;
- Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any;
- We face potential competition from different sources that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications;
- We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships;
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek;
- We are dependent on the services of our senior management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer;
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business;
- The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide commercial supply of our products, if approved, could be delayed or halted;
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely impacted;
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or

regulatory requirements, miss deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates;

- Our rights to develop and commercialize our product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Xencor, Inc. ("Xencor"). If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business;
- The operations of our suppliers, many of which are located outside of the United States, including our current sole contract manufacturing organization (''CMO'') for drug substance and drug product, WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), which is located in China, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.
- An active and liquid trading market for our common stock may not develop, and you may not be able to resell your shares of common stock at or above the public offering price, if at all; and
- The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed.

Corporate and Other Information

Zenas BioPharma, Inc. was originally incorporated on November 12, 2019, as Zenas BioPharma (Cayman) Limited as an exempted company organized under the laws of the Cayman Islands. On August 2, 2023, the Company was domesticated as a Delaware corporation and, concurrent therewith, we changed our name from Zenas BioPharma (Cayman) Limited to Zenas BioPharma, Inc. Our principal executive offices are located at 1000 Winter Street, Suite 1200, Waltham, MA 02451, and our telephone number is (857) 271-2954. Our corporate website address is https://www.zenasbio.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus contains references to our trademarks and trademarks belonging to other entities. "Zenas BioPharma" is registered as a trademark in the United States and other countries. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one Annual Report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging

growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We may continue to be a smaller reporting company until the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

THE OFFERING

Common stock offered by us	13,235,294 shares.
Underwriters' over-allotment option of common stock offered by us	1,985,294 shares.
Common stock to be outstanding immediately after this offering	39,792,381 shares (or 41,777,675 shares if the underwriters exercise their over-allotment option in full).
Use of proceeds	We estimate that our net proceeds from this offering will be approximately $204.0 million (or approximately $235.4 million if the underwriters exercise their over-allotment option in full), based on the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash, as follows: (i) approximately $100.0 million to advance the clinical development of obexelimab, including to complete the Phase 3 trial for patients with IgG4-RD, the Phase 2 trial for patients with MS, the Phase 2 trial for patients with SLE, and the Phase 2 portion of the trial for patients with wAIHA and (ii) the remainder to prepare for the obexelimab commercial launch in the U.S. and Europe, if approved, including for the manufacture of commercial supply, and for working capital and other general corporate purposes. See the section titled "Use of Proceeds."
Risk factors	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Nasdaq trading symbol	"ZBIO"

The number of shares of our common stock to be outstanding immediately following the completion of this offering is based on 26,557,087 shares outstanding as of June 30, 2024 (including 1,507 shares of unvested restricted common stock), after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 4,270,097 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2024, with a weighted-average exercise price of $9.21 per share;
- 35,745 shares of common stock reserved for issuance as of June 30, 2024 under our 2020 Equity Incentive Plan (the "2020 Plan");
- a number of shares of our common stock equal to 12% of shares issued and outstanding as of immediately following the consummation of this offering (not to exceed 5,657,830 shares) reserved for issuance under our 2024 Equity Incentive Plan (the "2024 Plan"), which became effective in connection with this offering (which includes up to approximately 4,408,100 shares of common stock underlying stock option awards granted to our directors, executive officers and other employees under the 2024 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share); and
- a number of shares of our common stock equal to one percent of the shares of common stock issued and outstanding as of immediately following the consummation of this offering reserved for issuance under our 2024 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with this offering.

Except as otherwise noted, all information in this prospectus assumes or gives effect to the following:

- a 1-for-8.6831 reverse stock split of our capital stock, which was effected on September 5, 2024;
- the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering;
- no exercise by the underwriters of their over-allotment option;
- the filing and effectiveness of our restated certificate of incorporation (the "Restated Charter") and the adoption of our amended and restated bylaws (the "Restated Bylaws") prior to the completion of this offering; and
- no vesting or exercise of the outstanding stock options described above.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following consolidated summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statements of operations and comprehensive loss data for the years ended December 31, 2023 and 2022 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The condensed consolidated statements of operations and comprehensive loss data for the six months ended June 30, 2024 and 2023 and the condensed consolidated balance sheet data as of June 30, 2024 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary consolidated financial and other data in this section are not intended to replace the financial statements and the related notes thereto included elsewhere in this prospectus and are qualified in their entirety by those consolidated financial statements and the related notes.

	Six Months Ended June 30,		Year Ended December 31,	
(in thousands except share and per share amounts)	2024	2023	2023	2022
Consolidated Statements of Operations Data:				
Revenue:				
Collaboration revenue	$ —	$ —	$ 50,000	$ —
Total revenue	—	—	50,000	—
Operating expenses:				
Research and development (includes $1,872, $2,117, $3,041 and $8,149 from related parties, respectively)	56,452	30,262	60,033	61,689
General and administrative (includes $0, $5, $8 and $103 from related parties, respectively)	10,828	7,729	17,114	13,510
Acquired in-process research and development	—	10,000	10,000	1,000
Total operating expenses	67,280	47,991	87,147	76,199
Loss from operations	(67,280)	(47,991)	(37,147)	(76,199)
Other income (expense), net:				
Fair value adjustments to convertible notes	(846)	—	(300)	(29,876)
Fair value adjustments to warrant liability	—	—	—	(13,268)
Other income (expense), net	2,349	(153)	624	61
Total other income (expense), net	1,503	(153)	324	(43,083)
Loss before income taxes	(65,777)	(48,144)	(36,823)	(119,282)
Income tax provision	—	—	(301)	—
Net loss attributable to common stockholders[1]	$ (65,777)	$ (48,144)	$ (37,124)	$ (119,282)
Net loss per share attributable to common stockholders–basic and diluted[2]	$ (42.15)	$ (31.62)	$ (24.25)	$ (79.94)
Weighted-average common stock outstanding–basic and diluted[2]	1,560,661	1,522,552	1,531,178	1,492,161
Pro forma net loss per share attributable to common stockholders–basic and diluted[3]	$ (3.78)		$ (2.88)	
Pro forma weighted-average common stock outstanding–basic and diluted[3]	17,415,875		12,879,648	

(1) See Note 1 to both our unaudited condensed consolidated financial statements and our audited consolidated financial statements included elsewhere in this prospectus for details on the presentation of our common stock, as our ordinary shares were converted into common stock upon our redomicile in August 2023, from the Cayman Islands to Delaware.

(2) See Note 12 to our unaudited condensed consolidated financial statements and Note 13 to our audited consolidated financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to holders of our common stock and the weighted-average number of shares of common stock used in the computation of the per share amounts.

(3) Pro forma basic and diluted net loss per share attributable to common stockholders has been prepared to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, as if such conversion had occurred at the beginning of the period presented or the issuance dates of the respective preferred stock, if later, and (ii) the filing and effectiveness of our Restated Charter, which will be effective immediately prior to the completion of this offering.

	As of June 30, 2024		
(in thousands)	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
Consolidated Balance Sheet Data:			
Cash	$ 183,930	$ 183,930	$ 389,402
Working capital[3]	149,492	149,492	357,232
Total assets	199,952	199,952	401,734
Total liabilities	39,122	39,122	36,854
Convertible preferred stock	449,612	—	—
Accumulated deficit	(296,180)	(296,180)	(296,180)
Total stockholders' (deficit) equity	(288,782)	160,830	364,880

(1) The pro forma balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, (ii) the reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering and (iii) the filing and effectiveness of our Restated Charter, which will be effective immediately prior to the completion of this offering.

(2) The pro forma as adjusted balance sheet data gives effect to the (i) pro forma adjustments described in footnote (1) above, and (ii) issuance and sale of 13,235,294 shares of our common stock in this offering at the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this prospectus, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our audited financial statements and the related notes. The events discussed below may occur and adversely impact our business, financial condition, results of operations and prospects, which may cause the trading price of our common stock to decline, resulting in you losing all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are a clinical-stage biopharma company with a limited operating history and no products approved for commercial sale; we have incurred substantial losses since our inception, and we anticipate incurring substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharma company with a limited operating history on which to base your investment decision. We have no product candidates approved for commercial sale in any country and have not generated any revenue from sales of products. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment on development or commercialization.

We have incurred, and will continue to incur, significant expenses related to the clinical development of our product candidates and ongoing operations. Our net losses for the six months ended June 30, 2024 and 2023 were $65.8 million and $48.1 million, respectively. Our net losses for the years ended December 31, 2023 and 2022 were $37.1 million and $119.3 million, respectively. As of June 30, 2024, we had an accumulated deficit of $296.2 million. Substantially all of our operating losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we advance the development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- continue clinical development of obexelimab and our other programs;
- advance our obexelimab program and our other product candidates through preclinical development and clinical trials;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or acquisitions and conduct development activities, including preclinical studies and clinical trials;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- procure the manufacturing of preclinical, clinical and commercial supply of our current or any future product candidates;
- seek marketing regulatory approvals for our current or any future product candidates that successfully complete clinical trials;
- commercialize our current or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- seek to continue to develop, maintain and defend our intellectual property portfolio, including against third-party interference, infringement and other intellectual property claims, if any;
- add and maintain operational, financial and information management systems;

- attempt to address any competing therapies and market developments;
- experience delays in our preclinical studies, clinical trials or regulatory approval for our current or any future product candidates, including with respect to failed studies, inconclusive results, safety issues or other regulatory challenges;
- establish agreements with contract research organizations ("CROs") and CMOs; and
- incur additional costs associated with being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance with an exchange listing and the Securities and Exchange Commission (the "SEC") requirements, director and officer insurance premiums and investor relations costs.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays and other events that adversely affect our business. The size of our future net losses will depend, in part, on the rate that our expenses increase and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital.

Even if this offering is successful, we will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, would cause us to delay, limit, reduce or terminate our product development efforts.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to substantially increase in connection with our ongoing and future activities. If we obtain regulatory approval for obexelimab or other product candidates, we also expect to incur significant commercialization expenses related to manufacturing, marketing, sales and distribution of such products. Because the outcome of any clinical trial or preclinical study is uncertain, we cannot reliably estimate the actual amount of capital necessary to successfully complete the development and commercialization of obexelimab and other product candidates. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company.

As of June 30, 2024, we had $183.9 million in cash. Based upon our current operating plan, we believe that the expected net proceeds from this offering, together with our existing cash, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We expect to attempt to raise additional cash in advance of exhausting our available capital resources.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, and we may not ever generate significant revenue or profits. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, and other expenses that we did not incur as a private company. If we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

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

- the scope, timing and progress of our ongoing obexelimab clinical studies and other research and development activities associated with the development of other and future product candidates;

- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new programs;
- the timing of and successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA, or any comparable foreign regulatory authority;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- our ability to establish arrangements with third-party manufacturers for the commercial supply of products that receive marketing approval, if any;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercialization;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- our ability to hire additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, chemistry, manufacturing and controls, quality and commercial personnel;
- commercializing product candidates, if approved, whether alone or in collaboration with others;
- the costs and timing of establishing or securing sales and marketing capabilities for our product candidates, if approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

We expect that our commercial revenue, if any, will initially be derived from sales of obexelimab, which we do not expect to be commercially available for several years, if ever. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise. If we are unable to raise sufficient additional capital, we would be forced to curtail our planned operations and the pursuit of our growth strategy.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, imposing restrictions on our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, that we generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other arrangements. 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 of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future debt or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other arrangements, we likely would relinquish valuable rights to our potential future revenue streams or product candidates. We also may grant licenses on terms that may not be favorable to us or that reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, or on acceptable terms, we would be required to delay, limit, reduce or terminate our product development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, we may not be able to access a portion of our existing cash due to market conditions. If banks and financial institutions with whom we hold accounts 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 may be threatened and could have a material adverse effect on our business and financial condition.

Risks Related to Product Candidate Development and Commercialization

Clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our current product candidates or any future product candidates.

We face substantial risk of failure with our product candidates and we may fail to receive regulatory approval for any of our product candidates. To obtain the requisite regulatory approvals to commercialize any product candidate, we must demonstrate, through extensive preclinical studies and lengthy, complex and expensive clinical trials, that a product candidate is safe, pure and potent and has a favorable risk-benefit profile. Clinical testing often takes many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not predict results of later-stage clinical trials, and results in one indication may not predict results for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials raise challenges for extrapolating the results of earlier clinical trials to later clinical trials.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. For example, we are developing obexelimab as a potential treatment for IgG4-RD, MS, SLE and wAIHA. Prior to our acquisition of obexelimab, Xencor conducted a Phase 2 trial of obexelimab in patients with SLE, where the primary endpoint was not achieved with statistical significance. The results of our clinical trials of obexelimab in SLE or other indications or our clinical trials for any other product candidates may not achieve statistical significance or demonstrate a favorable risk-benefit profile. Further, negative clinical trial results for a product candidate with respect to one indication may impact the potential or perceived potential of other indications. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates.

Commencing any future clinical trials is subject to finalizing the trial design and submitting an application, such as an IND, to the FDA or a comparable foreign regulatory authority. Even after the submission of an IND, the FDA or comparable foreign regulatory authorities could disagree that their requirements to commence a clinical trial have been satisfied or disagree with the study design, which may require the completion of additional trials or the amendment of the trial's protocols or the imposition of stricter conditions on the commencement of the clinical trial. We may be unable to establish clinical endpoints, dose levels and regimens or bioanalytical assay methods that regulatory authorities would consider clinically meaningful. A high failure rate characterizes product candidates proceeding through clinical trials, and failure may occur at all stages of the clinical trial process. Most product candidates that commence clinical trials are never approved as products, and our current or future clinical trials ultimately may fail to support the approval of our current or any future product candidates.

We expect to continue to rely, in part, on collaborators, CROs and clinical trial sites to conduct our clinical trials, including participant enrollment, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials and preclinical studies or other issues that delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- the FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies or impose additional requirements before permitting us to initiate a clinical trial;
- the FDA or comparable foreign regulatory authorities, Institutional Review Boards ("IRBs") or ethics committees may disagree with our study design, may require that we modify or amend our clinical trial

protocols, or may not authorize us or our investigators to commence 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 trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical investigators or clinical trial sites may deviate from trial protocols or Good Clinical Practice requirements ("GCPs") or drop out of a trial, and we may need to add new investigators or sites;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, if at all;
- the number of participants required for clinical trials may be larger than expected, enrollment in clinical trials may be slower than expected or participants may drop out or fail to return for post-treatment follow-up at a higher rate than expected;
- we may observe unexpectedly high placebo response rates;
- the cost of clinical trials and preclinical studies may be greater than we anticipate, or we may have insufficient funds to conduct such trial or study or to pay the substantial user fees required by the FDA upon the submission of a BLA;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials or preclinical studies may be insufficient or inadequate to initiate or complete a given clinical trial;
- our product candidates may have undesirable side effects or other unexpected characteristics that are viewed to outweigh their potential benefits;
- reports from clinical testing of other similar therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies or we may decide to abandon product candidate development.

In addition, delays occur when a clinical trial is suspended, put on clinical hold or terminated by the trial sponsor, the FDA or comparable foreign regulatory authorities, or the IRBs of the institutions in which such trials are being conducted, or when a clinical trial is recommended for suspension or termination by a data safety monitoring board. Suspensions and terminations are imposed due to a number of factors, including failure to conduct a clinical trial in accordance with regulatory requirements or trial protocols, failure to conduct the trial in accordance with GCPs or applicable regulatory guidelines, failed inspections of clinical trial operations or trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Clinical trials frequently are delayed or terminated as a result of ambiguous or negative interim results or unanticipated adverse events. If trials or tests are not positive or are only modestly positive or if there are safety concerns, we may be required to repeat or conduct additional clinical trials or preclinical studies for our product candidates beyond those that we currently contemplate, we may be delayed in or prevented from obtaining marketing approval or may obtain marketing approval in some countries and not in others, we may obtain approval for indications or patient populations that are not as broad as intended or desired or obtain approval with significant use or distribution restrictions or safety warnings, be subject to post-marketing testing requirements, or be subject to increased pricing pressure.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials also ultimately may lead to the denial of regulatory approval of a product candidate. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

When we conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities, we risk additional delays due to the frequent need to align on decisions.

Our product development costs have increased, and may continue to increase, when we experience delays in clinical testing. Our clinical trials may not begin when expected, may require restructuring or may not be completed on schedule, or at all. Significant clinical trial delays also shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully manufacture and commercialize our product candidates, if approved. Delays and increased costs in our clinical development programs would harm our business, financial condition, results of operations and prospects.

Delays or difficulties in the enrollment and dosing of patients in clinical trials, delay or prevent receipt of necessary regulatory approvals.

The timing of our clinical trials depends on our ability to recruit patients to participate in our studies as well as the dosing of such patients and completion of required follow-up periods. Participant enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the number and location of clinical sites, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, challenges in obtaining and maintaining participant consents, enrolled participants dropping out, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us. Rare or orphan diseases like IgG4-RD pose additional risk due to the difficulty identifying study subjects and ensuring each participant's disease state meets the study parameters. Further, because screening for many of these diseases is not widely adopted, and because it can be difficult to diagnose these diseases in the absence of screening, it can be difficult to find patients who are eligible to participate in our studies or trials.

In addition, our clinical trials currently, and may in the future, compete with other clinical trials for product candidates that address the same disease as our product candidates, and this competition reduces the number and types of participants available to us, because some participants who might have opted to enroll in our trials instead opt to enroll in a trial conducted by a competitor or elect to use a marketed therapy. We also could encounter delays if doctors face ethical challenges associated with enrolling participants in a clinical trial rather than prescribing an existing treatment with an established safety and efficacy profile.

If we or our collaborators are unable to enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate, continue or complete clinical trials for our product candidates. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment may result in increased costs, delay completion or adversely impact the outcome of the trial.

Additionally, our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including: difficulty in establishing or managing relationships with CROs and physicians; different standards for the conduct of clinical trials; different standard-of-care for patients with a particular disease; difficulty in locating qualified local consultants, physicians and partners; and potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

We experienced participant withdrawals or discontinuations from our trials. Participants, including in any control groups, frequently withdraw from a clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience adverse side effects or other issues. Withdrawal of participants from our clinical trials may compromise the quality of our data.

Difficulties enrolling a sufficient number of patients to conduct our clinical trials as planned require us to delay, limit or terminate clinical trials for our product candidates, or expand to additional jurisdictions, which could impose additional challenges on our company. Failure to successfully conduct our clinical trials as planned, it would have an adverse effect on our business, financial condition, results of operations and prospects.

Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any.

Unacceptable, undesirable or clinically unmanageable side effects, caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. We have observed certain adverse events ("AEs") and SAEs in our clinical trials of obexelimab administered through IV infusion.

Our clinical trials of obexelimab are administered through SC injection. In the Phase 1 pharmacokinetic ("PK") and relative bioavailability study of obexelimab administered either intravenously or subcutaneously, the most common related treatment emergent adverse events ("TEAEs") across all SC dose regimens were headache and injection site reactions. GI-related events seen with IV infusions were not observed in subjects who received SC formulation, but future studies may reveal similar issues.

AEs, SAEs or other side effects in clinical trials often make it difficult to recruit participants to clinical trials and results in participants dropping out of trials. While certain side effects may be reversible following discontinuation of the product candidate with sufficient recovery periods, we will need to monitor the severity and duration of side effects in our clinical trials. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide, or be required, to perform additional studies or to halt or delay further clinical development of our product candidates.

While we believe that obexelimab has the potential to offer benefits, including in regard to its side-effect profile, over B cell depleting agents, if obexelimab is shown to have adverse events, side effects or other safety or tolerability concerns, then our opportunity to disrupt the current standard of care will be limited. AEs and SAEs may be deemed to be related to our product candidates. Such a determination may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market or maintain approval of our product candidates.

We, the FDA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Many potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development and approval. Even if side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance.

Even if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to healthcare practitioners, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any product candidate that we obtain marketing approval for, several potentially significant negative consequences could result, including:

- regulatory authorities may limit, suspend or withdraw approvals of such product, or may refuse to approve supplemental applications for such product;
- regulatory authorities may require additional warnings on the label, such as a "Boxed Warning," contraindications or precautions, or otherwise limit the approved use of such product;
- regulatory authorities may impose additional restrictions on the marketing of, or the manufacturing processes for, the particular product, including requiring a REMS;
- we may be required to recall the product or change the way it is administered in patients;
- we may be required to conduct additional clinical trials;
- we may decide to remove such product from the market;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from obtaining or maintaining regulatory approvals or achieving or maintaining market acceptance of our current and future product candidates or could substantially increase the costs and expenses of commercializing the affected product, which in turn could significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Risks associated with the in-licensing or acquisition of product candidates could cause substantial delays in the preclinical and clinical development of our product candidates.

We have relied on, and continue to rely on, our licensing partners, such as Xencor, to have (i) conducted research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, (ii) accurately reported the results of all clinical trials conducted prior to our acquisition of the relevant product candidates and (iii) correctly collected and interpreted the data from these trials. If the research and development processes or the results of the development programs prior to our acquisition of our product candidates prove to be unreliable, this could result in increased costs and delays in the development of our product candidates, which could adversely affect any future revenue from such product candidates, if approved.

We may also acquire or in-license additional product candidates for preclinical or clinical development in the future as we continue to build our pipeline. The risks associated with acquiring or in-licensing product candidates could result in delays in the commencement or completion of our preclinical studies and clinical trials, if ever, and our ability to generate revenues from our product candidates may be delayed. Please see "—Risks Related to Our Intellectual Property—We may not obtain or maintain necessary rights to our product candidates through acquisitions and in-licenses" for additional information regarding such risks.

We face potential competition from different sources that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize, if approved, will compete with existing therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition, the existence of therapeutic alternatives and the availability of coverage and reimbursement from government and other third-party payors.

Many of the companies against which we are competing, or against which we may compete 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 drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our current product candidates, initially under development for treatment of various I&I indications would, if approved, face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing obexelimab for the treatment of IgG4-RD, MS, SLE and wAIHA. There are currently no approved therapies for IgG4-RD or wAIHA, but

there are two products approved for SLE, and a number of products approved for MS. Moreover, there are a number of product candidates in clinical development by other companies for IgG4-RD, MS, SLE and wAIHA which may become available in the future, including UPLIZNA (inebilizumab-cdon), an anti-CD19 antibody being developed by Amgen Inc., for which Amgen announced its intention to file a BLA based on the results of its Phase 3 clinical trial. See the section titled "—Business—Competition" for additional information.

To compete successfully, we need to disrupt currently marketed drugs, meaning we must demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered or less expensive than the current standard of care or future competing products. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of development and commercialization. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. If we are not able to effectively compete for any of the foregoing reasons, our business will be materially harmed.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time are subject to audit and verification procedures and may differ materially from final data as more patient data become available.

Preliminary or top-line data from our preclinical studies and clinical trials that we publish from time to time are based on preliminary analyses of then-available data, and the results, related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we also may disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease.

Furthermore, third parties, including regulatory authorities, 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 delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to disclose.

If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock after the completion of this offering.

Our ongoing Phase 3 clinical trial of obexelimab for IgG4-RD and other clinical trials of obexelimab, even if successfully completed, may not be sufficient for approval of obexelimab for the applicable indication.

FDA approval of a new biologic generally requires data from two well-controlled Phase 3 clinical trials of the relevant biologic in the relevant patient population; however, in some cases the FDA may accept data from

a single Phase 3 clinical trial to support marketing approval. We are conducting a Phase 3 trial of obexelimab for IgG4-RD, and we believe the results of this trial may be sufficient to support submission of a BLA for this indication. Although we have discussed our plans with the FDA, we do not have any agreement from the FDA that our regulatory development plans will provide adequate safety and efficacy data for the proposed dosing regimen or otherwise be sufficient for submission of a BLA. The FDA may require that we conduct additional clinical trials, including a comparative trial against an approved therapy, which would significantly delay our development timelines and require substantially more resources. If we are required to conduct two Phase 3 clinical trials for IgG4-RD, then our development timeline would be extended, and the related expenses would be significantly increased.

Although obexelimab has been granted orphan drug designation by the FDA for IgG4-RD, such designation does not guarantee that any regulatory authority will accept fewer trials, accelerate regulatory review of, or ultimately approve obexelimab for IgG4-RD.

If the FDA does not agree with our planned strategy, the FDA may ultimately require us to conduct additional Phase 3 clinical trials prior to approval of an indication. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory authorities requesting additional studies to show that our product candidate is superior to the new products.

We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships.

Our current or future collaborations or licensing arrangements may not be successful. Additionally, we intend to partner with third parties with respect to the clinical development and commercialization, if approved, of certain of our programs in certain regions outside the United States and Europe, and we may not be successful in identifying, negotiating and executing partnerships. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- agreements with collaborators may not provide exclusive rights to use their intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our future product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek.

We cannot commercialize a product candidate unless and until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process.

Regulatory authorities may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contraindications with respect to conditions of use, or they may grant approval subject to the performance of costly post marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations, and prospects.

Our clinical trial results may not support approval and our product candidates could fail to receive regulatory approval for many reasons, including the following:

- 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 our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their 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 our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may not approve our CMOs' manufacturing process or facilities;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from the U.S.; 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.

Regulatory approval for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

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

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our lead product candidate, obexelimab, for the treatment of IgG4-RD, MS, SLE and wAIHA. As a result, we may forgo or delay pursuit of opportunities with other product candidates or other indications for our existing product candidates that later prove to have greater commercial potential. Additionally, negative clinical trial results with respect to one indication of a product candidate may impact the potential or perception of other indications of the product candidate. Our resource allocation decisions may result in our failure to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates 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 product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We are currently conducting, and may in the future conduct, clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting clinical trials outside the United States, including in Europe and Asia, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application unless the data are applicable to the United States population and United States medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations and the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many comparable foreign regulatory authorities have similar approval requirements. In addition, foreign trials are subject to local laws of the foreign jurisdictions where the trials are conducted. The FDA or any comparable foreign regulatory authority may not accept data from trials conducted outside of the United States or the applicable jurisdiction, which would result in the need for additional trials that could be costly and time-consuming and could result in the product candidate not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market outside of the United States.

We plan to seek regulatory approval of our current or future product candidates outside of the United States. In order to market any product outside of the United States we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable jurisdictions. Marketing approval processes vary among countries but generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval and can require additional product candidate testing and additional administrative review periods. In many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in

such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would limit the commercial potential of the product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and other third party payors establish broad coverage, adequate reimbursement levels and favorable pricing for our products. Failure to obtain or maintain coverage and adequate reimbursement for any approved products could limit our ability to market those products and would decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare authorities or programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our approved products by third-party payors will affect our ability to successfully commercialize those products. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Even if we obtain coverage for a given product by a third-party payor, the reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Coverage and adequate reimbursement in the United States or elsewhere may not be available for any product that we may develop, and any coverage or reimbursement that may be obtained could be reduced or eliminated in the future.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. The coverage determination process is often time consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage will be obtained. Third party payors may not provide or may limit coverage, including to a subset of the patient population for which the treatment is approved by the FDA, or may control utilization including by requiring that patients try other therapies first or that prescribers obtain specific approval of coverage on a patient by patient basis. Many third-party payors refuse to provide coverage and reimbursement for particular drugs when equivalent generic drugs, biosimilars or less expensive therapies are available. A third-party payor may consider our product candidates, if approved, as substitutes for alternative products on the market now or in the future and only be willing to cover the cost of the alternative product.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services. Even if we show improved efficacy, safety or convenience of administration with obexelimab or any of our other product candidates, pricing of competitive products may limit the amount we will be able to charge for any of our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a product or establish payment for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. When new competitor generic and biosimilar products enter the market, pricing or reimbursement for the innovator compound may be reduced. More generally, the existence of generic and biosimilar products or other therapeutic alternatives within a “therapeutic category” may result in reduced reimbursement from payors. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. We may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. More generally, we may need to offer price concessions to third party payors to obtain favorable coverage or to purchasers to achieve sales. Such actions could have a negative impact on our ability to successfully commercialize any of our product candidates, if approved. Additionally, if a companion diagnostic test is developed for use with a drug product, any coverage and reimbursement for that test would be separate and apart from the coverage and reimbursement sought for such product. A lack of coverage or adequate reimbursement for such a test could adversely affect access to a drug product.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products like

our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be lower than in the United States and may be insufficient to generate meaningful revenue and profits.

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

We may not be able to obtain or maintain orphan drug designations for certain of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. For example, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. The FDA has granted orphan drug designation to obexelimab for IgG4-RD and we plan to seek orphan drug designation for obexelimab for AIHA, which will include wAIHA. We may not be able to obtain orphan drug designation for any additional indications for our product candidates, and we may not be able to maintain such designations if granted.

Generally, if a product with an orphan drug designation subsequently receives the first marketing 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 biologic for the same indications for seven years. Even if we are able to maintain orphan drug designation for IgG4-RD or obtain orphan drug exclusivity for obexelimab in wAIHA or any other product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if, among other things, the FDA concludes that the later drug is clinically superior, if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. Even if we receive orphan drug designation or orphan drug exclusivity for any of our product candidates, there is no guarantee that we will enjoy the benefits of such designations or exclusivity periods.

The decision of the U.S. Court of Appeals for the 11th Circuit in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021) has created uncertainty regarding the scope of orphan drug exclusivity. Although the FDA subsequently announced that it intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order and continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, it is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

We may seek fast track designation, breakthrough therapy designation and/or priority review designation from the FDA or similar designations from comparable foreign regulatory authorities for one or more of our product candidates. Even if one or more of our product candidates receive these designations, we may be unable to obtain or maintain the benefits associated with such designation.

The FDA has established various designations to facilitate more rapid and efficient development and approval of certain types of drugs intended to treat serious conditions that fill an unmet medical need. Such designations include fast track designation, breakthrough therapy designation, and priority review

designation. We intend to seek priority review designation for obexelimab for IgG4-RD. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. If any of our programs or product candidates receive any of these designations by the FDA or similar designations by comparable foreign regulatory authorities, there is no assurance that we will receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional procedures. A grant of these designations does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek accelerated approval for some of our product candidates but may not be able to obtain it as the sufficiency of our clinical trial results for accelerated approval are subject to the FDA's discretion.

We may explore strategies for our product candidates that involve use of the FDA's accelerated approval pathway. Obtaining accelerated approval requires demonstration of meaningful benefit over available therapies for a serious condition. The determination of what constitutes available therapy is wholly up to the FDA and is subject to change. No assurance can be given that other therapeutics will not receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved products. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving accelerated approval. If any of our drugs were ever to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

Risks Related to Our Business and Operations

Our business depends entirely on the success of our product candidates, and we may fail to successfully develop, receive regulatory approval for, or successfully commercialize any or all of our product candidates.

We do not have any products approved for commercial sale. We have invested substantially all of our efforts and financial resources in the development of our product candidates, each of which is still in clinical development, and we expect that we will continue to invest heavily in these product candidates and any future product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to acquire, develop, obtain regulatory approval for and successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts and further investment before we can generate any revenue from product sales. We may not meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons (see "—Risks Related to Product Candidate Development and Commercialization—Clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our current product candidates or any future product candidates."). Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote any product candidate before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all.

We have never submitted a BLA for our product candidates to the FDA, or a similar marketing application to a comparable foreign regulatory authority, and our current or any future product candidates may not be successful in clinical trials or receive regulatory approval.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing and maintain an acceptable safety profile for the products following approval;
- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- obtain and maintain healthcare coverage and adequate reimbursement;
- achieve market acceptance of our products by patients, the medical community and third-party payors;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our product candidates through our own marketing and sales activities or any co-promotion or other arrangements that we may otherwise establish;
- manufacture product candidates through CMOs in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establish sales and marketing capabilities, whether alone or through a collaboration, to support commercialization of our product candidates;
- establish and maintain agreements with wholesalers, distributors, pharmacies and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations and guidance including interactions with healthcare professionals, patient advocacy groups and communication of healthcare economic information to payors and formularies;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and capable of timely product delivery; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Any significant delays in obtaining approval for or inability to successfully commercialize our product candidates would adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our senior management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our Founder and Chief Executive Officer, Leon O. Moulder, Jr. We are also dependent on our President and Chief Operating Officer, Joseph Farmer, Chief Business Officer and Chief Financial Officer, Jennifer Fox, and Chief Commercial Officer, Orlando Oliveira and other members of our senior management and clinical development teams. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates, if approved. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be

successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the greater Boston area. If we are not able to attract, integrate, retain and motivate personnel necessary to accomplish our business objectives, we may experience constraints that significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of June 30, 2024, we had 114 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with third parties to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures, and we may not be able to implement improvements in an efficient or timely manner or may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide commercial supply of our products, if approved, could be delayed or halted.

Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our CMOs must comply with legal requirements, current Good Manufacturing Practices requirements ("cGMPs") and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our CMOs may have limited experience in the manufacturing of cGMP batches of our products.

Manufacturing biopharmaceuticals is highly susceptible to drug product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. The impact of drug product loss is compounded by the long lead times needed to procure additional drug product due to plant capacity limitations or other restrictions at our CMOs. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product liability claims, or other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely affect our business. Problems in third-party manufacturing process or facilities could restrict our ability to ensure sufficient clinical material for our clinical trials or delay or prevent us from obtaining marketing approval.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task and involves additional risks, including cost overruns, process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of sufficient quantity of raw materials. Even if we obtain regulatory approval for any of our product candidates, manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our third-party manufacturers are unable, or decide not, to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If our manufacturers are unable to produce sufficient quantities of drug substance and/or drug product for clinical trials or for commercialization we will need to identify and negotiate with other CMOs an agreement for

clinical and/or commercial supply and it is not certain we will be able to come to agreement timely or on terms acceptable to us, which would likely jeopardize our ability to provide any product candidates to study subjects in clinical trials and products to patients, if approved.

Any delay or interruption in clinical trial supplies will likely delay the completion of planned clinical trials, increases the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, proximity to global regions we intend to target or other reasons. Such changes may not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently or affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process require us to perform ex vivo comparability studies and to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a clinical trial to the product used in later clinical phases or later portions of the clinical trial. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Revenue from our product candidates, if approved, will be limited if the product does not achieve broad market acceptance.

As a company, we have never commercialized a product candidate for any indication. Even if a product candidate is approved by the appropriate regulatory authorities for marketing and sale, it may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and ease of administration of our product candidates;
- the prevalence and severity of side effects and AEs associated with our product candidates, and how the safety and tolerability profile of our product candidates compares to those of existing or emerging therapies;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings that may be more restrictive than competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;

- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not be receptive to such product candidates and may be slow to adopt them as an accepted treatment. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

Misconduct or other improper actions, including noncompliance with regulatory standards and requirements, by our employees, independent contractors, consultants, commercial partners and vendors exposes us to potential noncompliance with regulatory standards and requirements.

Employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and vendors exposes us to liability. Misconduct by these parties could be intentional, reckless and/or negligent conduct, including failure to comply with FDA or other regulations, provide true, complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, as will our costs associated with compliance. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials or creation of fraudulent data in preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, a person could allege fraud or other misconduct even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling known or unknown risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Any such actions instituted against us could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal or administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

The estimates of commercial opportunities for product candidates and forecasts of market growth included in this prospectus may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

We intend to initially focus our product candidate development on treatments for various I&I indications. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts included in this prospectus are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect in general or as to their applicability to our company. Further, new studies or trials may change the estimated incidence or prevalence of these diseases. For example, IgG4-RD is a relatively recently described disease that incorporates groups of manifestations that were diagnosed as separate disease entities prior to 2003. We estimate that the currently diagnosed population of IgG4-RD patients in the United States is approximately 20,000, with comparable prevalence rates globally.

Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our commercial opportunity may also be limited by future competitor treatments that enter the market with such patients. If any of our estimates prove to be inaccurate, the commercial opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business. Even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

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 our product candidates in foreign markets, including in the European Union ("EU"), United Kingdom ("UK"), Japan and China for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may not obtain foreign regulatory approvals on a timely basis, if at all. To obtain separate regulatory approval in 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 our product candidates. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our ability to realize the full commercial potential of our product candidates will be harmed. Failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our 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.

Strategic transactions could impact our liquidity, increase our expenses and present significant distractions to our management.

As a core part of our strategy, we intend to enter into strategic transactions, which could include acquisitions of companies, asset purchases and in-licensing and out-licensing of intellectual property. For example, we in-licensed the exclusive global rights to develop and commercialize obexelimab, ZB002 and ZB004 from Xencor, and, in August 2023, we entered into a strategic license and collaboration with BMS, pursuant to which we granted the exclusive rights to develop and, if approved, commercialize obexelimab in Japan, South Korea, Taiwan, Hong Kong, Singapore and Australia. The expected synergies in development programs, pipelines and other areas of focus between Zenas, Xencor and BMS may not be realized on a timely basis or at all, and there may be risks associated with the acquisition that we did not previously anticipate, such as unanticipated liabilities.

We also may enter into a variety of other business arrangements, including strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our business, financial condition, liquidity and results of operations.

Future acquisitions may require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business or assets may be disruptive, complex, risky and costly and we may never realize the full benefits of the acquisition.

Recent and future changes to tax laws could adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act of 2022 (the "IRA") enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock.

If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, are or were compromised, become unavailable or suffer security incidents, loss or leakage of data or other disruptions, we could suffer material adverse consequences, including operational or service interruption, harm to our reputation, litigation, fines, penalties, compromise of sensitive information related our business and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause security incidents.

Our internal information technology systems and those of our CROs, CMOs, clinical sites and other contractors and consultants are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including as a result of advanced persistent threat intrusions) and other attacks by computer hackers, cracking, application security attacks, social engineering (including through phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods and other similar threats.

Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments, or our insurance carrier objects to payment).

Some actors, including nation-state actors, also engage in cyber-attacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely are vulnerable to a heightened risk of these attacks, including

retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to conduct our development activities, including clinical trials. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive information about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used against us.

Additionally, remote work increases risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. We may be vulnerable to attacks as a result of vulnerabilities introduced through our supply chain, including vendors we engage to provide us with security and other technologies.

Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities present in acquired or integrated entities' systems and technologies, including security issues that are not identified during due diligence. Additionally, it may be difficult to integrate companies into our information technology environment and security program.

We may not be able to detect and remediate all vulnerabilities and the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, vulnerabilities could be exploited but 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.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including cloud-based infrastructure, encryption and authentication technology, employee email and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services or otherwise to operate our business. Our ability to perform diligence on or monitor third parties' information security practices is limited, and 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. If the information technology systems of our CROs, CMOs, clinical sites and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us.

A security incident or other interruption could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely, any of which could disrupt our ability (and that of third parties upon whom we rely) to advance clinical development or commercial activities for any products, if approved. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts, significantly increase our costs to recover or reproduce the data or limit our ability to effectively execute a product recall, if required. In addition, we could incur liability if any disruption or security incident results in the loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information. Applicable data privacy and security obligations also 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. Any disruption or security incident could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, damage to our reputation or a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates. Although we have obtained cyber insurance, we cannot be sure that

our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of a cybersecurity incident or that such coverage will continue to be available on commercially reasonable terms in the future.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new therapies. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval to market any product candidate, product liability claims could result in FDA or other investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants or inability to enroll participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We may require higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates, and our insurance may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

Public opinion and scrutiny of I&I treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to I&I treatments in general could result in greater government regulation and stricter labeling requirements of products to treat immunological diseases, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. AEs in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants or impact our ability to enroll participants or lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely impacted.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing and licensing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Although we in-license issued patents, we do not own any issued patents and our pending and future patent applications may not result in patents being issued. Issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, and the patents issued may be infringed, designed around, invalidated by third parties, or may not effectively prevent others from commercializing competitive technologies, 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 third parties from using our technology that is in the public domain.

Composition of matter patents for biological 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, the claims in our or our collaborators' or licensors' pending patent applications directed to composition of matter of our product candidates may not be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or the claims in any of our or our licensors' issued patents may not be considered valid and enforceable by courts in the United States or foreign countries. 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 biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued which protect our product candidates, effectively prevent others from commercializing our product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and we may not be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and

other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our or our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review proceedings, oppositions, derivations, reexaminations, interferences, *inter partes* review proceedings or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed 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 owned or in-licensed 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.

In addition, 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. 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.

We have in-licensed patent portfolios, but have no solely owned issued patents relating to our product candidates.

Although we exclusively in-license patent portfolios from Xencor related to obexelimab, ZB002 and ZB004, we have no solely owned issued patents. Although the exclusively in-licensed patent portfolios contain pending patent applications, we may not obtain any issued patents from the pending applications directed to our product candidates. Claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign jurisdictions, or those of our licensors, may not be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, and any issued claims may be found invalid or unenforceable if challenged. Additionally, our provisional applications may never result in issued patents. Accordingly, we or our licensors may never obtain issued patents or that any issued patents we or our licensors obtain may not provide us with any competitive advantage. Failure to obtain adequate patent protection for our product candidates and technology could adversely affect our business, financial condition, results of operations and prospects.

We may not obtain or maintain necessary rights to our product candidates through acquisitions and in-licenses.

The growth of our business depends in part on our ability to acquire, in-license, or use third-party proprietary rights, and we may not be able to do so on commercially reasonable terms or at all. Licenses may

be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, or could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our licensors or collaboration partners. For example, under our license and collaboration agreements with Xencor, Xencor is responsible for patent prosecution of certain licensed intellectual property. If any of our current or future licensors or collaboration partners fails to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Patent rights relating to inventions described and claimed in our or our licensors' pending patent applications may not issue and patents based on our or our licensors' patent applications could be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and we, our licensors, or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. We and our licensors have several pending U.S. and foreign patent applications in our portfolio. We cannot predict:

- if and when patents may issue based on our and our licensors' patent applications;
- the scope of protection of any patent issuing based on our and our licensors' patent applications;
- whether the claims of any patent issuing based on our and our licensors' patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our and our licensors' patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our and our licensors' patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our and our licensors' patent rights which will be costly whether we win or lose;
- 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; or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates due to global pandemics and epidemics.

The claims in our or our licensors' pending patent applications directed to our product candidates may not be considered patentable by the USPTO or by patent offices in foreign countries, and any such patent

applications may not issue as granted patents. One aspect of the determination of patentability of our and our 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 our 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 our 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. For example, there may be prior art not considered by the patent office that is raised by a third party to challenge the validity of any patents that issue from our or our licensors' patent applications. Furthermore, even if they are unchallenged, patents in our and our 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 may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or 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 and our 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 and 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 pharmaceuticals, which could make it difficult for us to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or our licensors are 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, financial condition, results of operations and prospects 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.

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.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or the patents or patent applications that we license;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned or licensed intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our and our licensors' patent applications, including whether the patent applications that we own, presently in-license, or, in the future, in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

Should any of these or similar events occur, they could significantly harm 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, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners may file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our or our 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. Claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or our 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 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 ours or our 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 our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our 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 our licensors' patents could limit our ability to assert our or our 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, business, financial condition, results of operations or 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 may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Intellectual property rights of third parties could adversely affect our ability to commercialize obexelimab, or future product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market obexelimab or future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the valid intellectual property and other proprietary rights of third parties. Identifying third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent

claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware.

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. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States 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.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting 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 which could adversely effect the market price of our common stock and harm our reputation. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot be certain that our product candidates will not infringe existing or future valid patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of their merit. We may decide in the future to seek a license to such third-party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As this burden is a high one, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent or find that our product candidates do not infringe any such claims. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non-infringing manner, which may not be commercially feasible. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our

business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* reexamination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office ("EPO"), or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates. Further, third-party patents or other intellectual property rights may be enforced against our current technology, including our research programs, product candidates, and their respective methods of use, manufacture and formulations thereof, which could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings.

Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or our licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours or our licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any

patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, 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 future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology, products and enforce our intellectual property rights. We cannot assure you that subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted. For example, the U.S. Supreme Court, in the case *Amgen v. Sanofi*, held that broad functional antibody claims are invalid for lack of enablement. As such, our ability to obtain patents with functional claims, or to protect our patent rights with functional claims from third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification, is uncertain. In addition, in *Juno v. Kite*, the Federal Circuit held broad antibody claims supported by few examples invalid for lack of written description. Recently, the Federal Circuit issued a precedential decision in *In re Cellect* (No. 22-1293) that could shorten or eliminate extended patent term awarded under Patent Term Adjustment ("PTA") if challenged on the basis of Obvious-Type Double Patenting. Furthermore, the U.S. Supreme Court and Federal Circuits have repeatedly held that the use of biomarkers in diagnosis or monitoring therapeutic treatment is not patent eligible.

Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways, particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our or our licensors' or collaborators' existing patents and patents that we might obtain in the future.

We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. 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, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our owned or licensed European patent applications, if issued, could be challenged in the UPC. 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 owned or licensed future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if the patent owner of our owned or licensed future European patents do not meet all of the formalities and requirements for opt-out under the UPC, said future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our owned or licensed European patents, and allow for the possibility of a competitor to obtain a pan-European injunction in UPC member states. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and any future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects in Europe. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

We may become subject to claims challenging the inventorship or ownership of our or our licensors' 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 our 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 to defend 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 U.S. government, such that our 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 and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we 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, 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.

Patent terms may be inadequate to protect our competitive position on products or product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has 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 products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours. For example, the patent covering obexelimab's composition of matter expires in May 2028, excluding any extension of patent term that may be available.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also

dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term ("PTE") of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent 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 patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate ("SPC"). However, we may not be granted any extensions for which we apply 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. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If approved, our product candidates that are regulated as biological products ("biologics"), may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), to establish an abbreviated pathway for the approval of biosimilar and interchangeable with an FDA-licensed reference biologic product. 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, reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. 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 develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product or sponsor's data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for 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 the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the 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 our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our product candidates in these other regions could adversely affect our business in those regions. To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates it could adversely affect our business, financial condition, results of operations and prospects.

In China, the Fourth Amendments to the PRC Patent Law became effective on June 1, 2021, and for the first time, provides for PTE, PTA and a patent linkage system for eligible Chinese patents. To date, no PTE or PTA has been granted for any Chinese patent, and the patent linkage system is still in its early stage. In view of the potential changes and development in the implementation rules in PTE, PTA, patent linkage and data exclusivity in China, a lower-cost generic drug can emerge onto the market much more quickly, which would result in weaker protection for us against generic competition in China than could be available to us in the United States, and would materially harm our business, financial condition, results of operations, and prospects.

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 that 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 our 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 our 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. 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, our trade secrets and other confidential proprietary information could be disclosed or competitors could 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.

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 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.

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, we 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 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 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, former employees, consultants or other third parties may assert an ownership right in our owned or licensed 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 product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

Our product candidates and any future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

Our company has no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of obexelimab or any of our other product candidates or any future product candidates.

Further, the FDA and its foreign counterparts may respond to any BLA that we may submit by requesting additional data or studies that we do not anticipate. Such responses could delay clinical development of our product candidates or any future product candidates. The FDA also may consider its approvals of competing products, which may alter the treatment landscape, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate withdrawal of our BLA submissions.

Any delay or failure in obtaining required approvals would adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We also are subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also 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 or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMPs. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We will not have complete control over compliance with applicable rules and regulations by such manufacturers.

Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products. If we promote our products in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. The failure by us or our collaborators to comply with applicable regulatory requirements in the United States or foreign jurisdictions in which we seek to market our product candidates may result in, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Disruptions at the FDA or comparable foreign regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new products from being developed, approved or commercialized in a timely manner or otherwise prevent those authorities 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 and comparable foreign regulatory authorities to review and approve new products is affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the regulatory authority's ability to perform routine functions. Average review times at the FDA and other regulatory authorities have fluctuated in recent years. In addition, government funding of other authorities and agencies that fund research and development activities is subject

to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities may also slow the time necessary for new biologics or modifications to approved or licensed biologics to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, future pandemics may lead to similar inspectional delays. If any future prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the delivery of, and payment for, healthcare services, including cost-containment measures that may limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. See also "Business—Government Regulation-Healthcare Reform."

For example, in March 2010, the ACA was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA. For example, tax reform legislation was enacted that eliminated the tax penalty established by ACA for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Beyond the ACA, there have been ongoing healthcare reform efforts, including under the Biden administration. Notably, the IRA includes a number of healthcare reform provisions, which have varying implementation dates. The IRA extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025; lowers the beneficiary maximum out-of-pocket cost; establishes a new manufacturer discount program; imposes new Medicare Part B and Part D drug price inflation rebates, and implements a drug price negotiation program for certain high spend Medicare Part B and D drugs. Such provisions have been and likely will continue to be subject to legal challenge.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in addition to the IRA drug pricing reforms, federal legislation enacted in 2021 eliminates the statutory cap on Medicaid drug rebate program rebates (currently set at 100% of a drug's "average manufacturer price"), effective January 1, 2024.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the

United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. 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, hospitals and health systems are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 that remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

We expect that current and any future healthcare or budget reform measures may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the payment that we receive or price that we may charge for any approved product. The implementation of such reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

The marketing of biopharmaceutical products and related arrangements with healthcare providers, third-party payors, patients and other third parties in the healthcare industry are subject to a wide range of federal and state healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, some of which will apply only if and when we receive marketing approval for a product candidate, include the following:

- federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims, false statements and civil monetary penalties laws which prohibit, among other activities, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid and may be implicated if claims are submitted that result from a violation of the federal anti-kickback statute;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Food, Drug, and Cosmetic Act (“FDCA”), which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called “federal sunshine” law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician healthcare practitioners and teaching hospitals to the federal government, as well as certain ownership and investment interests held by these physicians and their immediate family members for re-disclosure to the public;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws 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 healthcare providers or marketing expenditures. Other state laws may require pharmaceutical companies to file reports relating to pricing and marketing information, and state and local laws may require registration of pharmaceutical sales representatives.

Efforts to ensure that our business arrangements with third parties 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 significant civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare 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 U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including FDA and the Center for Medicare & Medicaid Services, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

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

In some countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of drugs such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our products, if approved, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal

data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act ("CCPA") applies to personal information of consumers, business representatives, and employees, and among other things requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties of up to $7,500 per violation as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact our processing of personal information and increases our compliance costs. Additionally, the California Privacy Rights Act of 2020 ("CPRA") significantly expands the CCPA, such as granting additional rights to California residents, including the right to correct personal information and additional opt-out rights. The CPRA also establishes a regulatory agency dedicated to enforcing the CCPA and the CPRA. At least 11 other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self- regulatory standards that may place additional burdens on us.

There are also various laws and regulations in other jurisdictions outside the United States relating to data privacy and security, with which we may need to comply. For example, the EU GDPR and the UK's equivalent ("UK GDPR" and collectively, "GDPR"), impose strict requirements for processing personal data. We also have operations in Asia, and may be subject to new and emerging data privacy regimes such as Japan's Act on the Protection of Personal Information and China's Personal Information Protection Law. Notably, the EU GDPR and UK GDPR impose large penalties for noncompliance, including the potential for fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or 4% of the annual global revenue of the noncompliant entity, whichever is greater. The EU GDPR and UK GDPR also provide for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Additionally, EU member states and other jurisdictions may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of special categories of personal data, including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to collect, use and share data from the EU and other jurisdictions, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to countries whose privacy laws it believes are inadequate. Case law from the Court of Justice of the European Union ("CJEU"), however, states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an

adequate personal information transfer mechanism—alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. In October 2022, President Biden signed an Executive Order that introduced new mechanisms and safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework (and corresponding UK data protection framework, collectively the "DPF"), as released on December 13, 2022. The European Commission adoption of its Adequacy Decision means the DPF is effective as an EU GDPR transfer mechanism to U.S. entities self-certified under the DPF. While we have certified as a participant in the DPF, we cannot guarantee that the validity of the DPF will not undergo further legal challenge as occurred with previous transfer mechanisms like the EU/US Privacy Shield.

Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses and the recently approved DPF, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs, CMOs or business associates or another third party, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The implementation of the CCPA, GDPR and other similar laws have increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with these and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any actual or perceived failure by us or our third-party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct,

regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We cannot assure you that our CROs, CMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants' and employees' sensitive information for which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and by our customers. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

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. Further, the successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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. Compliance with these legal standards could impair our ability to compete in domestic and international markets. 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 ("FCPA"), 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 recipients in the public or private sector. We may engage third parties to sell our products outside the United

States, 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.

Risks Related to Our Reliance on Third Parties

We currently rely on a single third-party manufacturer, WuXi Biologics, to supply our product candidates, including certain drug substances and drug products used in our product candidates. If we are unable to source these supplies on a timely basis, at sufficient quantities or at acceptable quality or prices, establish longer-term contracts with our CMOs, or our third party manufacturers fail to comply with applicable regulatory requirements, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely on a single third-party manufacturer, WuXi Biologics, located in China, to manufacture and supply the drug substances and drug products for our product candidates, and currently do not have any redundant supply outside of WuXi Biologics, for drug substance and drug product. Reliance on a single third-party manufacturer exposes us to different risks than if we were to manufacture product candidates ourselves. While we believe our current inventory of drug substance and drug product will be sufficient to complete our ongoing trials of obexelimab, our preclinical and clinical development product supplies may be limited, interrupted, terminated or be of unsatisfactory quality or unavailable at acceptable prices. WuXi Biologics does not solely hold any of the necessary intellectual property, technology or know-how required to manufacture our product candidates. However, while we are able to transfer our manufacturing process of our product candidates to another CMO without the involvement of WuXi Biologics, establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects.

We order obexelimab drug substance and drug product pursuant to a master services agreement with WuXi Biologics. If any of our product candidates receives marketing approval, we intend to rely on third-party CMOs for commercial manufacturing. As our product candidates advance through development, we expect to enter into longer-term commercial supply agreements to fulfill and secure our production needs. We are in the process of establishing redundant manufacturing capacity for commercial drug substance and drug product at WuXi Biologics' facilities in Europe. In addition, we are currently evaluating potential new CMOs not affiliated with WuXi Biologics in the United States and the EU to establish additional sources of supply for drug substance and drug product for both commercial and clinical use. We currently plan to select the additional suppliers for drug substance and drug product in the second half of 2024. For the medical device component of our product (i.e., prefilled syringe or autoinjector), we plan to utilize device assembly facilities in the United States or EU for the global supply.

We do not have long-term supply contracts with any of our CMOs, and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. Additionally, we have not entered into any agreements for commercial supply of our products, if approved. We may be unsuccessful in negotiating and entering into long-term master supply agreements with certain of our current or future CMOs on favorable terms or at all, which would likely jeopardize our ability to provide any product candidates to participants in clinical trials and products to patients, if approved. Any change in our relationship with our CMO or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects. Additionally, legislation and regulations, such as the proposed BIOSECURE Act, a draft of which is in the legislative process in the U.S. Congress, could restrict our ability to enter into long-term commercial

agreements with certain CMOs if the proposed legislation and regulations are enacted into law. Please see "—Risks Related to Our Reliance on Third Parties—The operations of our suppliers, many of which are located outside of the United States., including our current sole CMO for drug substance and drug product, WuXi Biologics, which is located in China, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects."

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Any interruption or delay in the supply of sole source or limited source components for our product candidates, including as a result of us needing to seek alternative sources, which may not be available at reasonable prices or at all, would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and delayed revenue, if our product candidates are approved, and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The manufacturing process for our product candidates is subject to the FDA and comparable foreign regulatory authority review. We and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If our CMOs cannot successfully manufacture material that conforms to our specifications and regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Additionally, our CMOs may face resource constraints due to labor disputes or unstable political environments that impact their ability to supply product candidates on schedule, which would impact the timing of our clinical trials or commercial supply for any products that may be approved.

We expect to continue to rely on CMOs if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. 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. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

In the event that any of our manufacturers fails to comply with regulatory requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted or more costly than anticipated, we may need to secure manufacturing from a different third party, which we may not be able to do timely or on reasonable terms, if at all. 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 applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. The delays and costs

associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to continue to rely on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current and future product candidates. Because of this reliance, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than if we conduct them ourselves. Third parties are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties have contractual relationships with other entities, some of which may be our competitors, which may divert time and resources from our programs.

Our reliance on third parties reduces our control over our development activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards. For example, we remain responsible for ensuring that each of our preclinical studies are conducted in accordance with good laboratory practices ("GLPs") and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for 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 trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If our third party contractors do not successfully carry out their contractual duties, meet deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding contractors involves cost, takes time and diverts management's attention. In addition, there is a natural transition period when a new third party commences work. Delays could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We may be required to report some of these relationships to the FDA, and the FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affects interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection,

of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.

We are currently party to license and collaboration agreements with Xencor and BMS, and we expect to enter into similar strategic transactions in the future. Our current or any future collaborators may act in a manner that is adverse to our best interests and our interests may conflict with theirs, including concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. Any disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

Our rights to develop and commercialize our product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Xencor. If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property that are important or necessary to the development of our current or future product candidates. For example, we depend on licenses from Xencor for certain intellectual property relating to the development and commercialization of obexelimab, ZB002 and ZB004. However, we have no development and commercialization rights for obexelimab in Japan, South Korea, Taiwan, Hong Kong, Singapore, and Australia, all of which rights have been sublicensed to BMS.

Xencor may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If our licensors, including Xencor, fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize our current or future product candidates that are or may be the subject of such licensed rights could be adversely affected. Further development and commercialization of our product candidates and development of any future product candidates may require us to enter into additional license or collaboration agreements. For example, our licensors or other third parties may obtain intellectual property covering our current or future product candidates which we have not licensed. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our current or future product candidates.

In spite of our efforts, Xencor or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend

our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our 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;
- our financial or other obligations under the license agreement;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

The operations of our suppliers, many of which are located outside of the United States, including our current sole CMO for drug substance and drug product, WuXi Biologics, which is located in China, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, many of our suppliers primarily operate outside of the United States, including our current sole CMO, WuXi Biologics, which provides its services to us from facilities located in China. As a result, we are subject to risks associated with doing business abroad, including:

- geopolitical tensions, political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured, particularly China;
- the imposition of new laws and regulations, including those relating to labor conditions and safety standards, information and data transfer, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate, including China, pursuant to our master supply agreement with WuXi Biologics;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trade secret protection, in some countries, particularly China;
- disruptions in operations due to global, regional, or local epidemics, pandemics and other public health crises, or other emergencies or natural disasters;
- disruptions or delays in shipments; and

- changes in local economic conditions in countries where our manufacturers or suppliers are located.

If enacted, the BIOSECURE Act, which was introduced this year in Congress, would prohibit U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract. This legislation would restrict the ability of biopharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act. The current version of the BIOSECURE Act introduced in the House of Representatives names WuXi Biologics as a "biotechnology company of concern."

If adopted into law, the BIOSECURE Act in its current form would not prevent us from sourcing drug product from WuXi Biologics for clinical use, and we believe our current inventory of drug substance and drug product will be sufficient to complete our ongoing trials of obexelimab. Depending on the final language of the BIOSECURE Act, and how the law is interpreted by U.S. federal agencies, however, we could be potentially restricted from pursuing U.S. federal government business or government reimbursement for our products if we enter into long-term commercial arrangements with WuXi Biologics or other suppliers or partners determined to be "biotechnology companies of concern." Additionally, the legislation could adversely impact WuXi Biologics' operations or financial position, which, in turn, could impact its ability to supply us with product in the future. We may also face additional manufacturing and supply-chain risks due to the regulatory and political structure of China, or due to the deterioration of the relationship between China and the U.S., including but not limited to potential sanctions imposed by the U.S. government on WuXi Biologics, or any of the other countries in which our products are marketed.

We also are currently evaluating potential new contract manufacturing organizations in the United States and the EU to establish additional sources or supply for drug substance and drug product for both commercial and clinical use with third-party manufacturers that are not affiliated with WuXi Biologics or another "biotechnology company of concern" identified in the proposed BIOSECURE Act. However, securing new manufacturers requires significant effort and time and there may be a limited number of qualified replacement CMOs, and a delay in securing, or inability to secure, a commercial supplier of drug substance or drug product for a product candidate, if approved, would delay commercialization timelines or prevent commercial sales if manufacturers cannot be qualified. For additional information on risks related to our current reliance on a sole manufacturer, please see "— Risks Related to Our Reliance on Third Parties — We currently rely on a single third-party manufacturer, WuXi Biologics, to supply our product candidates, including certain drug substances and drug products used in our product candidates. If we are unable to source these supplies on a timely basis, at sufficient quantities or at acceptable quality or prices, establish longer-term contracts with our CMOs, or our third party manufacturers fails to comply with applicable regulatory requirements, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed."

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all and inhibit our suppliers' ability to procure certain materials, any of which could delay our clinical trials or otherwise harm our business, financial condition, results of operations and prospects.

Risks Related to this Offering and Ownership of Our Common Stock

An active and liquid trading market for our common stock may not develop, and you may not be able to resell your shares of common stock at or above the public offering price, if at all.

Prior to this offering, no market for shares of our common stock existed. Our common stock has been approved for listing on Nasdaq under the symbol "ZBIO". After the consummation of this offering, an active or liquid trading market for our common stock may never develop or be sustained following the completion of this offering. To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliated public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and affiliated stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to

sell your shares. Moreover, the initial public offering price for our common stock was determined through negotiations with the underwriters, and will vary from the market price of our common stock following the completion of this offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price or at a price that you consider reasonable. Furthermore, an inactive market may reduce the fair market value of your shares, impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- volatility in our operating results or the failure of our operating results to meet the expectations of investors or securities analysts;
- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical and clinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- our failure to commercialize our product candidates;
- the success of the development of companion diagnostics, if required, for use with our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales or perceived potential sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- any changes to our relationship with manufacturers, suppliers, collaborators or other strategic partners;
- manufacturing or supply shortages;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- press reports, whether or not true, about our business;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

- changes in the structure of healthcare payment systems;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement or expectation of additional financing efforts;
- the inability to obtain additional funding;
- market conditions in the pharmaceutical and biotechnology sectors;
- general global economic, industry, political and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, such as COVID-19, many of which are beyond our control; and
- the other factors described in this "Risk Factors" section and elsewhere in this prospectus, including those which are outside of our control.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following the completion of this offering. The market price of our common stock may decline below the initial public offering price, and you may lose some or all of your investment. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future.

You will incur immediate and substantial dilution as a result of the completion of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $7.83 per share, representing the difference between the initial public offering price of $17.00 per share, and our pro forma net tangible book value per share as of June 30, 2024 after giving effect to the completion of this offering. To the extent that shares are issued upon the exercise of options or the underwriters exercise their over-allotment option, you will incur further dilution. For a further description of the dilution you will experience immediately after the completion of this offering, see the section titled "Dilution."

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales upon the expiration of the lock-up agreements (described in the "Underwriting" section of this prospectus), the early release of the lock-ups, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After the completion of this offering, we will have 39,792,381 shares of common stock outstanding, or 41,777,675 shares if the underwriters exercise their over-allotment option in full, in each case based on the shares of our common stock outstanding as of June 30, 2024. Of these shares, the 13,235,294 shares (or 15,220,588 shares if the underwriters exercise their over-allotment option in full) we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after the completion of this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time in their sole discretion and without notice, except for directors and officers, which would allow for earlier sales of shares in the public market.

Moreover, after the completion of this offering, holders of an aggregate of 26,557,087 shares of our common stock will have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also plan to register all shares of common stock that we may issue under our equity compensation plans or

that are issuable upon exercise of outstanding options. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders will continue to have substantial influence over us after the completion of this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.

After the completion of this offering, our directors, executive officers and greater than 5% stockholders and their affiliates, in the aggregate, will beneficially own shares representing approximately 32% of our outstanding common stock (assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options and excluding any purchases that may be made in this offering). As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

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

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

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

We are an "emerging growth company," as defined in the JOBS Act and we may remain an emerging growth company until December 31, 2029. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or

(ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

Provisions in our Restated Charter, our Restated Bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our Restated Charter and Restated Bylaws, which will become effective prior to the completion of this offering, and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our Restated Charter and Restated Bylaws, which will become effective prior to the completion of this offering, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our Restated Bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our Restated Charter and Restated Bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. 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 we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware ("DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our Restated Charter, Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our Restated Charter will designate specific courts as the sole and exclusive forum for certain claims or causes of action that may be brought by our stockholders, which could discourage lawsuits against us and our directors and officers.

Our Restated Charter will provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if, and only if, the Court of Chancery of the State of Delaware dismisses a Covered Claim (as defined below) for lack of subject matter jurisdiction, any other state or federal court in the State of Delaware that does have subject matter jurisdiction) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the following types of claims: (i) any derivative claim brought in the right of the Company, (ii) any claim asserting a breach of a fiduciary duty to the Company or the Company's stockholders owed by

any current or former director, officer or other employee or stockholder of the Company, (iii) any claim against the Company arising pursuant to any provision of the DGCL, our Restated Charter or Restated Bylaws, (iv) any claim to interpret, apply, enforce or determine the validity of our Restated Charter or Restated Bylaws, (v) any claim against the Company governed by the internal affairs doctrine, and (vi) any other claim, not subject to exclusive federal jurisdiction and not asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"), brought in any action asserting one or more of the claims specified in clauses (a)(i) through (v) herein above (each a "Covered Claim"). This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our Restated Charter will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Restated Charter will provide that any person or entity purchasing or otherwise acquiring any interest in the shares of capital stock of the Company will be deemed to have notice of and consented to these choice-of-forum provisions and waived any argument relating to the inconvenience of the forums in connection with any Covered Claim.

The choice of forum provisions to be contained in our Restated Charter may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions to be contained in our Restated Charter are inapplicable or unenforceable if they are challenged in a proceeding or otherwise, which could cause us to incur additional costs associated with resolving such action in other jurisdictions. The choice of forum provisions may also impose additional litigation costs on stockholders who assert that the provisions are not enforceable or invalid.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the "Use of Proceeds" section of this prospectus. Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in

unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

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

After the completion of this offering, as a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a

quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

As a private company, we do not currently have any internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include workers' compensation, clinical trials, and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects. We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the trading price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. Additionally, the dramatic increase in the cost of directors' and

officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

We could be subject to changes in tax rates, the adoption of new tax legislation or could otherwise have exposure to additional tax liabilities, which could harm our business.

Changes to tax laws or regulations in the jurisdictions in which we operate, or in the interpretation of such laws or regulations, could significantly increase our effective tax rate, and otherwise materially affect our financial condition. In addition, other factors or events, including business combinations and investments, changes in stock-based compensation, changes in the valuation of our deferred tax assets and liabilities, adjustments to taxes upon finalization of various tax returns or as a result of deficiencies asserted by taxing authorities, increases in expenses not deductible for tax purposes, changes in available tax credits, changes in transfer pricing methodologies, other changes in the apportionment of our income and other activities among tax jurisdictions and changes in tax rates, could also increase our effective tax rate. Our tax filings are subject to review or audit by the U.S. Internal Revenue Service (the "IRS") and state, local and foreign taxing authorities. We may also be liable for taxes in connection with businesses we acquire. Our determinations are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in our tax provisions, accruals and returns. An assessment of additional taxes because of an audit could harm our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the commercial opportunities stemming from the development of obexelimab for multiple I&I diseases;
- our ability to develop and, if approved, ultimately commercialize obexelimab and, with partners, our other programs;
- our ability to obtain or maintain orphan drug designation for certain of our product candidates;
- the initiation, timing, progress, results, and cost of our development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of our clinical trials, and the period during which the results of the trials will become available;
- the success, cost and timing of our clinical development of our product candidates;
- our ability to establish clinical differentiation of our product candidates;
- our ability to develop product candidates that have broad therapeutic potential;
- our ability to utilize our business development strategy and expertise to build a balanced portfolio;
- our ability to identify collaborations and strategic partnerships to maximize the value of our portfolio;
- our ability to build our operational and commercial capabilities for supplying and marketing our products, if approved, in key markets;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- the trading volume of our common stock;
- an inability to obtain additional funding;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our reliance on third parties to manufacture drug substance for use in our clinical trials;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our expected uses of the net proceeds to us from this offering and our existing cash and the sufficiency of our existing cash and proceeds from this offering to fund our future operating expenses and capital expenditure requirements;
- the potential benefits of strategic collaboration agreements;
- our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships, and our ability to attract collaborators with development, regulatory and commercialization expertise;

- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- our expectations regarding the time during which we will be an emerging growth company and smaller reporting company under the JOBS Act;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;
- our financial performance;
- developments and projections relating to our competitors or our industry; and
- other risks and uncertainties, including those included in the section titled "Risk Factors."

The forward-looking statements in this prospectus may prove incorrect. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as guarantees of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and management cannot predict all risks and uncertainties. Except as required by applicable law, we do not undertake to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, market and industry data contained in this prospectus, including potential market opportunities, is based on our management's estimates and research, as well as industry and general publications and research and studies conducted by third parties. Although we believe that the information from these third-party publications, research and studies included in this prospectus is reliable, neither we nor the underwriters have independently verified the accuracy or completeness of this information. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations and the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $204.0 million, or approximately $235.4 million if the underwriters exercise their over-allotment option in full, based on the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of June 30, 2024, we had $183.9 million in cash.

We currently intend to use the net proceeds from this offering, together with our existing cash, as follows:

- approximately $100.0 million to advance the clinical development of obexelimab, including to complete the Phase 3 trial for patients with IgG4-RD, the Phase 2 trial for patients with MS, the Phase 2 trial for patients with SLE and the Phase 2 portion of the trial for patients with wAIHA; and
- the remainder to prepare for the obexelimab commercial launch in the U.S. and Europe, if approved, including for the manufacture of commercial supply, and for working capital and other general corporate purposes.

We also may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our preclinical development efforts, our operating costs and other factors described under “Risk Factors” in this prospectus.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 24 months from the date of this prospectus and will enable us to complete our Phase 3 trial for patients with IgG4-RD, and our Phase 2 trials for patients with MS, SLE and wAIHA. These estimates, including our expectation regarding the sufficiency of the net proceeds from this offering to advance the clinical development of obexelimab for IgG4-RD, MS, SLE and wAIHA, are based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We do not anticipate that the expected net proceeds from this offering, together with our existing cash, will be sufficient for us to fund all of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including the anticipated growth of our business, and we may find it necessary or advisable to use the net proceeds for other purposes. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2024:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, (ii) the reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering and (iii) the filing and effectiveness of our Restated Charter, which will be effective immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis giving effect to: (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 13,235,294 shares of our common stock in this offering at the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with the financial statements and related notes as appearing at the end of this prospectus and the information set forth under the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of June 30, 2024		
(in thousands, except share and per share amounts)	Actual	Pro Forma	Pro Forma As Adjusted
Cash	$ 183,930	$ 183,930	$ 389,402
Series Seed convertible preferred stock, par value $0.0001 per share; 1,785,714 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$ 956	$ —	$ —
Series A convertible preferred stock, par value $0.0001 per share; 17,589,380 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	55,840	—	—
Series B convertible preferred stock, par value $0.0001 per share; 81,242,587 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	193,290	—	—
Series C convertible preferred stock, par value $0.0001 per share; 116,275,239 shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	199,526	—	—
Stockholders' (deficit) equity:			
Preferred stock, $0.0001 par value; no shares authorized, issued or outstanding, actual; 25,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.0001 par value; 294,784,925 shares authorized, 1,578,372 shares issued and outstanding, actual; 175,000,000 shares authorized, 26,557,087 shares issued and outstanding, pro forma; 175,000,000 shares authorized, 39,792,381 shares issued and outstanding, pro forma as adjusted	—	3	4
Additional paid-in capital	7,294	456,903	660,952
Accumulated other comprehensive income	104	104	104
Accumulated deficit	(296,180)	(296,180)	(296,180)
Total stockholders' (deficit) equity	(288,782)	160,830	364,880
Total capitalization	$ 160,830	$ 160,830	$ 364,880

If the underwriters' over-allotment option is exercised in full, our pro forma as adjusted cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization as of June 30, 2024, would be $420.8 million, $692.3 million, $396.3 million and $396.3 million, respectively.

The number of shares of our common stock to be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 26,557,087 shares of common stock outstanding as of June 30, 2024 (including 1,507 shares of unvested restricted common stock) after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, and excludes:

- 4,270,097 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2024, with a weighted-average exercise price of $9.21 per share;
- 35,745 shares of common stock reserved for issuance as of June 30, 2024 under the 2020 Plan;
- a number of shares of our common stock equal to 12% of shares issued and outstanding as of immediately following the consummation of this offering (not to exceed 5,657,830 shares) reserved for issuance under the 2024 Plan, which became effective in connection with this offering (which includes up to approximately 4,408,100 shares of common stock underlying stock option awards granted to our directors, executive officers and other employees under the 2024 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share); and
- a number of shares of our common stock equal to one percent of the shares of common stock issued and outstanding as of immediately following the consummation of this offering reserved for issuance under the ESPP, which became effective in connection with this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of June 30, 2024 was $(292.5) million, or $(185.30) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our convertible preferred stock, which is not included within stockholders' (deficit) equity. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 1,578,372 shares of common stock outstanding as of June 30, 2024, which includes 1,507 shares of unvested restricted common stock.

Our pro forma net tangible book value as of June 30, 2024 was $157.1 million, or $5.92 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our liabilities, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering.

After giving further effect to our issuance and sale of 13,235,294 shares of common stock in this offering at the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2024 would have been $364.9 million, or $9.17 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $3.25 per share to existing stockholders and an immediate dilution of $7.83 in pro forma as adjusted net tangible book value per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$17.00
Historical net tangible book value (deficit) per share as of June 30, 2024	$(185.30)	
Increase per share attributable to pro forma adjustments as described above	191.22	
Pro forma net tangible book value per share as of June 30, 2024	5.92	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	3.25	
Pro forma as adjusted net tangible book value per share immediately after this offering		9.17
Dilution per share to new investors participating in this offering		$ 7.83

If the underwriters exercise in full their over-allotment option of common stock from us in this offering, our pro forma as adjusted net tangible book value per share after the offering would be approximately $9.49, representing an immediate increase in pro forma as adjusted net tangible book value per share of approximately $3.57 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of approximately $7.51 to new investors purchasing common stock in this offering, based on the an initial public offering price of approximately $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of June 30, 2024, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration and the weighted-average price per share (1) paid by existing stockholders and (2) to be paid by new investors participating in this offering at the initial public offering price of $17.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	26,557,087	66.7%	$358,281,722	61.4%	$13.49
New investors	13,235,294	33.3	224,999,998	38.6	$17.00
Total	39,792,381	100.0%	$583,281,720	100.0%	

The table above assumes no exercise of the underwriters' over-allotment option in this offering. If the underwriters' over-allotment option is exercised in full, the number of shares of common stock held by existing stockholders would be reduced to 63.6% of the total number of shares of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to 36.4% of the total number of shares of our common stock to be outstanding upon completion of the offering.

The foregoing tables and calculations (other than historical net tangible book value) are based on 26,557,087 shares outstanding as of June 30, 2024 (including 1,507 shares of unvested restricted common stock), after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering and (ii) the reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering, and excludes:

- 4,270,097 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2024, with a weighted-average exercise price of $9.21 per share;
- 35,745 shares of common stock reserved for issuance as of June 30, 2024 under the 2020 Plan;
- a number of shares of our common stock equal to 12% of shares issued and outstanding as of immediately following the consummation of this offering (not to exceed 5,657,830 shares) reserved for issuance under the 2024 Plan, which became effective in connection with this offering (which includes up to approximately 4,408,100 shares of common stock underlying stock option awards granted to our directors, executive officers and other employees under the 2024 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share); and
- a number of shares of our common stock equal to one percent of the shares of common stock issued and outstanding as of immediately following the consummation of this offering reserved for issuance under the ESPP, which became effective in connection with this offering.

New investors participating in this offering will experience further dilution when any new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities for lower consideration per share than in this offering in the future. In addition, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. See "Special Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies for patients in need. With the evolving understanding of the pathogenesis of autoimmune diseases, along with the expansion of promising immunology-based pharmacologic targets, we are building an I&I focused biopharmaceutical company. Our core business strategy combines disciplined product candidate acquisition with strategic deployment of internal expertise and effective use of external resources. We leverage our experienced executive management team and our established networks throughout the biopharmaceutical industry to identify, acquire and develop product candidates that we believe can provide superior clinical benefits to patients living with autoimmune diseases.

Our lead I&I product candidate, obexelimab, is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb, which are broadly present across B cell lineage, in order to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. Based on existing clinical data generated to date, we believe that targeting B cell lineage via CD19 and FcγRIIb can inhibit B cells and has been shown to be well-tolerated. While anti-CD20 or other anti-CD19 targeting agents may effectively deplete B cells in systemic circulation, these agents do not fully impact B cells in relevant tissue, and the intermittent dosing regimens of these agents may not provide optimal benefits for all patients. In addition, anti-CD20 and other anti-CD19 targeting agents cause prolonged depletion of circulating B cells for six months or longer, placing patients at higher risk of opportunistic infections and potentially reducing their ability to respond to, and receive full benefit from vaccines. We believe obexelimab's mechanism of action and chronic dosing regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease. Across five clinical trials in which 198 subjects were dosed, obexelimab was well-tolerated and demonstrated clinical activity that we believe provides POC for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases and, together with its mechanism of action, positions obexelimab to be a potentially differentiated B cell therapy for the treatment of such patients.

We are developing obexelimab as a potential I&I franchise for patients in several autoimmune diseases, representing substantial commercial opportunities individually and in the aggregate. The first four indications we are pursuing include IgG4-RD through an ongoing registration-directed Phase 3 trial, MS and SLE through Phase 2, double-blind, randomized, placebo-controlled trials, each of which we initiated in the third quarter of 2024, and wAIHA through an ongoing Phase 2/3 trial, currently in the Phase 2 open label portion.

Beyond our lead product candidate, obexelimab, we are advancing a pipeline of clinical programs for the potential treatment of other I&I indications that we may continue to develop and ultimately commercialize with partners. Our pipeline includes two global programs, ZB002 (an anti-TNFα monoclonal antibody) and ZB004 (a CTLA-4-Ig fusion), and two regional programs, ZB001 (also known as VRDN-001, an IGF-1R monoclonal antibody), and related programs, and ZB005 (also known as DNTH103, an anti-active C1s monoclonal antibody), both of which we hold the development and commercialization rights for in greater China. Based on the ongoing clinical studies and clinical data generated to date, we intend to determine future potential indications in which to pursue further clinical development of these programs, and ultimately, if approved, commercialization with one or more partners.

Since inception, our operations have focused on research and development activities with respect to our product candidates as described above, as well as raising capital, business planning, organizing and staffing our company, establishing our intellectual property portfolio, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations. Through June 30, 2024, we have financed our operations primarily with the proceeds from the issuance of shares of our common stock and Series Seed convertible preferred stock ("Series Seed Preferred Stock"), Series A convertible preferred stock ("Series A Preferred Stock"), Series B convertible preferred stock ("Series B Preferred Stock"), and Series C convertible preferred stock ("Series C Preferred Stock"), which we refer to collectively as our "Preferred Stock", and from payments received under our strategic license and collaboration agreement with BMS (the "BMS Agreement"), and from the issuance of our convertible notes. From inception through June 30, 2024, we have raised aggregate gross proceeds of $358.3 million through the sale and issuance of our common stock, Preferred Stock, convertible promissory notes, and $50.0 million through our BMS Agreement.

To date, we have no product candidates approved for commercial sale in any country and have not generated any revenue from product sales.

We have incurred significant operating losses and negative cash flows since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net losses for the six months ended June 30, 2024 and 2023 were $65.8 million and $48.1 million, respectively. Our net losses for the years ended December 31, 2023 and 2022 were $37.1 million and $119.3 million, respectively. As of June 30, 2024, we had an accumulated deficit of $296.2 million. We expect to continue to incur significant and increasing losses for the foreseeable future. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue clinical development of obexelimab and our other programs;
- advance our obexelimab program and our other product candidates through preclinical development and clinical trials;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or acquisitions and conduct development activities, including preclinical studies and clinical trials;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- procure the manufacturing of preclinical, clinical and commercial supply of our current or any future product candidates;
- seek marketing regulatory approvals for our current or any future product candidates that successfully complete clinical trials;
- commercialize our current or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- continue to develop, maintain and defend our intellectual property portfolio, including against third-party interference, infringement and other intellectual property claims, if any;
- seek to attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- attempt to address any competing therapies and market developments;
- experience delays in our preclinical studies, clinical trials or regulatory approval for our current or any future product candidates, including with respect to failed studies, inconclusive results, safety issues or other regulatory challenges;
- establish agreements with CROs and CMOs; and

- incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with an exchange listing and the SEC requirements, director and officer insurance premiums and investor relations costs.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, and we cannot assure you that we will ever generate significant revenue or profits. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical studies and expenditures related to our research and development activities.

Furthermore, following the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant audit, legal, regulatory and tax-related expenses, as well as director and officer insurance premiums and investor relations costs that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy as a public company. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity financings, debt financings or other capital sources, which could include collaborations with other companies, or other strategic transactions and licensing agreements. We may be unable to obtain financing on acceptable terms, or at all, and we may be unable to enter into collaborations or other arrangements. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition, including requiring us to have to delay, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves.

As there are numerous risks and uncertainties associated with development of I&I therapeutics, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. We will need to generate significant revenue to achieve profitability, and we may never do so. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of June 30, 2024, we had $183.9 million in cash. We believe that our existing cash as of June 30, 2024, together with the anticipated net proceeds from this offering will be sufficient to fund our operations and capital expenditure requirements through at least the next 24 months. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. See section titled “—Liquidity and Capital Resources.”

Redomicile

On August 2, 2023, we (“Zenas BioPharma Cayman Limited” or “Zenas Cayman”) de-registered in the Cayman Islands and registered by way of continuation in the State of Delaware, whereby we filed a Certificate of Domestication to incorporate in the State of Delaware under the name of Zenas BioPharma, Inc. In connection with this redomicile, (i) the existing shares of convertible preferred stock and ordinary shares of Zenas Cayman automatically converted into the same number and classes of common stock and convertible preferred stock of Zenas BioPharma, Inc. on a one-to-one basis, with rights substantially similar to the converted shares of Zenas Cayman; and (ii) all of our outstanding stock under the 2020 Plan, previously exercisable for ordinary stock, were automatically converted into outstanding awards of Zenas BioPharma, Inc., exercisable for our common stock, with no other changes to the underlying terms of our awards.

Upon the completion of the redomicile and name change, the historical consolidated financial statements of Zenas Cayman became the historical financial statements of Zenas BioPharma, Inc. There was no impact on our consolidated financial statements as a result of the redomicile.

Components of Our Results of Operations

Revenue

To date, we have no product candidates approved for commercial sale in any country, and we have not generated any revenues from the sale of products. Our revenue has been derived from collaboration arrangements and license fees.

Collaboration Revenue

Collaboration revenue is generated exclusively from our collaboration arrangement with BMS. Pursuant to the BMS Agreement, we sublicensed the rights to develop and commercialize obexelimab in Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia (the "BMS Territory"). We retain exclusive rights to commercialize the licensed products containing obexelimab outside of the BMS Territory. The revenue recognized to date pursuant to this arrangement relates to the license of obexelimab and the related technology transfer, which was recognized upon delivery of the license. This arrangement includes the participation by BMS in certain joint global studies of obexelimab in accordance with the terms of the BMS Agreement, in which BMS will reimburse us for its share of the related study costs. Such reimbursements will be classified as a reduction to research and development expense in the period such costs are incurred. We will recognize development and regulatory milestones defined in the BMS Agreement when the achievement of the underlying milestone events is deemed probable, which is expected to be upon achievement. Sales milestones and royalties on future sales will be recognized in the period the related sales occur.

For a more detailed description of this agreement, see the section titled "Business—Licensing and Collaborations," Note 7 to our unaudited condensed consolidated financial statements and Note 8 to our audited consolidated financial statements included elsewhere in this prospectus.

Operating Expenses

Our operating expenses consists of (i) research and development expenses, (ii) general and administrative expenses and (iii) acquired in-process research and development expenses.

Research and Development Expenses

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with the preclinical and clinical development of obexelimab, ZB002, ZB004, ZB001 and ZB005, and include:

Direct Costs:

- external research and development expenses incurred under agreements with CROs and consultants that conduct our clinical studies and other scientific development services;
- costs incurred under agreements with CMOs for manufacturing material for our preclinical studies and clinical trials;
- costs to obtain and maintain licenses to intellectual property, and related future payments should milestones described in those agreements be achieved; and
- costs related to compliance with regulatory requirements.

Indirect Costs:

- employee-related expenses including salaries, bonuses, benefits, stock-based compensation and other related costs for those employees involved in research and development activities; and
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors or our estimate of the level of service that has been performed at each reporting date. Payments for

these external development activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid expenses or accrued expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

A significant portion of our research and development costs have been external costs, which we track on an individual product candidate basis after a clinical product candidate has been identified. We utilize third party contractors for our research and development activities and CMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development. Our internal research and development costs are primarily personnel-related costs and other indirect costs. We do not track internal costs on a program specific or stage of program basis because these costs are deployed across multiple programs and, as such, are not separately classified.

Where we share costs with our collaboration partners, such as in our BMS Agreement, research and development expenses may include cost sharing reimbursements from our partner.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we advance clinical trials for our product candidates, pursue additional indications, continue to develop additional product candidates, expand our headcount and maintain, expand and enforce our intellectual property portfolio. We also expect our manufacturing costs to increase with our CMOs as we scale up our processes for commercial manufacturing. Product candidates in later stages of clinical development will 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 and additional manufacturing activities. There are numerous factors associated with the successful development and commercialization of any product candidates we may develop, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products, and future commercial and regulatory factors beyond our control that will impact our clinical development program and plans.

The successful development of our current product candidates, or any product candidates we may develop in the future is highly uncertain. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of our product candidates, if approved, and any other product candidates that we may develop. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of any current or future product candidate, if approved. This is due to the numerous risks and uncertainties associated with product development, including the uncertainty of:

- the scope, timing and progress of our ongoing obexelimab clinical studies and other research and development activities associated with the development of our other and future product candidates;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new programs;
- the timing of and successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA, or any comparable foreign regulatory authority;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- our ability to establish arrangements with third-party manufacturers for the commercial supply of products that receive marketing approval, if any;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercialization;

- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- our ability to hire additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, chemistry, manufacturing and controls ("CMC"), quality and commercial personnel;
- commercializing product candidates, if approved, whether alone or in collaboration with others;
- the costs and timing of establishing or securing sales and marketing capabilities for our product candidates if approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

Any changes in the outcome of any of these variables with respect to the development of our current product candidates or any future product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently anticipate would be required for the completion of clinical development, or if we experience significant delays in enrollment in any clinical trials following the FDA's acceptance and clearance of an IND application, we could be required to expend significant additional financial resources and time to complete clinical development than we currently expect. We may never obtain regulatory approval for any product candidates that we develop.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expenses for personnel in executive, finance, accounting, human resources and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, tax and consulting and other professional services, and expenses for rent, insurance and other operating costs not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase in the next few years as we increase our headcount to support our continued research and development activities of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with the rules and regulations of the SEC, listing standards applicable to companies listed on a national securities exchange, director and officer insurance costs, and investor and public relations costs. In addition, if we obtain regulatory approval for our current product candidates or any product candidates we may develop in the future and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Acquired In-Process Research and Development Expenses

We expense acquisition costs for assets purchased for use in research and development activities that have no alternative future use as in-process research and development ("IPR&D") expense as of the acquisition date. When we become obligated to make contingent milestone payments under the terms of the agreements by which we acquired the IPR&D assets, we will recognize additional IPR&D expense. We measure and recognize contingent consideration in the period in which the related milestone is achieved and becomes payable.

Total Other Income (Expense), Net

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income generated from interest bearing cash accounts and realized and unrealized gains and losses on foreign currency transactions.

Change in Fair Value of Convertible Notes

In November 2021, we closed the sale and issuance of our convertible promissory notes (the "2021 Notes") for proceeds of $58.0 million. We elected to record the 2021 Notes at fair value upon issuance and to remeasure the fair value at every subsequent reporting date until the 2021 Notes were converted. In November 2022, concurrent with our issuance of Series B Preferred Stock which was deemed to be a qualified financing pursuant to the terms of the 2021 Notes, the 2021 Notes were converted into 37,471,107 shares of our Series B Preferred Stock. We reassessed the estimated fair value immediately prior to the conversion and recorded the change in fair value as component of other income (expense), net in our consolidated statement of operations and comprehensive loss during the year ended December 31, 2022.

In August 2023, we issued a convertible note to BMS (the "BMS Note") in connection with the BMS Agreement as described above. We elected to record the BMS Note at fair value upon issuance and will subsequently remeasure the note at fair value at the end of each reporting period and will record the change in fair value as a component of other expense in our consolidated statement of operations and comprehensive loss. In May 2024, in connection with our Series C Preferred Stock financing, the BMS Note plus accrued interest was automatically converted into 12,284,686 shares of Series C Preferred Stock. For additional details, see Note 3 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus. We reassessed the estimated fair value of the BMS Note immediately prior to the conversion utilizing the fair value of the shares of Series C Preferred Stock for which the note subsequently converted into and recorded the change in fair value as a component of other income (expense), net in our condensed consolidated statement of operations and comprehensive loss during the six months ended June 30, 2024.

Change in Fair Value of Warrant Liability

In May 2021, we issued a warrant with a fair value of $20.7 million to Xencor (the "Xencor Warrant") in connection with the 2021 Xencor Agreement (as defined herein). We elected to record the Xencor Warrant at fair value upon issuance and to remeasure the fair value at every subsequent reporting date until the Xencor Warrant was settled or exercised. In November 2022, concurrent with our issuance of Series B Preferred Stock, the Xencor Warrant was exercised and Xencor received 14,441,793 shares of our Series B Preferred Stock. We reassessed the estimated fair value immediately prior to the conversion and recorded the change in fair value as component of other expense in our consolidated statement of operations and comprehensive loss during the year ended December 31, 2022.

Income Taxes

Since our inception, we have not recorded income tax benefits for any of our deferred tax assets, including the net operating losses ("NOLs") incurred or the research and development tax credits generated in each year, as we have concluded that it is more likely than not that these deferred tax assets will not be realized.

We did not record an income tax provision for the six months ended June 30, 2024. We generated taxable income in the U.S. for the year ended December 31, 2023 as a result of the up-front payment received pursuant to the BMS Agreement and the required capitalization of research and development expenses pursuant to Internal Revenue Code Section 174 ("Section 174"). This resulted in an income tax provision of $0.3 million for the year ended December 31, 2023 related to current federal taxes. As of December 31, 2023, we had approximately $2.3 million of U.S. federal NOL carryforwards. We had no state NOL carryforwards as of December 31, 2023. As of December 31, 2022, we had approximately $22.9 million and $22.2 million of U.S. federal and state NOL carryforwards, respectively. We utilized our available NOL carryforwards to offset the taxable income generated in 2023.

Results of Operations

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for each of the periods presented (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 56,452	$ 30,262	$ 26,190
General and administrative	10,828	7,729	3,099
Acquired in-process research and development	—	10,000	(10,000)
Total operating expenses	67,280	47,991	19,289
Loss from operations	(67,280)	(47,991)	(19,289)
Other income (expense), net:			
Fair value adjustments to convertible notes	(846)	—	(846)
Other income (expense), net	2,349	(153)	2,502
Total other income (expense), net	1,503	(153)	1,656
Net loss	$(65,777)	$(48,144)	$(17,633)

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Direct research and development expenses by program:			
Obexelimab	$35,082	$12,937	$22,145
Global programs (ZB002 & ZB004)	1,466	3,195	(1,729)
Regional programs (ZB001 & ZB005)	4,023	3,854	169
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	15,160	9,773	5,387
Other expenses	721	503	218
Total research and development expenses	$56,452	$30,262	$26,190

Research and development expenses were $56.5 million for the six months ended June 30, 2024, compared to $30.3 million for the six months ended June 30, 2023. The increase of $26.2 million was primarily attributable to the following:

- a $22.1 million increase in costs related to the development of obexelimab, our lead product candidate, driven by a $10.5 million increase in costs related to the conducting and initiation of clinical trials and an $11.6 million increase in manufacturing costs largely to produce drug substance and clinical materials for our trials;
- a $1.7 million decrease in costs related to our global programs, including a $1.2 million decrease related to ZB002 and a $0.5 million decrease related to ZB004, largely driven by a decrease in clinical and non-clinical work associated with our Phase 1 clinical trials and formulation work; and
- a $5.4 million increase in personnel costs, including a $3.8 million increase in salary and benefit related expense, primarily due to an increase in headcount, a $0.6 million increase in stock-based compensation expense, and a $1.0 million increase in other personnel costs.

General and Administrative Expense

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Six Months Ended June 30,		
	2024	2023	Change
Personnel related expenses (including stock-based compensation)	$ 6,094	$4,720	$1,374
Legal and professional fees	2,820	1,728	1,092
Facilities and supplies	1,050	971	79
Other expenses	864	310	554
Total general and administrative expenses	$10,828	$7,729	$3,099

General and administrative expenses were $10.8 million for the six months ended June 30, 2024, compared to $7.7 million for the six months ended June 30, 2023. The increase of $3.1 million was primarily attributable to the following:

- a $1.4 million increase in personnel costs, including a $0.5 million increase in stock-based compensation expense, and a $1.1 million increase in salary and benefit related expense, primarily due to an increase in headcount, partially offset by a $0.2 million decrease in external contractor expenses; and
- a $1.1 million increase in professional fees, including legal, audit and tax expenses, primarily due to preparation for an initial public offering, and increased business development activities.

Acquired In-Process Research and Development Expenses

There was no acquired IPR&D expense recorded for the six months ended June 30, 2024. Acquired IPR&D was $10.0 million for the six months ended June 30, 2023, and was made up of a $10.0 million development milestone payment related to obexelimab.

Total Other Income (Expense), Net

Total other income (expense), net was $1.5 million for the six months ended June 30, 2024, and was made up of interest income of $2.2 million, partially offset by the change in fair value of the BMS Note of $0.8 million upon remeasurement immediately prior to conversion. Total other expense, net was $0.2 million for the six months ended June 30, 2023, and was made up primarily of immaterial realized and unrealized gains and losses on foreign currency transactions.

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for each of the periods presented (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Revenue:			
Collaboration revenue	$ 50,000	$ —	$50,000
Total revenue	50,000	—	50,000
Operating expenses:			
Research and development	60,033	61,689	(1,656)
General and administrative	17,114	13,510	3,604
Acquired in-process research and development	10,000	1,000	9,000
Total operating expenses	87,147	76,199	10,948
Loss from operations	(37,147)	(76,199)	39,052
Other income (expense), net:			
Fair value adjustments to convertible notes	(300)	(29,876)	29,576
Fair value adjustments to warrant liability	—	(13,268)	13,268
Other income, net	624	61	563
Total other income (expense), net	324	(43,083)	43,407
Loss before income taxes	(36,823)	(119,282)	82,459
Income tax provision	(301)	—	(301)
Net loss	$(37,124)	$(119,282)	$82,158

Revenue

Collaboration revenue was $50.0 million for the year ended December 31, 2023, and was derived from our BMS Agreement. There was no collaboration revenue for the year ended December 31, 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for each of the periods presented (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Direct research and development expenses by program:			
Obexelimab	$25,446	$24,562	$ 884
Global programs (ZB002 & ZB004)	6,242	10,641	(4,399)
Regional programs (ZB001 & ZB005)	6,738	9,783	(3,045)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	20,458	15,663	4,795
Other expenses	1,149	1,040	109
Total research and development expenses	$60,033	$61,689	$(1,656)

Research and development expenses were $60.0 million for the year ended December 31, 2023, compared to $61.7 million for the year ended December 31, 2022. The decrease of $1.7 million was primarily attributable to the following:

- a $0.9 million increase in costs related to the development of obexelimab, our lead product candidate, driven by a $5.0 million increase in costs related to the initiation of clinical trials and a $1.0 million increase in non-clinical work to support the trials, partially offset by a $4.1 million decrease in shared development costs as a result of the cost sharing reimbursement arrangement pursuant to the BMS Agreement, and a $1.0 million decrease in manufacturing that was primarily related to the costs of manufacturing clinical trial materials in 2022;
- a $4.4 million decrease in costs related to our global programs, including a $1.5 million decrease related to ZB002 and a $2.9 million decrease related to ZB004, largely driven by a decrease in IND supporting costs in research and manufacturing for regulatory agencies, partially offset by the initiation of clinical studies;
- a $3.0 million decrease in costs related to our regional programs, ZB001 and ZB005, driven by a decrease in CMC and preclinical work needed to support an IND and create Phase 1 materials, partially offset by an increase in Phase 1 clinical trial expenses; and
- a $4.8 million increase in personnel costs, including a $1.2 million increase in stock-based compensation expense and a $3.4 million increase in salary and benefit related expense, primarily due to an increase in headcount, and a $0.1 million increase in other personnel costs.

General and Administrative Expense

The following table summarizes our general and administrative expenses for each of the periods presented (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Personnel related expenses (including stock-based compensation)	$ 9,859	$ 7,489	$2,370
Legal and professional fees	4,626	3,635	991
Facilities and supplies	1,825	1,567	258
Other expenses	804	819	(15)
Total general and administrative expenses	$17,114	$13,510	$3,604

General and administrative expenses were $17.1 million for the year ended December 31, 2023, compared to $13.5 million for the year ended December 31, 2022. The increase of $3.6 million was primarily attributable to the following:

- a $2.4 million increase in personnel costs, including a $1.5 million increase in stock-based compensation expense, a $1.4 million increase in salary and benefit related expense, primarily due to an increase in headcount, and a $0.6 million increase in external consultant costs, partially offset by a $1.1 million decrease in recruiting expense; and
- a $1.0 million increase in professional fees, including legal, audit and tax expenses, primarily due to preparation for an initial public offering, and increased business development activities.

Acquired In-Process Research and Development Expenses

Acquired IPR&D was $10.0 million for the year ended December 31, 2023, and was made up of a $10.0 million development milestone payment made during the year related to obexelimab, compared to IPR&D of $1.0 million for the year ended December 31, 2022, which was made up of a $1.0 million milestone payment made in 2022 related to ZB001.

Total Other Income (Expense), Net

Total other income, net was $0.3 million for the year ended December 31, 2023, and was made up primarily of interest income of $0.7 million, offset by the change in fair value of the BMS Note of $0.3 million

upon remeasurement as of December 31, 2023. Total other expense, net was $43.1 million for the year ended December 31, 2022. The change was due to the remeasurement of the 2021 Notes of $29.9 million prior to conversion into our Series B Preferred Stock, par value $0.0001 per share in 2022 and the remeasurement of the Xencor Warrant liability of $13.3 million prior to settlement upon the issuance of the Series B Preferred Stock in 2022. As these liabilities were settled in November 2022, we did not recognize any expense related to these liabilities in 2023.

Income Taxes

The provision for income taxes was $0.3 million for the year ended December 31, 2023, and was primarily attributable to the taxable income generated as a result of the BMS upfront payment and the required capitalization of research and development expenses. There was no income tax provision recorded for the year ended December 31, 2022.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant operating losses since inception. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates or from other sources for several years, if at all. As of June 30, 2024, we had $183.9 million in cash and we had an accumulated deficit of $296.2 million. Through June 30, 2024, we have funded our operations primarily with gross proceeds of $358.0 million through the sale and issuance of our Preferred Stock, the sale and issuance of our 2021 Notes and the BMS Note, as well as $50.0 million through our BMS Agreement.

Cash Flows

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

	Six Months Ended June 30,		Year Ended December 31,	
	2024	2023	2023	2022
Net cash used in operating activities	$ (50,061)	$(46,975)	$(30,529)	$(65,652)
Net cash used in investing activities	(57)	—	(17)	(2,198)
Net cash provided by financing activities	177,125	66	20,116	59,391
Effect of exchange rate changes on cash and restricted cash	68	161	78	(41)
Net increase (decrease) in cash and restricted cash	$127,075	$(46,748)	$(10,352)	$ (8,500)

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2024 was $50.1 million, and was primarily due to our net loss of $65.8 million, and a $1.3 million decrease in prepaid expenses and other assets, partially offset by a $2.9 million increase in accounts payable, a $0.5 million increase in other current liabilities, a $10.2 million increase in accrued expenses, a $0.8 million increase in the fair value of our BMS Note liability and $2.5 million of stock-based compensation expense. The increase in accrued expenses and accounts payable was primarily attributable to an increase in research and development expenses, while the decrease in prepaid expenses and other assets was primarily due to the timing of vendor payments.

Net cash used in operating activities for the six months ended June 30, 2023 was $47.0 million, and was primarily due to our net loss of $48.1 million, a $6.4 million decrease in accrued expenses, a $1.7 million decrease in prepaid expenses and other assets, and a $2.2 million decrease in accounts payable, partially offset by a $10.0 million acquisition of in-process research and development and $1.4 million of stock-based compensation expense. The decrease in accrued expenses and accounts payable was primarily attributable to a decrease in research and development expenses, while the decrease in prepaid expenses and other assets was primarily due to the timing of vendor payments.

Net cash used in operating activities for the year ended December 31, 2023 was $30.5 million, and was primarily due to our net loss of $37.1 million, a $3.6 million decrease in accrued expenses, a $3.3 million increase in prepaid expenses and other assets, and a $0.4 million decrease in accounts payable, partially offset by $10.0 million of non-cash acquired in-process research and development expense related to a milestone payment, a $0.3 million increase in the fair value of our BMS Note liability, and $3.5 million of stock-based compensation expense. The decrease in accrued expenses and accounts payable was primarily attributable to a decrease in research and development expenses, while the increase in prepaid expenses and other assets was primarily due to the timing of vendor payments.

Net cash used in operating activities for the year ended December 31, 2022 was $65.7 million, and was primarily due to our net loss of $119.3 million and a $4.5 million increase in prepaid expenses and other assets, partially offset by a $29.9 million increase in the fair value of the 2021 Notes, a $13.3 million increase in the fair value of our Xencor Warrant liability, a $12.1 million increase in accrued expenses, a $1.1 million increase in accounts payable, $1.0 million of non-cash acquired in-process research and development expense related to a milestone payment, and $0.7 million of stock-based compensation expense. The increase in accrued expenses and accounts payable was primarily attributable to an increase in research and development expenses, while the increase in prepaid expenses and other assets was primarily due to the timing of vendor payments.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2024 was $0.1 million and consisted of purchases of property and equipment. There was no cash used in or provided by investing activities for the six months ended June 30, 2023.

Net cash used in investing activities for the year ended December 31, 2023 was less than $0.1 million and consisted of immaterial purchases of property and equipment.

Net cash used in investing activities for the year ended December 31, 2022 was $2.2 million, resulting from payments for product candidate license acquisitions and development milestones of $2.0 million and purchases of property and equipment of $0.2 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2024 was $177.1 million, resulting from $178.4 million in proceeds received from the issuance and sale of shares of our Series C Preferred Stock, net of issuance costs, and $0.2 million of proceeds received from the exercise of stock options, partially offset by a $1.4 million payment of offering costs.

Net cash provided by financing activities for the six months ended June 30, 2023 was $0.1 million, resulting entirely from proceeds received from the exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2023 was $20.1 million, resulting from $20.0 million in proceeds received from the sale of the BMS Note and $0.1 million in proceeds received from the exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2022 was $59.4 million, resulting entirely from proceeds received from the issuance and sale of shares of our Series B Preferred Stock, net of issuance costs.

Future Funding Requirements

As of June 30, 2024, we had $183.9 million in cash. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our operations and capital expenditure requirements for at least twelve months from the date that our financial statements are issued. In addition, we estimate that the anticipated net proceeds from this offering, together with our existing cash as of the date of this prospectus, will be sufficient to fund our projected operations and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical development, seek regulatory approval, and pursue commercialization of any approved drug candidates. We expect that our research and development and general and administrative costs will increase in connection with our planned research and clinical activities. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company, including significant audit, legal, regulatory and tax-related expenses, as well as director and officer insurance premiums, investor relations costs, and other expenses that we did not incur as a private company. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

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

- the scope, timing, progress results and costs of our ongoing obexelimab clinical studies and other research and development activities associated with the development of our other and future product candidates;
- the costs, timing and outcome of regulatory review of product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;
- the costs of establishing and maintaining arrangements with third party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the costs and timing of manufacturing for obexelimab and other product candidates, including commercial manufacturing at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the cost of implementing operational, financial and management systems;
- 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 and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, current or future product candidates, if any; and
- the costs associated with operating as a public company following the completion of this offering, including legal, accounting or other expenses in operating our business.

A change in the outcome of any of these or other variables with respect to the development of obexelimab or any other product candidate could significantly change the costs and timing associated with our operating plans. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, which could include collaborations, strategic alliances, or licensing arrangements. We currently have no credit facility or committed sources of capital. Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of such stockholders. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could adversely impact our ability to conduct our business.

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

Material Cash Requirements for Known Contractual and Other Obligations

Leases

We lease office space in both Waltham, Massachusetts and in Shanghai, China. Both leases are classified as operating leases and will expire in June 2025 and September 2025, respectively. Future minimum commitments under these leases are $0.8 million as of June 30, 2024. Of the $0.8 million balance, $0.8 million is due in less than 12 months and an immaterial amount is due in greater than 12 months. These commitments are also recognized as operating lease liabilities on our balance sheet as of June 30, 2024. See Note 6 in both our unaudited condensed consolidated financial statements and our audited consolidated financial statements appearing elsewhere in this prospectus for more information on our lease obligations.

License and Option Agreements

We have also entered into license agreements under which we may be obligated to make milestone and royalty payments, which are contingent upon future events, such as achieving certain development, regulatory, and commercial milestones or generating product sales. As of June 30, 2024 and December 31, 2023, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See Note 8 in our unaudited condensed consolidated financial statements and Note 9 in our audited consolidated financial statements appearing elsewhere in this prospectus for a description of our license agreements.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, CMOs, and other third-party vendors for clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service provided up to one year after the date of cancellation.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be 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. On an ongoing basis,

we evaluate our judgments and estimates in light of changes in circumstances, facts and experiences. Actual results may differ from these estimates under different assumptions or conditions. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates. See Note 2 in both our unaudited condensed consolidated financial statements and our audited consolidated financial statements appearing elsewhere in this prospectus for a description of our other significant accounting policies.

Revenue Recognition

To date, our revenues have consisted solely of payments received related to the BMS Agreement. We apply the revenue recognition guidance in accordance with the Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC"), Topic 606, *Revenue Recognition* ("ASC 606"). Under ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

There is judgement involved in determining whether a collaboration agreement is subject to ASC 606 or FASB ASC 808, *Collaborative Arrangements* ("ASC 808"), in part or in full. An agreement, or portion thereof, are considered to be a collaborative arrangement when they satisfy the following criteria defined in ASC 808: (i) the parties to the contract must actively participate in the joint operating activity and (ii) the joint operating activity must expose the parties to the possibility of significant risks and rewards, based on whether or not the activity is successful. Payments received from or made to a partner as a result of a collaboration relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction or increase to research and development expense, respectively.

For an agreement, or portion thereof, that is not subject to ASC 808, but rather with that of a customer relationship, ASC 606 will be applied. Under ASC 606, there is judgement involved in identifying the promised goods or services in the collaboration agreement, determining whether these are distinct in the context of the contract, and determining if these represent a performance obligation to a customer. These determinations are highly subjective and can differ between arrangements based on specified contractual terms. The identified performance obligations will impact most significantly the timing of revenue recognition, and is a point-in-time assessment performed at the outset of a collaboration agreement.

To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to our customer. All variable consideration, including milestones and royalties, is constrained until the cumulative revenue related to the consideration is no longer probable of reversal. Due to the uncertainty of research and development based milestones that are not within our control, payment becomes probable upon achievement.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services.

We receive payments from our customers based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until we satisfy our obligations under these arrangements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued third-party research and development expenses as of each balance sheet date. This process involves

reviewing open contracts and purchase orders, communicating with our personnel and with vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Research and development expenses also include reimbursements owed to and received from collaboration partners to satisfy cost sharing requirements. These reimbursement amounts reflect our estimates of research and development expense as discussed above. As such, a change in estimates or judgments by us can result in a change to a reimbursement amount. To date, there have been no material true ups from estimated to actual reimbursements owed.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-Based Compensation

We measure stock-based awards granted to employees, non-employee consultants and members of our board of directors based on the grant date fair value and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. For non-employee awards, compensation expense is recognized as the services are provided, which is generally ratably over the vesting period. We account for forfeitures as they occur.

The fair value of each restricted stock award ("RSA") at its grant date is based on the estimated fair value of our common stock on that date as determined by our board of directors. The fair value of each stock 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 expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. As there is currently no public market for our common stock, we determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies. The expected volatility has been determined by comparison to the historical volatility measures of this group of guideline companies. We expect to estimate expected volatility based on the group of guideline companies until we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options granted to employees and non-employee directors has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. 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. We have not paid, and do not anticipate paying, dividends on our common stock; therefore, the expected dividend yield is assumed to be zero.

The fair value of each RSA at its grant date is based on the estimated fair value of our common stock on that date as determined by our board of directors. See Note 11 in our unaudited condensed consolidated financial statements and Note 12 in our audited consolidated financial statements included elsewhere in this prospectus for information concerning the assumptions we used in applying the Black-Scholes option-pricing model to determine the estimated fair value of our stock options.

We recorded stock-based compensation expense of $2.5 million and $1.4 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, there was $25.0 million of unrecognized stock-based compensation expense related to unvested stock options, to be recognized over a weighted-average period of 3.4 years. As of June 30, 2024, there was immaterial unrecognized stock-based compensation expense related to outstanding restricted stock awards, to be recognized over a weighted-average period of 0.1 years.

Determination of Fair Value of Common Stock

As there has been no public market for our common stock to date, the historical estimated fair value of our common stock has been determined by our board of directors, with input from management, considering our most recently available independent third-party valuations of common stock.

In accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, a third-party valuation firm prepared valuations of our common stock using a market approach to estimate our enterprise value, and an option pricing method ("OPM") to allocate value to the common stock. 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 exceed 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.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Given the absence of a public market for our common stock to date, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock. The factors included, but were not limited to:

- contemporaneous valuations performed by an independent third-party valuation firm;
- our stage of development and business strategy and the material risks related to our business and industry;
- the progress of our research and development efforts, including the status of preclinical and clinical studies for our product candidates;
- the achievement of enterprise milestones;
- our operating results and financial performance;
- the prices of our preferred stock sold to or exchanged between outside investors in arm's length transactions, if any, and the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock;
- the lack of liquidity of our equity as a private company;
- the valuation of publicly traded companies in the biopharmaceutical industry, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions, trends, and developments affecting the biopharmaceutical industry;
- the likelihood of achieving a liquidity event for the holders of our preferred shares and common stock, such as an IPO, or a sale of our company, given prevailing market conditions;

- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry; and
- the economy in general.

Once a public trading market for our common stock has been established in connection with the completion of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 in both our unaudited condensed consolidated financial statements and audited consolidated financial statements appearing elsewhere in this prospectus.

Quantitative and Qualitative Disclosures About Market Risks

Interest Rate Risk

We are exposed to interest rate risk in the ordinary course of our business. As of June 30, 2024 and December 31, 2023, we had no cash equivalents or investments in marketable securities. As of June 30, 2024, we had no outstanding debt obligations. As of December 31, 2023, our outstanding debt obligation of $20.0 million for the BMS Note was at a fixed interest rate.

Foreign Currency Exchange Risk

Our reporting currency is the U.S. dollar ("USD"). Our functional currency for Zenas BioPharma (HK) Limited, our wholly owned subsidiary in Hong Kong, is the USD, and our functional currency for Shanghai Zenas Biotechnology Co. Limited, our wholly-owned subsidiary in China, is the Chinese Yuan. The functional currency of our wholly-owned U.S. subsidiaries, Zenas BioPharma (USA) LLC and Zenas Biopharma Securities Corporation, is the USD. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in other income (expense), net in the consolidated statements of operations and comprehensive loss as incurred. Realized foreign currency transaction gains (losses) were immaterial for the six months ended June 30, 2024 and for the year ended December 31, 2023.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material impact on our financial statements included elsewhere in this prospectus.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our business, or on our consolidated financial statements included elsewhere in this prospectus.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would

cease to be an emerging growth company earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non affiliates (and we have been a public company for at least twelve months and have filed one Annual Report on Form 10-K) or we issue more than $1.0 billion of non convertible debt securities over a three year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We may continue to be a smaller reporting company until the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

BUSINESS

Overview

We are a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies for patients in need. With the evolving understanding of the pathogenesis of autoimmune diseases, along with the expansion of promising immunology-based pharmacologic targets, we are building an I&I focused biopharmaceutical company. Our core business strategy combines disciplined product candidate acquisition with strategic deployment of internal expertise and effective use of external resources. We leverage our experienced executive management team and our established networks throughout the biopharmaceutical industry to identify, acquire and develop product candidates that we believe can provide superior clinical benefits to patients living with autoimmune diseases.

Our lead I&I product candidate, obexelimab, is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb, which are broadly present across B cell lineage, in order to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. Based on existing clinical data generated to date, we believe that targeting B cell lineage via CD19 and FcγRIIb can inhibit B cells and has been shown to be well-tolerated. While anti-CD20 or other anti-CD19 targeting agents may effectively deplete B cells in systemic circulation, these agents do not fully impact B cells in relevant tissue, and the intermittent dosing regimens of these agents may not provide optimal benefits for all patients. In addition, anti-CD20 and other anti-CD19 targeting agents may cause prolonged depletion of circulating B cells for six months or longer, placing patients at higher risk of opportunistic infections and potentially reducing their ability to respond to, and receive full benefit from, vaccines. We believe obexelimab's mechanism of action and chronic dosing regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease. Across five clinical trials, in which 198 subjects were dosed, obexelimab was well-tolerated and demonstrated clinical activity that we believe provides POC for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases and, together with its mechanism of action, positions obexelimab to be a potentially differentiated B cell therapy for the treatment of such patients.

We are developing obexelimab as a potential I&I franchise for patients in several autoimmune diseases, representing substantial commercial opportunities, individually and in the aggregate. The first four indications we are pursuing include IgG4-RD through an ongoing registration-directed Phase 3 trial, MS and SLE through Phase 2, double-blind, randomized, placebo-controlled trials, each of which we initiated in the third quarter of 2024, and wAIHA through an ongoing Phase 2/3 trial, currently in the Phase 2 open label portion. We estimate that the commercial opportunity across these four indications is approximately $50 billion in the aggregate in the U.S. alone.

Beyond our lead product candidate, obexelimab, we are advancing a pipeline of clinical programs for the potential treatment of other I&I indications that we may continue to develop and ultimately commercialize with partners. Our pipeline includes two global programs, ZB002 (an anti-TNFα monoclonal antibody) and ZB004 (a CTLA-4-Ig fusion), and two regional programs, ZB001 (also known as VRDN-001, an IGF-1R monoclonal antibody), and related programs, and ZB005 (also known as DNTH103, an anti-active C1s monoclonal antibody), for which we hold the development and commercialization rights in greater China. Based on the ongoing clinical studies and clinical data generated to date, we intend to determine future potential indications in which to pursue further clinical development of these programs and ultimately, if approved, commercialization with one or more partners.

To date, we have no product candidates approved for commercial sale in any country and have not generated any revenue from product sales.

Obexelimab Overview

We are developing obexelimab for the treatment of several I&I diseases summarized in the pipeline figure below:

Our lead product candidate, obexelimab, was engineered to mimic the natural antigen-antibody complex for the inhibition of B cells. By targeting CD19, obexelimab is designed to inhibit a broader B cell population, including plasmablasts and the subpopulation of CD19 expressing plasma cells, each of which produces high amounts of auto-antibodies. Co-engagement of CD19 and FcγRIIb by obexelimab has been shown to inhibit B cell activity, including antibody production, proliferation, cytokine secretion, B cell differentiation, and antigen presentation to T cells. In addition, obexelimab is designed to inhibit rather than destroy or deplete B cell lineage. Other anti-CD19 and CD20 targeting antibodies rely on antibody-dependent cell-mediated cytotoxicity ("ADCC"), complement-dependent cytotoxicity ("CDC") and/or apoptosis or programmed cell death as a key component of their mechanism of action. ADCC, CDC and apoptosis activity are generally lower in disease-relevant tissue than the peripheral blood. In addition, in clinical practice other CD19 and CD20 targeted antibodies are typically dosed once every six months which has demonstrated efficacy, but may not provide sustained benefit in all patients due to variability in B cell depletion and recovery. The obexelimab mechanism of action and chronic dosing regimen may more broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease and has the potential to show greater clinical benefits, especially over a longer course of maintenance treatment.

The inhibitory mechanism of obexelimab is believed to reduce the number of B cells in systemic circulation through margination of B cells to other tissues such as the lymph nodes and the spleen, rather than through depletion. The concept of margination is supported by preclinical and clinical data, where the substantial return of B cells in circulation of subjects receiving obexelimab was observed to occur as soon as six weeks after discontinuation of obexelimab administration, contrasted with the much longer period of B cell recovery observed with other CD19 and CD20 targeted depleting agents, which can take six months or longer following the last dose. The risks of prolonged B cell depletion include limitations on a patient's ability to fight serious and opportunistic infections and on a patient's ability to generate an adequate response to vaccines such as influenza, shingles, respiratory syncytial virus, and COVID-19. We believe the rapid return in B cell activity following the cessation or pause in obexelimab dosing could allow the patient's immune system to more quickly return to baseline to protect against infections and allow a patient to receive vaccinations within as few as six weeks of his or her last dose, rather than potentially waiting six months or longer following treatment with an anti-CD19 or anti-CD20 targeted depleting therapy.

Obexelimab has been evaluated in five completed clinical trials in which a total of 198 subjects have received obexelimab either as IV infusion at doses of up to 10 mg/kg (n=158) or as a SC injection at doses of up to 375 mg (n=40). Obexelimab was well-tolerated across these five trials and demonstrated PK, as well as clinical activity providing POC in multiple I&I indications. Based on this clinical data, we believe obexelimab could have potential advantages over anti-CD19 and -CD20 targeted depleting agents.

We believe obexelimab holds the potential to provide meaningful clinical benefit for patients in multiple I&I indications. We are currently pursuing a registration-directed trial in patients with IgG4-RD, initiated Phase 2, double-blind, randomized, placebo-controlled clinical trials of obexelimab in patients with MS and SLE in the third quarter of 2024, and are conducting a Phase 2/3 trial, currently in the Phase 2 open label portion, in patients with wAIHA.

Other Pipeline Programs

Beyond our lead product candidate, obexelimab, we are advancing a pipeline of clinical programs for the potential treatment of other I&I indications that we may continue to develop and ultimately commercialize with partners.

Product Candidate	Territory	Phase of Development
ZB002 (anti-TNFα mAb)	Global	Phase 1b MAD study in patients with RA ongoing
ZB004 (CTLA-4-Ig fusion)	Global	Phase 1 SAD study in healthy volunteers
ZB001 (IGF-1R mAb)	Greater China	Phase 1 MAD study in Chinese patients with active TED
ZB005 (anti-active C1s mAb)	Greater China	

We are developing ZB002, an anti-TNFα therapy designed to have an extended half-life as compared to existing anti-TNFα therapies. ZB002 is a recombinant human monoclonal antibody directed at human TNFα. ZB002 has an identical amino acid sequence to Humira (adalimumab) in the TNFα-binding region of the fragment variable domain; however, the Fc domain of ZB002 contains modifications designed to extend its half-life *in vivo*. In December 2022, we initiated a Phase 1, double-blind, randomized, placebo-controlled, SAD study designed to evaluate the safety, tolerability, and PK profile of ZB002 in healthy volunteers. Our Phase 1 SAD study demonstrated a half-life of approximately 55 days for ZB002, which we believe may allow for dosing once every four to eight weeks. In the second quarter of 2024, we initiated a Phase 1b MAD study of ZB002 in patients with rheumatoid arthritis. If the results of our ongoing Phase 1b MAD study of ZB002 are favorable, we will seek to identify a partner to advance ZB002 in subsequent trials for potential use as a treatment for certain I&I diseases that can benefit from TNFα inhibition.

We also are developing ZB004, a CTLA-4-Ig fusion protein designed to have an extended half-life compared to approved CTLA-4-Ig fusion protein therapies, such as Orencia (abatacept) and Nulojix (belatacept). Similar to approved CTLA-4-Ig fusion protein therapies, the ZB004 mechanism of action is selective inhibition of T cell co-stimulation. The CTLA-4 motif binds to CD80 and CD86 on antigen-presenting cells, blocking the interaction of these receptors with CD28 on T lymphocytes, and thus inhibiting T cell co-stimulation. ZB004 contains two CTLA-4 extracellular domain substitutions designed to potentially produce greater CD80 and CD86 binding. In June 2023, we initiated a Phase 1, double-blind, randomized, placebo-controlled, SAD study designed to evaluate the safety, tolerability, PK and PD profile of ZB004 in healthy volunteers. Our Phase 1 single ascending dose ("SAD") study demonstrated a half-life of approximately 17.4 days at the highest dose level of 200 mg, where CD86 receptor occupancy reached a maximum peak value of 81%, overcoming the effect of target mediated drug disposition. There were no dose limiting toxicities, AEs leading to discontinuation or SAEs. All AEs were mild or moderate in severity. Based on the ongoing analysis of data from the Phase 1 study, along with the known clinical efficacy of approved CTLA-4-Ig fusion protein therapies, we are seeking to advance the clinical development of ZB004 with a potential partner in indications where it could be uniquely positioned given its profile.

We also have in-licensed the greater China rights to each of ZB001 (also known as VRDN-001), an IGF-1R monoclonal antibody, and related programs from Viridian, and ZB005 (also known as DNTH103), an anti-active C1s monoclonal antibody, from Dianthus. Following the initial clinical development for each of ZB001 and ZB005, we intend to seek to enter into an agreement with a third party who can complete the clinical development work, obtain regulatory approval, and ultimately, if approved, commercialize these programs in greater China.

Our Management Team and Investors

Our executive management team is comprised of seasoned executives and scientists with extensive experience in the biopharmaceutical industry leading drug development and commercialization and executing successful business development strategies. Our company is led by Leon (Lonnie) O. Moulder, Jr., our Founder, Chief Executive Officer and Chairman, and the Managing Member of Tellus BioVentures, LLC, an early-stage

life sciences investment fund. Prior to founding Zenas, Mr. Moulder co-founded TESARO, an oncology-focused biopharmaceutical company, serving as Chief Executive Officer and Director until its acquisition by GlaxoSmithKline. He previously served as President and Chief Executive Officer of Abraxis BioScience and as Vice Chairman of Eisai Corporation of North America following Eisai's acquisition of MGI PHARMA, where he served as President and Chief Executive Officer. Mr. Moulder is joined by our team of veteran biopharmaceutical executives, including Joseph Farmer, Jennifer Fox and Orlando Oliveira, who together with the leadership team, bring exceptional track records and experiences across the industry at companies such as TESARO, GlaxoSmithKline, Amgen, Nuvation, Mirati, Cubist and other biopharmaceutical companies. Our leadership team has collectively been responsible for numerous INDs and NDAs/BLAs and the associated commercial product launches of several successful pharmaceutical products.

Since our inception, we have raised $358.3 million from investors including Enavate Sciences, SR One, Longitude Capital, Tellus BioVentures, Fairmount, New Enterprise Associates, Norwest Venture Partners and Bristol-Myers Squibb. Potential investors should not consider investments made by our existing investors as a factor when making a decision to purchase shares in this offering since our existing investors may have had different risk tolerances and paid less per share than the price at which the shares are being offered in this offering.

Our Strategy

Our vision is to become a global leader in delivering transformative I&I therapeutics to patients in need. We intend to leverage the experience and capabilities of our executive management team and our established networks throughout the biopharmaceutical industry to identify, acquire, develop and, if approved, commercialize product candidates that we believe can offer enhanced efficacy, safety and/or convenience over existing therapies and thereby provide superior benefits to patients. We intend to achieve our goals by implementing the following strategies:

- **Develop and commercialize our obexelimab franchise across multiple I&I indications**. Across five clinical trials, in which 198 subjects were dosed, obexelimab was well-tolerated and demonstrated clinical activity that we believe provides POC for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases. We are developing obexelimab as a potential I&I franchise for patients in several autoimmune diseases, representing substantial commercial opportunities individually and in the aggregate. The first four indications we are pursuing include IgG4-RD through an ongoing registration-directed Phase 3 trial; MS and SLE through Phase 2, double-blind, randomized, placebo-controlled trials, each of which we initiated in the third quarter of 2024; and wAIHA through an ongoing Phase 2/3 trial, currently in the Phase 2 open label portion.
- **Build our operational capabilities to develop and potentially commercialize our products in key regions.** With plans to advance our obexelimab franchise in multiple I&I indications, we intend to build the commercial capabilities necessary to achieve our goal of becoming a global development and commercial stage biopharma company. To do so, we plan to leverage the extensive experience of our executive team in launching products in major markets globally. Our intent since inception has been to maintain a global physical presence, and we currently have development and medical affairs capabilities in the United States, Europe and Asia. We intend to continue to expand these capabilities, particularly in the United States and Europe, as we continue to advance our programs into late-stage clinical development and potential commercialization.
- **Utilize our business development experience and expertise to continue to build a deep and balanced portfolio of products and product candidates.** We acquired each of our product candidates through in-licensing from third parties. Our ability to identify, acquire and efficiently advance obexelimab into Phase 3 and Phase 2 clinical trials across multiple indications demonstrates our capabilities and initiative to acquire and advance product candidates that fit our strategic vision. We intend to continue to utilize our business development strategy and expertise to build a balanced portfolio of new product candidates from preclinical through commercial assets. We leverage the deep clinical and preclinical development, regulatory, manufacturing and commercialization expertise of our team to identify, evaluate and acquire product candidates that we believe can be clinically differentiated in terms of efficacy, safety and/or convenience.

- **Leverage success with initial indications to expand into broader I&I opportunities.** We believe that the biological pathways that are involved in many I&I diseases are related and, therefore, therapies that effectively address these pathways may be applicable in multiple I&I diseases. Our strategy for each product candidate is to initially pursue indications where the clinical translatability of the mechanism of action has been validated, where we believe we can independently and efficiently pursue clinical development and regulatory approval, and where we believe an attractive commercial opportunity exists. We also intend to pursue additional indications with larger patient populations where we believe our product candidates' mechanisms may be relevant.
- **Evaluate strategic collaborations as appropriate.** We have in the past and may in the future seek arrangements with other biopharmaceutical companies with strong and proven commercial capabilities for them to commercialize our potential therapies in such territories, if approved. For example, in August 2023, we entered into the BMS Agreement, pursuant to which we granted the exclusive rights to develop and, if approved, commercialize obexelimab in Japan and certain other Asian-Pacific countries. In addition, for certain product candidates, including ZB001, ZB002, ZB004 and ZB005, or indications that may require larger clinical development plans and commercial infrastructure, we may selectively seek to partner to help fund development and commercialization.

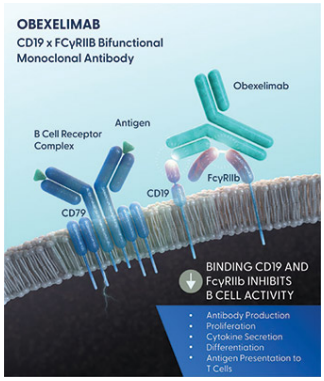
Obexelimab (CD19 x FcγRIIb bifunctional monoclonal antibody) Program

We believe that our lead product candidate, obexelimab, has the potential to address key unmet needs in multiple I&I indications due to its mechanism of action and chronic dosing regimen that may broadly and effectively address the pathogenic role of B cell lineage through reversible inhibition of B cell activity without causing B cell depletion.

Obexelimab is a bifunctional, non-depleting, humanized monoclonal antibody designed to bind CD19 and FcγRIIb to inhibit B-lineage cell activity. The antibody variable region of obexelimab has been engineered to bind CD19, whereas the constant region has been engineered to enhance affinity for the inhibitory FcγRIIb receptor. FcγRIIb is the only Fc receptor on B cells and serves as an antibody-sensing down-regulator of humoral immunity that is naturally engaged by immune complexes. In addition, FcγRIIb regulates the activity of other B cell stimulators including interleukin-4, lipopolysaccharide and B cell activating factor ("BAFF") that amplify BCR-driven proliferation and differentiation. By binding CD19 and FcγRIIb, obexelimab mimics the action of naturally occurring antigen-antibody complexes and inhibits B cell activity without depleting B cells in the lymph nodes or spleen.

The mechanism of action of obexelimab shown below in Figure 1, involves co-engagement of CD19 and FcγRIIb, leading to inhibition of B cell activity, including antibody production, proliferation, cytokine secretion, B cell differentiation, and antigen presentation to T cells.

Figure 1: Mechanism of Action of Obexelimab



Through *in vitro, in vivo* and classical animal models of autoimmune disease, obexelimab's binding to CD19 and FcγRIIb has been shown to enable the inhibition of B cell activity without depleting B cells. Preclinical and clinical studies have demonstrated that obexelimab potently inhibited B cell activity along with a decrease of approximately 50% in circulating B cell levels observed within one to two days. We believe the decrease in circulating B cell levels results from margination of B cells in lymphatic tissues, such as the lymph nodes and spleen, rather than depletion or elimination of the B cells. In contrast, anti-CD20 and other anti-CD19 B cell-targeting agents deplete B cells through B cell destruction. In clinical studies, we have observed substantial recovery of B cell levels in circulation following cessation of therapy with obexelimab within six weeks, as opposed to six months or longer that has been observed with B cell depleting agents. This rapid return in B cell activity following the cessation or pause in obexelimab dosing could allow the patient's immune system to more quickly return to baseline to protect against infections and could allow a patient to receive vaccination within as few as six weeks of his or her last dose, rather than potentially waiting six months or more following treatment with an anti-CD19 or anti-CD20 targeted depleting therapy.

Clinical Development

Obexelimab has been evaluated in five completed clinical trials in which a total of 198 subjects have received obexelimab either as an IV infusion at doses of up to 10 mg/kg (n=158) or as a SC injection at doses up to 375 mg (n=40). Across these five trials obexelimab was well-tolerated and demonstrated clinical activity that we believe provides POC for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases. Our current ongoing and planned future trials of obexelimab utilize a fixed 250 mg, dosed weekly as a self-administered SC injection.

Summary of Completed Clinical Trials for Obexelimab

Study Description*	Phase	N	Key Results
Healthy Volunteers Study	Phase 1a	48	Demonstrated tolerability, PK and target engagement
Rheumatoid Arthritis ("RA") Trial	Phase 1b / 2a	56	Demonstrated POC by showing clinical activity in patients with RA
IgG4-RD Trial	Phase 2	20	Demonstrated POC in patients with IgG4-RD
SLE Trial	Phase 2	104	Demonstrated POC in patients with SLE by showing increased response rates**
SC & IV Formulation Bioavailability Study	Phase 1	50	Established bridging of IV to SC formulation

* These clinical studies were conducted by Xencor. The results of these studies are further described below.

** Primary endpoint did not achieve statistical significance.

- **Study in Healthy Adult Volunteers:** XmAb5871-01 was a Phase 1, randomized, blinded, placebo-controlled, SAD IV study of the safety, tolerability and PK of obexelimab in 48 healthy adult volunteers, with 36 receiving study drug, conducted in the United Kingdom. The primary objective of the study was to evaluate the safety and tolerability profile of a single-dose IV administration of obexelimab. The secondary objective was to characterize the single-dose PK and immunogenicity of obexelimab. The study demonstrated that obexelimab was well tolerated at all doses, including the highest dose of 10 mg/kg. Gastrointestinal ("GI")-related TEAE (including nausea, vomiting, abdominal pain, abdominal discomfort, epigastric discomfort and diarrhea) were the most frequently reported (14/36, 38.9%). There were no SAEs reported. The study was not powered for statistical significance.
- **Trial in Rheumatoid Arthritis:** XmAb5871-02 was a Phase 1b/2a, randomized, placebo-controlled, double-blind, ascending multiple-IV dose trial of the safety, tolerability, PK, and PD of obexelimab in 56 patients with RA, with 40 receiving study drug. The trial was conducted at nine sites in four countries, including, Hungary, Poland, Czech Republic and Slovakia. The primary objective of the trial was to evaluate the safety and tolerability profile of multiple-dose, every 14-day, IV administration of obexelimab in patients with RA. The secondary objectives were to (i) characterize the PK and immunogenicity of multiple-dose, IV administered obexelimab in patients with RA and (ii) evaluate

the effect of obexelimab on RA disease response. Complete CD19 receptor occupancy was seen at doses as low as 1 mg/kg from the first dose through the completion of dosing. The efficacy parameters evaluated in the trial showed an improvement trend in RA patients who received obexelimab when compared to patients who received placebo, although the trial was not powered to show significant changes. Patients who received obexelimab generally had improvement in ACR20, ACR50, ACR70, and DAS28-CRP Disease Activity when compared to patients who received placebo. In general, obexelimab was well tolerated, and the most common TEAEs were vomiting (7/40, 17.5%), headache (7/40, 17.5%), nausea (6/40, 15.0%), pyrexia (4/40, 10.0%), and arthralgia (4/40, 10.0%). Two subjects experienced infusion-related reactions (both at 10.0 mg/kg), one of which was considered an SAE. The other event, associated with the first infusion, was considered of moderate severity. In both cases, the infusion was terminated, and the patients recovered without sequelae. The trial was not powered for statistical significance.

- **Trial in IgG4-RD:** XmAb5871-03 was a Phase 2, open-label, single-arm IV, trial in 20 patients with IgG4-RD, including 15 patients dosed with 5 mg/kg of obexelimab, conducted in Boston, Massachusetts. The primary objective of the trial was to evaluate the effect of every-other-week IV administration of obexelimab on the IgG4-RD RI. The secondary objectives were to (i) evaluate the safety and tolerability of every-other-week IV administration of obexelimab in subjects with active IgG4-RD and (ii) evaluate the PK and immunogenicity of every-other-week IV administration of obexelimab in subjects with active IgG4-RD. In the primary efficacy analysis, in patients receiving 5 mg/kg, the IgG4-related disease Responder Index ("RI") score at Day 169 had decreased by two or more points versus baseline in 12 (80%) patients, eight (67%) of whom had a score of zero (complete remission). Fourteen (93%) patients achieved an improvement on the RI of two or more points during at least one trial assessment at a median of 15 days (range 14 to 90) from treatment initiation. We believe these data demonstrated POC for obexelimab in IgG4-RD. In general, obexelimab was observed to be well tolerated in patients with IgG4-RD. The most common TEAEs were abdominal pain and nausea (4/20, 20.0%), vomiting (3/20, 15.0%), and diarrhea, chills, headache, nasal congestion, and upper respiratory tract infection (2/20, 10.0%). There was one case of pneumonia accounting for two SAEs (initial and recurrence due to non-compliance with therapy) in one patient and a second patient experienced one SAE (chronic inflammation demyelinating polyradiculoneuropathy in the setting of small lymphocytic lymphoma (pre-existing)). None of the SAEs were considered to be related to obexelimab. The trial was not powered for statistical significance.
- **Trial in SLE:** XmAb5871-04 was a Phase 2, double-blind, randomized, placebo-controlled, potential POC trial in 104 patients with SLE administered IV, with 52 receiving study drug. The trial was conducted at 23 sites in the United States. The primary objective of the trial was to determine the ability of obexelimab to maintain SLE disease activity improvement achieved by a brief course of disease-suppressing intramuscular ("IM") steroid therapy. The secondary objectives were to (i) evaluate time to loss of SLE disease activity improvement achieved by a brief course of disease-suppressing IM steroid therapy, (ii) evaluate the safety and tolerability of every-other-week IV administration of obexelimab in subjects with SLE and (iii) evaluate the PK and immunogenicity of every-other-week IV administration of obexelimab in subjects with SLE. Although the primary endpoint (the proportion of patients without loss of improvement in SLE disease activity) in the Efficacy Evaluable ("EE") population was not achieved with statistical significance, the absolute treatment difference in the ITT population was 17.3% (40.4% obexelimab versus 23.1% placebo response, $p = 0.06$). The ITT analysis is relevant because all patients are considered in these analyses, whereas in the EE analysis there was a larger number of patients treated with placebo who discontinued treatment for reasons that removed them from the analysis. The difference in response rates between the obexelimab and placebo arms in this trial was similar to that observed in SLE registration-directed trials with other agents, although with different trial design and endpoints. Accordingly, we believe these data demonstrated POC for obexelimab in SLE. Obexelimab was generally well tolerated in patients with SLE. The most frequently occurring TEAEs were nausea (20/52, 39%), headache (12/52, 23%), vomiting (9/52, 17%), back pain and dizziness (8/52, 15%), flushing (7/52, 14%), and pain in extremity (6/52, 12%). There were eight SAEs in patients administered obexelimab, only one SAE (infusion-related reaction) of which was considered related to study drug. Adverse events led to the withdrawal of seven (13%) obexelimab-treated patients (most of which were infusion-related reactions) and two (4%) patients that were administered placebo.

- **PK and Relative Bioavailability Study of SC versus IV Formulation:** XmAb5871-05 was a Phase 1 PK and relative bioavailability study of obexelimab administered either intravenously or subcutaneously in 50 healthy volunteers, conducted in Glendale, California, USA. The primary objectives of the study were to (i) characterize and compare the PK and bioavailability of obexelimab administered either IV or SC and (ii) evaluate the safety and tolerability of obexelimab administered SC. The secondary objectives of the study were to (i) determine the immunogenicity of obexelimab administered SC and (ii) characterize and compare the PK of healthy subjects with healthy Japanese subjects. In this study, five separate cohorts were treated with five separate obexelimab dosing regimens: 125 mg SC, 250 mg SC, 375 mg SC, or 250 mg IV every two weeks for six weeks, or 125 mg SC every week for three weeks. The absolute bioavailability of obexelimab across all cohorts after the SC administration was observed to be 58.1% and 53.6% after the first and third doses, respectively. All of the SC doses were observed to be well tolerated in all subjects. In the SC cohorts, the only TEAE occurring in more than two subjects was injection site bruising, which occurred in less than 2% of injections, was considered mild and resolved within 24 hours. The incidence of GI TEAE attributed to SC administration of obexelimab was less than 3%. There were no SAEs reported. Accordingly, we believe that the PK, relative bioavailability, and tolerability demonstrated in this study support the continued clinical development of the SC formulation of obexelimab.

Obexelimab has demonstrated clinical activity across multiple I&I indications. We are currently pursuing a registration-directed trial in patients with IgG4-RD, planning Phase 2, double-blind, randomized, placebo-controlled clinical trials of obexelimab in patients with MS and SLE, and are conducting a Phase 2/3 trial, currently in the Phase 2 open label portion, in patients with wAIHA. Despite the promising results from the Phase 1b/2a trial of obexelimab in RA, we do not intend to develop obexelimab further in RA due to the competitive landscape in that disease.

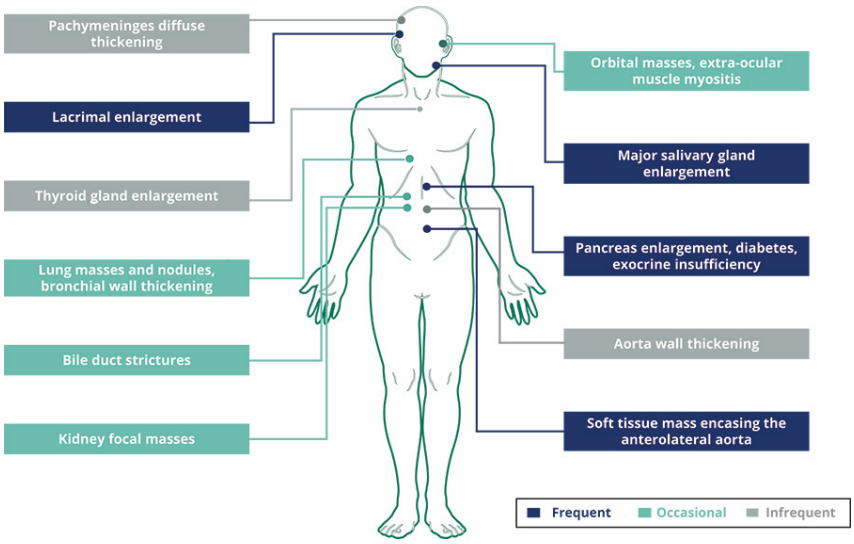
Obexelimab for the Treatment of IgG4-RD

We believe obexelimab's differentiated mechanism of action as an inhibitor of B cell lineage supports its potential to play an important role in the treatment of IgG4-RD. The reported evidence for the role of B cells in the pathogenesis of IgG4-RD, the observed effects of B cell targeting agents in previous trials in IgG4-RD and the data from our Phase 2 IgG4-RD trial with obexelimab support the continued development of obexelimab in patients with IgG4-RD. We are enrolling patients in our INDIGO Trial, a global Phase 3 registration-directed, randomized, double-blind placebo-controlled trial of obexelimab delivered 250 mg subcutaneously weekly to evaluate the prevention of flares in patients with IgG4-RD. We expect to report topline data from our INDIGO Trial in 2025 and, subject to the data, submit a BLA in 2026.

IgG4-RD Histology and Disease Background

IgG4-RD is a chronic fibro-inflammatory condition that can affect virtually all organ systems, including the pancreas, biliary tract, salivary and lacrimal glands, lungs, and kidneys. Patients with IgG4-RD may present with a single organ involved but more frequently present with multiple organ involvement. As the disease progresses and patients experience new or worsening symptoms (i.e., flares), lesions develop in additional organs and the cellular inflammation characterizing early disease moves toward a more fibrotic stage, which can lead to major irreversible tissue damage and ultimately organ failure. The most common symptoms in patients with IgG4-RD and their relative frequency of presentation are highlighted below in Figure 2. IgG4-RD is a relatively recently described disease that incorporates groups of manifestations that were diagnosed as separate disease entities prior to 2003. We estimate that the currently diagnosed population of IgG4-RD patients in the United States is approximately 20,000, with comparable prevalence rates globally. We estimate IgG4-RD to be an approximately $3 billion commercial opportunity in the U.S. alone. The pathogenesis of IgG4-RD suggests that B cell-targeted therapies may provide therapeutic benefit. Several B cell subsets have recently been shown to be elevated in the peripheral blood of IgG4-RD patients. Moreover, plasmablasts have been shown to actively contribute to tissue fibrosis through multiple mechanisms, including production of pro-fibrotic molecules and stimulation of collagen production by fibroblasts.

Figure 2: IgG4-RD: A Chronic Fibro-inflammatory Disease Characterized by Flares



Current Treatment and Unmet Need

Despite the growing recognition of IgG4-RD and advances in the understanding of its pathophysiology, there are no approved therapies for the treatment of this disease and there remains high unmet medical need. There are few treatment options, which are often limited by co-morbidities common among patients with IgG4-RD, including diabetes, obesity and hypertension. The current standard of care is glucocorticoid treatment ("GCs"), however such treatment often results in various complications. Although GCs are initially effective in most patients, up to 60% of patients with IgG4-RD will relapse within 12 months of discontinuing GC treatment.

IgG4-RD is a disease commonly marked by flares, which can lead to the accumulation of fibrosis, resulting in irreversible organ damage, often involving multiple organs, and past flares are often a strong indicator of future flares. Therefore, patients are in need of long-term maintenance treatment. However, maintenance therapy with GCs has not been shown to prevent recurrence of disease and can lead to significant toxicity and complications, including osteoporosis, hypertension, and diabetes, especially in elderly patients.

In addition to GCs, the pathogenesis of IgG4-RD suggests that B cell-targeted therapies may provide therapeutic benefit. As a result, although not approved by any regulatory bodies to treat IgG4-RD, certain B cell depleting agents (e.g. rituximab) are occasionally used in such patients. However, B cell depleting agents are often associated with infections, including serious opportunistic infections, and can compromise a patient's ability to mount a response to vaccinations. This was shown in a small pilot study of rituximab, a B cell-targeted therapy, in patients with IgG4-RD. We believe this is due to the fact that rituximab and other B cell depleting agents can cause prolonged depletion of B cells for six months or longer, which places patients at risk of opportunistic infections and potentially reduces response to vaccines.

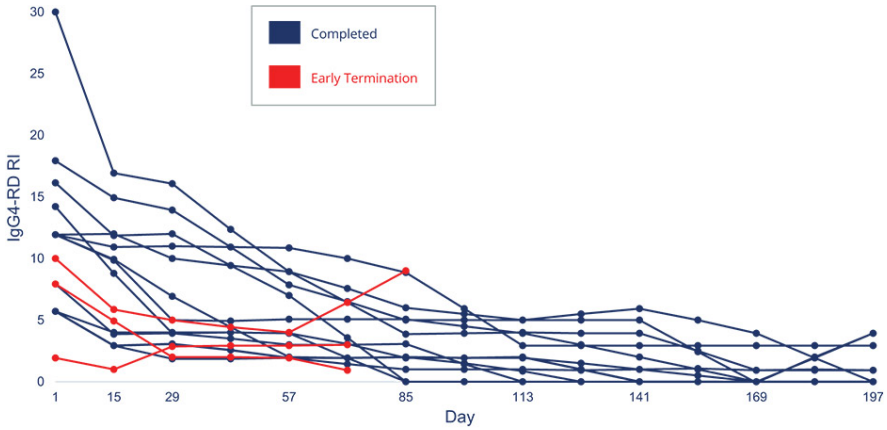
Summary of the Completed Phase 2 Trial of Obexelimab in IgG4-RD

In August 2023, the results of the Phase 2, open-label, single-arm, trial of obexelimab for the treatment of patients with IgG4-RD were published in The Lancet Rheumatology. Twenty patients with active IgG4-RD, defined as an IgG4-RD RI score of three or more, were enrolled. Fifteen patients received obexelimab 5 mg/kg

IV every two weeks for 24 weeks. The protocol was later amended to also provide for the enrollment of an additional five patients who would receive a fixed dose of obexelimab of 90 mg IV or 180 mg IV every two weeks for 24 weeks.

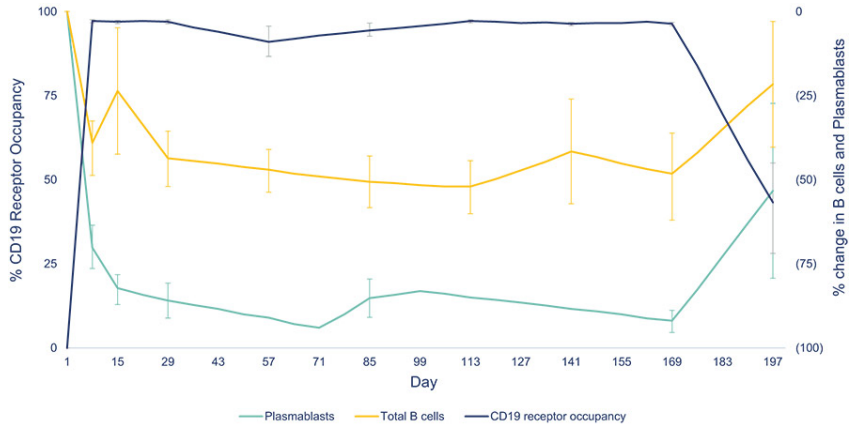
The pre-specified primary analysis of this study focused on the 15 patients enrolled at obexelimab 5 mg/kg. At baseline, the median IgG4-RD RI score was 12 (IQR 7-13). In the primary efficacy analysis, as shown in Figure 3 below, the median decrease in the IgG4-RD RI score was 11.5 points (IQR 7.5-14.5). The IgG4-RD RI score at day 169 had decreased by two or more points from baseline in 12 (80%) patients, eight (67%) of whom had a score of zero (complete remission). These patients included four (80%) of five patients who had achieved remission on previous therapies. Fourteen (93%) patients achieved an improvement on the RI of two or more points during at least one trial assessment at a median of 15 days (range 14 to 90) from treatment initiation. One (7%) patient did not achieve an improvement on the RI score of two or more points, and further evaluation found that this patient who failed to achieve at least a two point improvement on the RI scale had atypical disease activity in only the larynx. Twelve (80%) patients achieved a combined (secondary) endpoint of a decrease on the RI of two or more points at day 169, with no steroid use after day 57, and no disease flares. All primary responders had sustained responses through the end of the trial. The one (7%) patient who did not meet clinical response criteria had a RI score of two at baseline and a score of one before withdrawing from the trial after the Day 71 dose due to lack of efficacy (an IgG4-RD RI score reduction of less than two). Two responders also did not complete the trial: one discontinued after experiencing a disease relapse and one discontinued after an infusion-related hypersensitivity reaction during the fifth infusion. Thirteen (87%) patients experienced adverse events with the most common adverse event of GI infusion-related, including nausea, abdominal pain, and diarrhea.

Figure 3: Rapid and Sustained IgG4-RD RI Responses from Phase 2 Trial



Furthermore, as shown in Figure 4 below, circulating B cell counts decreased by approximately 60% throughout the treatment period. However, among seven patients with post-treatment follow-up data, four (57%) demonstrated recovery of circulating B cells to at least 75% of baseline within 42 days of the final obexelimab dose. Circulating plasmablasts also decreased quickly, by approximately 70 to 80%, and began returning following cessation of obexelimab. Obexelimab inhibited B cell receptor-linked signaling pathways but did not induce B cell depletion. Both reductions in circulating B cells without evidence of depletion during obexelimab treatment and their rapid rebound after treatment discontinuation suggest that obexelimab might lead to B cell sequestration (margination) in lymphoid organs or the bone marrow. After the first dose of obexelimab, CD19 receptor occupancy was nearly 100% for most patients and remained at or near complete occupancy until after the last dose of obexelimab at day 155. We believe these results are promising and support the continued development of obexelimab for the treatment of IgG4-RD and potentially other B cell-mediated immunology and inflammation conditions.

Figure 4: Rapid Recovery of Systemic B Cells Upon Discontinuation



Following enrollment of the first 15 patients treated at 5 mg/kg every other week, an additional five patients were enrolled in a separate cohort to explore a fixed dose regimen of obexelimab 90 mg IV every other week. All five patients achieved a decrease of two points or greater in the IgG4-RD RI at some time during the trial; however, three patients required an increased dose of obexelimab 180 mg IV every other week for disease flare, and two patients also received corticosteroids after Day 57. Peak serum concentration for patients who received 90 mg of obexelimab was approximately 25% and at 180 mg were approximately 50% of those patients who received 5 mg/kg.

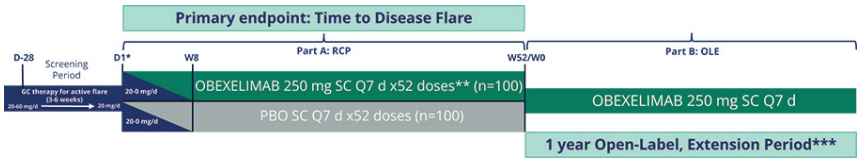
Safety Summary

One patient experienced pneumonia accounting for two SAEs (initial and recurrence due to non-compliance with antibiotic therapy), and a second patient experienced one SAE (chronic inflammatory demyelinating polyradiculoneuropathy in the setting of small lymphocytic lymphoma (preexisting)). None of these events were considered by the investigator to be related to obexelimab. Certain patients also experienced mild to moderate IV infusion-related GI symptoms. The most common TEAEs were abdominal pain and nausea (4/20, 20.0%), vomiting (3/20, 15.0%), and diarrhea, chills, headache, nasal congestion and upper respiratory tract infection (2/20, 10.0%).

INDIGO Trial—Our Ongoing Phase 3 Trial in IgG4-RD

We are enrolling patients in our INDIGO Trial, a global Phase 3 registration-directed, double-blind, placebo-controlled trial to evaluate the safety and efficacy of SC obexelimab in patients with active IgG4-RD in a randomized controlled period followed by an optional open-label extension period. We expect to enroll up to approximately 200 patients and complete enrollment in the RCP in 2024. All patients from the RCP will be eligible for the OLE period. The trial will be conducted at approximately 100 sites in 20 countries. The RCP consists of a screening period (Day -28 to Day -1) and a 52-week treatment period, during which 250 mg of obexelimab or placebo will be administered as an SC injection every seven days. Following the 52-week RCP, eligible patients will have the opportunity to continue in an OLE period where all patients will receive obexelimab.

Figure 5: INDIGO Trial Schema



To be considered eligible for the screening period, patients must have a clinical diagnosis of IgG4-RD, meet the 2019 ACR/EULAR classification criteria for IgG4-RD, as determined by an Adjudication Committee ("AC"), and have active IgG4-RD signs/symptoms (i.e., flare) that require, as assessed by the investigator, the initiation of GC therapy or an increase in background long-term GC therapy. All patients are required to receive three to six weeks of GC treatment at a dose of 20 to 60 mg/day prednisone equivalent prior to randomization. The required GC therapy can be either newly initiated or an increase in long-term GC therapy (i.e., patient was previously on a dose of ≤ 10 mg/day prednisone equivalent). The exact dose and taper schedule during the screening period and prior to randomization are at the discretion of the investigator. However, on the day of randomization, patients must have no disease activity and be at a dose of 20 mg/day prednisone equivalent. Patients will be randomized 1:1 to receive obexelimab or placebo. The primary efficacy assessment is time to first IgG4-RD flare, as determined by the investigator and the AC. If the investigator suspects an IgG4-RD flare, based on reappearance of previous signs/symptoms or appearance of new signs/symptoms of IgG4-RD, organ-specific diagnostic assessments will be conducted, including a physical examination, imaging and/or testing of biochemical parameters specific to the involved organ(s), to correlate symptoms and to document disease activity. The investigator will then determine if an IgG4-RD flare has occurred and whether the initiation of rescue therapy is required. The AC will independently review these diagnostic assessments to determine if, in their judgement, the signs/symptoms represent a flare. Patients who meet the protocol-defined criteria for IgG4-RD flare, by both the investigator and the AC, will be counted as treatment failures for the primary endpoint of time to first flare and the key secondary endpoint of proportion of patients who remain free of IgG4-RD flare (i.e., complete remission). Rescue therapy outside of permitted GC therapy will result in discontinuation from obexelimab or placebo treatment, as the case may be. The trial was designed with approximately 90% power to detect a hazard ratio of 0.376 using a one-sided log-rank test at a significance level equal to 0.025.

Patients who have completed the RCP Week 52 visit and meet all OLE eligibility criteria will have the option to participate in the trial for up to an additional 60 weeks (52-week treatment period followed by an eight-week follow-up) in the OLE period. During the OLE, all patients will receive obexelimab once every seven days beginning on Day 1 of the OLE period, regardless of their treatment assignment during the RCP. The primary objectives for the OLE are to evaluate the safety and efficacy of obexelimab in patients with IgG4-RD.

Obexelimab for the Treatment of MS

We believe obexelimab's differentiated mechanism of action as an inhibitor of B cell lineage supports its potential for the treatment of MS. The role of B cells in the pathogenesis of MS has been demonstrated through the successful clinical development, approval and clinical use of anti-CD20 B cell targeting therapies of other companies, including OCREVUS (ocrelizumab) and KESIMPTA (ofatumumab), which selectively deplete peripheral CD20-expressing B cells. B cells are thought to play a central role in MS pathology and its concomitant neurodegeneration via multiple mechanisms. In addition to antibody secretion by plasmablasts and plasma cells, B cell functions implicated in MS pathogenesis include antigen presentation to T cells and production of pro-inflammation cytokines. We believe this activity observed from B cells may contribute to both MS relapses as well as the underlying disease progression. In the third quarter of 2024, we initiated a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with MS.

MS Histology and Disease Background

MS is the most common immune-mediated, chronic inflammatory demyelinating disease of the central nervous system ("CNS"), affecting over two million people worldwide including as many as 1,000,000 in the

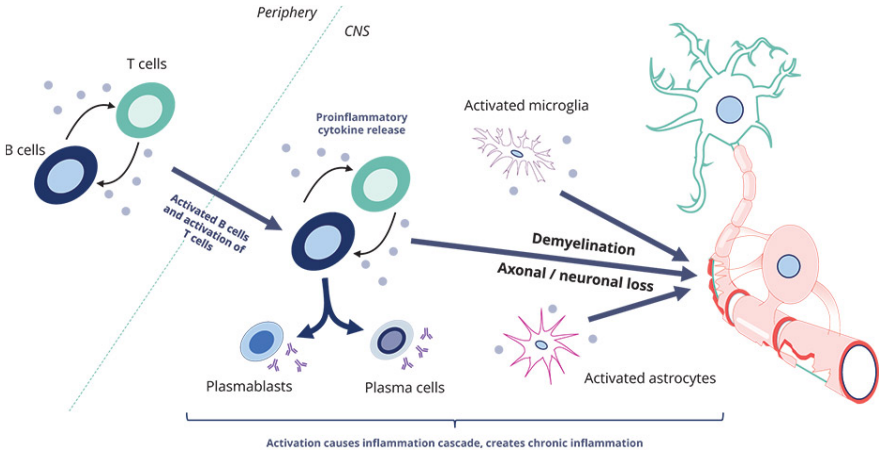
United States, according to the National MS Society and the MS Foundation. We estimate a diagnosed prevalence of approximately 650,000 patients in the United States with MS. We estimate the commercial opportunity in MS to be approximately $37 billion in the U.S. alone, where B-cell therapies currently represent 50 – 60% of the overall market share.

MS is characterized by numerous demyelinating lesions of the brain and spinal cord. The magnetic resonance imaging ("MRI") hallmark of the disease are multiple areas of demyelination in the CNS. The clinical features of an MS attack depend on the areas of the brain or spinal cord involved, thus symptoms may include sensory and visual disturbances, motor, coordination impairment and spasticity, fatigue, pain, and cognitive deficits. Its peak onset is typically in adults between 20 – 40 years old. The most common course of MS is relapsing-remitting ("RRMS"), which affects as many as 85% of MS patients. Patients with RRMS experience episodes of neurological dysfunction followed by complete or incomplete recovery. Over time, the majority of RRMS patients develop disease progression, with or without relapses, referred to as secondary progressive MS ("SPMS"). Patients with RRMS and SPMS with relapses are typically referred to as having RMS. Lastly, 10 to 15% of patients present with a gradually progressive disease course from onset known as primary progressive MS ("PPMS").

Most patients initially diagnosed with RRMS experience two distinct clinical phases, the relapsing-remitting and progressive phases, each of which is reflected by a distinct pathological process. During the relapsing-remitting phase, inflammation drives disease activity while neurodegeneration, which is characterized by accumulating disability, is predominant in the progressive phase. However, underlying progression occurs in all forms of MS, and obexelimab's unique mechanism of action has the potential to impact both the inflammation and neurodegeneration aspects of MS pathogenesis.

Currently, the cause of MS remains unknown; however, both B and T cells play an important role in the pathogenesis of the disease, including inflammation and demyelination process. In addition to producing autoantibodies and inflammatory cytokines, B cells have an important function as antigen-presenting cells ("APCs") involved in T cell activation. The APC function of B cells is thought to be an important reason for the beneficial effects of B cell therapies in MS. Chronic CNS inflammation in the MS lesion is maintained, in part, with activated pro-inflammatory macrophages, microglia and astrocytes at the rim of chronic active or slowly expanding MS lesions, which are the site of ongoing demyelination and neuronal damage. The continued expansion of chronic active lesions is believed to play a role in the pathogenesis of disease progression in MS.

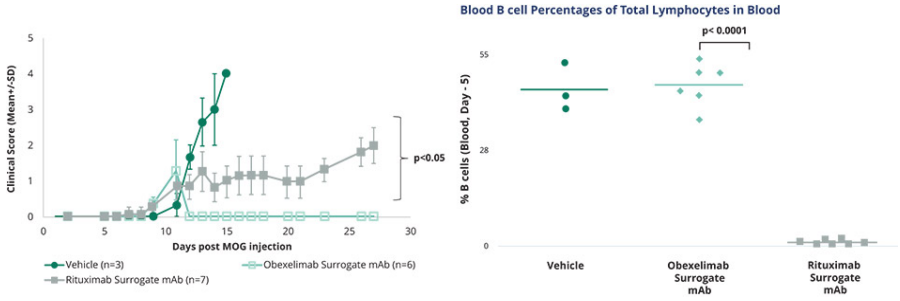
Figure 6: Role of B and T Cells in Multiple Sclerosis



The potential efficacy of obexelimab in the treatment of MS has been demonstrated preclinically in a prophylactic disease animal model. An obexelimab surrogate antibody (XENP8206) was evaluated versus a

rituximab surrogate antibody and vehicle control in a preclinical experimental autoimmune encephalomyelitis ("EAE") model. As shown in Figure 7 below, XENP8206 prevented disease incidence to a greater extent than the rituximab surrogate antibody and the activity of XENP8206 was not associated with B cell depletion.

Figure 7: Suppression of Disease Activity in EAE Model Without B Cell Depletion



Current Treatment, Limitations and Remaining Unmet Need

Despite various treatments available for MS patients, unmet clinical needs remain, including a lack of an effect on progression independent of relapse activity (also known as "silent progression"), which has been observed even in patients with early RMS on highly effective therapies. Gadolinium enhancement is a sensitive technique for detecting active MS lesions and confirms the inflammatory activity of the disease. Monitoring the change in these MRI contrast enhancing lesions is routine and decreased MRI activity represents the earliest treatment effects in clinical trials. In many MS Phase 3 clinical trials, including those of B cell therapies, reductions in inflammatory lesions, initially demonstrated in Phase 2 POC trials utilizing MRI endpoints, were often accompanied by clinical improvements. The paramagnetic rim lesion may serve as another important emerging MRI marker of chronic neuroinflammation, with any modification observed in a clinical trial potentially indicating a change in disease progression. In the third quarter of 2024, we initiated a Phase 2 potential POC trial of obexelimab in RMS patients, utilizing various MRI detection techniques and biomarkers to assess its impact in both the acute and chronic aspects of the disease.

To date, there are a number of therapies that have been approved for the treatment of MS, including injectable, oral and infused medications. Although MS is historically considered a T cell disease, blockade of B cell autoreactivity inhibits neuroinflammation through several pathways, including (i) preventing B cells from acting as antigen-presenting cells that activate autoreactive T cells, (ii) preventing B cells from releasing proinflammatory cytokines, (iii) preventing B cells from transforming into plasma cells that may produce myelin-directed autoantibodies, and (iv) preventing B cells from forming meningeal lymphoid follicles. Despite effective treatment for relapses, there remains a considerable proportion of patients who experience ongoing disease activity and/or accumulating progression of disability. Within 20 years of diagnosis, 30 – 60% of patients with RRMS convert to SPMS with relapse-independent disability progression resulting in severe limitations on quality of life. Despite currently approved therapies, there is an enduring need for additional safe and effective treatments that address the underlying progression seen in MS to potentially alter the course of disability.

Our Phase 2 Trial in RMS

Given the clinical activity observed with B cell depleting agents, we initiated the MoonStone Trial, a Phase 2 potential POC trial of obexelimab in RMS patients, in the third quarter of 2024. The Phase 2 trial in RMS is a randomized, placebo-controlled trial in patients with relapsing active forms of MS in order to assess the safety and efficacy of a 250 mg weekly SC dose of obexelimab, utilizing various MRI detection techniques and biomarkers to assess its impact in both the active and chronic aspects of the disease. The primary objective of this trial will be to assess the change from baseline in the cumulative number of new Gd-enhancing lesions identified on T1-weighted MRI over the course of three months. Upon completion of the three-month period, patients on placebo will receive obexelimab treatment for at least three months and patients initially

randomized to obexelimab will continue on treatment. Important secondary endpoints will include changes in various other MRI assessments (i.e., changes in T2-weighted lesions, changes in the number of new phase RIM lesions, number of T1 lesion conversions to phase RIM lesions, etc.). We expect to report data from the MoonStone Trial on the primary endpoint at 12 weeks in mid-2025 and additional data at 24 weeks in the fourth quarter of 2025.

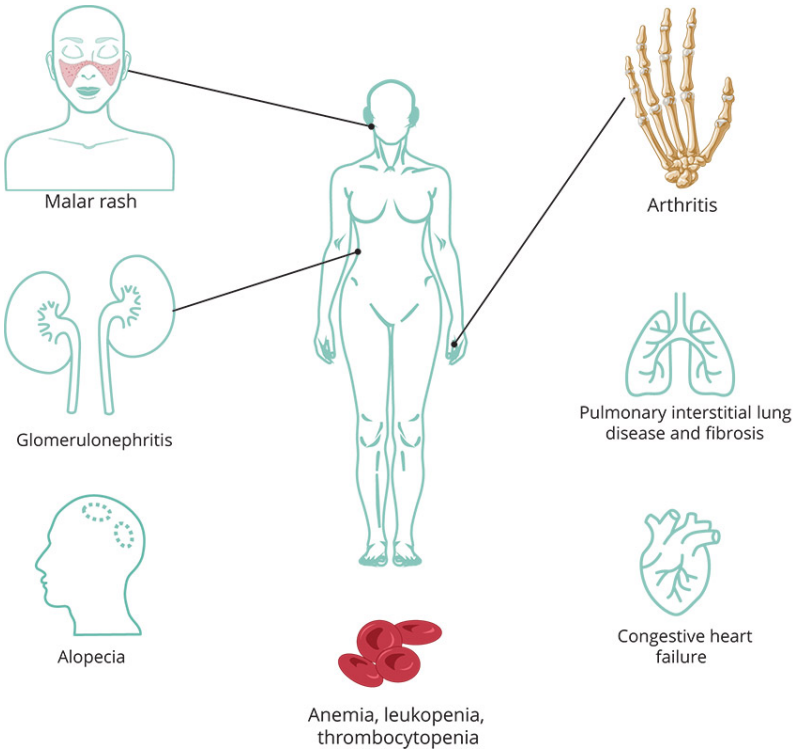
Obexelimab for the Treatment of SLE

The crucial role of B cells in SLE pathogenesis is well recognized, from producing autoantibodies to abnormal regulation of immune responses. Moreover, SLE is an autoimmune disease characterized by B cell dysfunction, the production of autoantibodies toward cellular and nuclear components, and multiorgan damage caused by immune complex deposition and inflammation within affected tissues. Obexelimab has demonstrated clinical activity as a B cell-directed agent due to its inhibitory effect on B cell lineage via its binding to CD19 and FcγRIIb, and a prior Phase 2 double-blind, randomized trial we believe demonstrated POC in SLE. In the third quarter of 2024, we initiated the SunStone Trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab to reduce disease activity in patients with SLE.

SLE Histology and Disease Background

SLE, the most common form of lupus, is a complex, chronic autoimmune disease characterized most notably by unpredictable flares in joints, skin, kidneys and other vital organs that cause progressive organ damage. The prognosis of SLE varies from patient to patient, with alternating periods of active symptoms and remission throughout their lifetime. SLE ranges from a relatively benign disease to rapidly progressive and even fatal. Comorbidities, such as infections, malignancies, hypertension, lipid disorders and diabetes, increase the risk of disability and death in patients. SLE commonly affects the central nervous system, kidneys, gastrointestinal system, mucous membranes, heart, skin, hematologic system, musculoskeletal system and lungs.

Figure 8: SLE Disease Characteristics



Increased B cell activity and survival mediated through BCR abnormalities is a classic feature of SLE. BCR signals are impacted by several regulatory surface proteins, including CD19 and FcγRIIb. Activation of FcγRIIb is known to effectively dampen BCR signaling and decrease B cell responses to activating signals, which may play a pivotal role in suppressing a patient's own immune system from attacking cells. In addition, data in both murine lupus models and human lupus studies provide a rationale for targeting CD19 and FcγRIIb as a treatment for SLE.

Current Treatment, Limitations and Remaining Unmet Need

According to the Lupus Foundation of America, at least 1.5 million Americans are afflicted by lupus and more than 16,000 new cases are reported annually. It is estimated that five million people throughout the world suffer from some form of lupus, of which 70% suffer from the most common form, SLE. Lupus affects primarily women of childbearing age (15 to 44 years). However, men, children and teenagers can also develop lupus. We estimate a diagnosed prevalence of approximately 245,000 patients in the United States having lupus, with approximately 172,000 having SLE. We estimate SLE to be an approximately $8 billion commercial opportunity in the U.S. alone.

The current treatment strategy for SLE is based on treating the affected organ(s) and focuses on achieving a defined state of remission or low disease activity. Targeting B and plasma cells may have positive results in the overall treatment of SLE because of the role autoantibodies play in the pathogenesis of the disease.

Current treatments include non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, hydroxychloroquine, Benlysta (belimumab) (FDA approved for SLE in 2011), and Saphnelo (anifrolumab)

(FDA approved for SLE in 2021). These limited options are modestly effective with improvement over placebo in clinical trials of nine to seventeen percentage points. We believe there is an opportunity to identify a clinically-validated biomarker to guide the selection or optimal administration of treatments.

Summary of Obexelimab—Phase 2 Trial in Patients with SLE

Study XmAb5871-04 was a Phase 2, double-blind, randomized, placebo-controlled trial to evaluate the ability of obexelimab to maintain SLE disease activity improvement in patients after brief treatment of active disease with corticosteroids. Patients were randomized 1:1 to receive intravenous obexelimab (5 mg/kg) or matching placebo every two weeks for 16 doses or until loss of improvement ("LOI"). LOI was defined by either a 4-point increase in the hybrid Systemic Lupus Erythematosus Disease Activity Index ("hSLEDAI") score or at least one British Isles Lupus Assessment Group ("BILAG") A or B score rated "new" or "worse". One hundred and four patients were randomized, with 52 assigned to obexelimab treatment and 52 to placebo. Patients completing the trial included 28 (53.8%) receiving obexelimab and 17 (32.7%) receiving placebo. Median months of treatment was 6.9 (range 0 – 7.4) with obexelimab and 3.6 (range 0 – 7) with placebo.

The primary endpoint was assessed as the proportion of patients reaching week 32 without LOI, using an EE population, defined as patients who completed the trial or withdrew for flare or treatment-related toxicity. Twenty-one out of 50 (42.0%) obexelimab-treated patients versus 12 out of 42 (28.6%) placebo-treated patients achieved the primary endpoint. Although the primary endpoint was not achieved with statistical significance ($p = 0.183$), the ITT population revealed a larger absolute treatment difference of 17.3% (40.4% versus 23.1%, $p=0.06$) in the obexelimab-treated group versus the placebo-treated group. The ITT analysis is relevant since all patients are considered in this analysis, whereas in the EE analysis a larger number of placebo-treated patients than obexelimab-treated patients discontinued treatment for reasons that removed them from the analysis (10 patients versus 2 patients). Furthermore, the placebo response rate (28.6% in the EE analysis and 23.1% in the ITT analysis) was higher than the 10% rate which was assumed in the statistical assumptions for the trial. Nevertheless, the difference in response rates between the obexelimab and placebo arms in this trial was similar to that observed in SLE registration-directed trials with other agents, although with different trial design and endpoints.

Further, there was an association between obexelimab concentration and time to LOI. PK analysis revealed that quartiles of patients with progressively higher drug concentration had progressively longer time to LOI. In the EE analysis, patients in C_{trough} quartiles three and four exhibited a larger absolute LOI treatment difference of 35% in the obexelimab-treated group versus the placebo-treated group. Accordingly, we believe these data demonstrated POC for obexelimab in SLE.

Fourteen (26.9%) patients that received obexelimab and 25 (48.1%) patients that received placebo withdrew for LOI. Adverse events led to the withdrawal of seven (13%) obexelimab-treated patients (most of which were infusion-related reactions) and two (4%) patients that were administered placebo. Withdrawal for other reasons occurred in three patients that were administered obexelimab and eight that were administered placebo. There was no increase in the proportion of patients with infection in obexelimab as compared to placebo treated groups. The most frequently occurring TEAEs in patients who received obexelimab administered IV were nausea (20/52, 39%), headache (12/52, 23%), vomiting (9/52, 17%), back pain and dizziness (8/52, 15%), flushing (7/52, 14%) and pain in extremity (6/52, 12%).

Biomarker analysis identified baseline gene expression profiles associated with increased response to obexelimab. Patients with adequate baseline RNA samples (71 in total) were assigned into one of seven clusters (immunophenotypes) as defined by Guthridge et al. 2020 using the Oklahoma Lupus Cohort. Patients in gene expression clusters three and six exhibited greater prolongation of time-to-flare with obexelimab, whereas in the other clusters obexelimab was not associated with a prolongation in time-to-flare. Patients in gene expression clusters three and six exhibited a larger absolute treatment difference in LOI of 52% in the obexelimab-treated group versus the placebo-treated group. There was a relatively small difference in time-to-flare between patients treated with placebo in clusters three and six compared with patients treated with placebo in the other clusters, suggesting that clusters three and six had higher predictive than prognostic value. Clusters three and six represent 38% of the population tested, which is similar to the 31% of cluster three and six patients in the original Oklahoma cohort. These clusters include patients of African and European descent and share increased expression of B cell pathways and low expression of inflammation pathways. These

responsive immunophenotype subgroups are thus consistent with the drug's mechanism of action, inhibition of B cell, plasmablasts, and plasma cell activity, an impact that was observed in patients treated with obexelimab.

We believe the obexelimab efficacy data in the overall trial population and the increased response in biomarker-defined subpopulations, coupled with the safety data obtained to date, provide support for further clinical trials and the use of a SC obexelimab formulation in patients with SLE.

Our Phase 2 Trial in Patients with SLE

In the third quarter of 2024, we initiated the SunStone Trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of obexelimab when used to reduce disease activity in patients with SLE. We expect to enroll approximately 190 patients and to conduct the trial at multiple sites worldwide. We expect to complete enrollment of the SunStone Trial in 2025 and report data on the primary endpoint at 24 weeks in the first half of 2026.

To be eligible for the trial, patients enrolled must have active SLE at screening, as defined by BILAG 2004 and hSLEDAI. Patients will be randomized 1:1 to obexelimab 250 mg or placebo SC injection every seven days over 24 weeks. The primary endpoint will be the percentage of responders, defined by BILAG-based Composite Lupus Assessment, with a reduction of SLE disease activity at week 24. Biomarker analysis is planned to be conducted in all patients. This includes baseline RNA expression profiles to immunophenotype patients and evaluation of their differential responses to treatment. Additional biomarker assessments include serum cytokines and chemokines, SLE disease markers (complement C3/ C4, anti-dsDNA), and immune cell subsets (B cells, plasma cells, etc.).

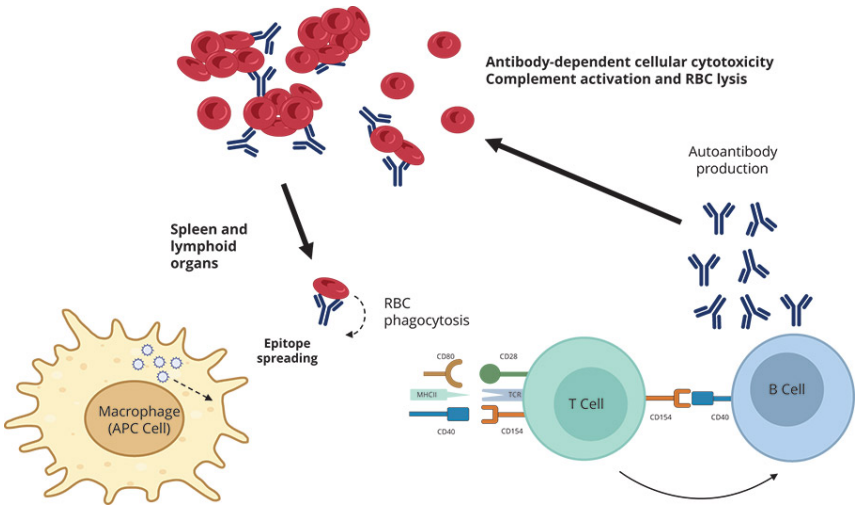
Obexelimab for the Treatment of wAIHA

IgG autoantibodies are the key pathogenic factors involved in most forms of wAIHA. Accordingly, we believe that obexelimab's ability to inhibit or down-regulate B cells and the clinical activity and tolerability profile observed in previous clinical studies provide a strong rationale for its development in wAIHA. In 2023, we initiated SApHiAre, a two-part global trial that includes a potential registration-directed, randomized, double-blind, placebo-controlled evaluation of obexelimab delivered SC weekly to evaluate the efficacy and safety of obexelimab in patients with wAIHA.

wAIHA Histology and Disease Background

AIHA is an acquired disorder in which autoantibodies directed against a patient's own red blood cell ("RBC") membrane antigens lead to their accelerated destruction, and the rate of production of new cells in the bone marrow can no longer compensate for their loss. wAIHA can be either primary (or idiopathic) or it can be associated with an underlying disease, which occurs in at least half the cases and is classified as secondary wAIHA. As depicted in Figure 9 below, B cells contribute to the pathogenic process in immune-mediated disorders by producing autoantibodies and inflammatory cytokines and by acting as antigen-presenting cells, leading to T cell activation. Recent findings have also pointed to an important role of different T cell subtypes in the onset and progression of various autoimmune disorders, including wAIHA. A vital role of B cells in the pathogenesis of wAIHA is supported by a randomized, double-blind, placebo-controlled trial of 32 adult patients that showed rituximab was effective in treating wAIHA over the course of 4.5 years (2.5 years of treatment and 2 years of follow-up).

Figure 9: Pathogenesis of wAIHA



Current Treatment, Limitations and Remaining Unmet Need

wAIHA is the most prevalent form of AIHA and accounts for 70% to 80% of all cases in adults and almost 50% of all cases in children. We estimate that the currently diagnosed population of wAIHA patients in the U.S. is approximately 40,000, with similar prevalence rates in other countries. We estimate wAIHA to be a multi-billion-dollar commercial opportunity in the U.S. alone. Glucocorticoids (prednisone or prednisolone) are commonly given as first-line treatment. Although there is an initial clinically significant response achieved in 70% to 80% of cases, approximately 60% to 80% of patients require additional treatment within one year of initial treatment. However, similar to IgG4-RD patients, long-term steroid maintenance therapy can lead to significant toxicity and complications, including osteoporosis, high blood pressure, and diabetes. For patients that do not adequately respond to and/or are unable to tolerate corticosteroids, other unapproved treatments carrying higher risk such as rituximab, other immunosuppressant therapies, blood transfusions and/or splenectomy are used.

Despite not being approved for use by any regulatory agency for the treatment of wAIHA, rituximab is the preferred second-line therapy for steroid refractory patients. However, only a minority of patients achieve long-term disease remission with rituximab in the second-line setting, even though most patients (60% to 70%) initially respond well to treatment. In addition, rituximab carries a boxed warning for fatal infusion- related reactions, severe mucocutaneous reactions, hepatitis B virus reactivation and progressive multifocal leukoencephalopathy. Further, similar to IgG4-RD, rituximab is a B cell depleting agent, which carries the same potential limitations and risks discussed above.

Obexelimab—SApHiAre Trial

In late 2023, we initiated our SApHiAre Trial, a global Phase 2/3, multicenter, randomized, double-blind, placebo-controlled trial, with an SRP to evaluate the efficacy and safety of obexelimab in patients with wAIHA. We expect initial data from the SRP will be available in the fourth quarter of 2024 for patients enrolled prior to such date. After considering a number of factors, including whether the results of the SRP portion of the SApHiAre Trial are favorable, we may meet with the FDA to finalize the design, including the proposed endpoints, of the RCP. If we continue with the Phase 3 RCP of this trial, we expect that a total of approximately 134 patients would be enrolled in the trial, including the patients enrolled in the SRP, at approximately 90 sites in 18 countries. If we continue with the Phase 3 RCP portion of the SApHiAre Trial

and if the results of the RCP portion are then favorable, we would intend to seek regulatory approval for the treatment of wAIHA.

Open-Label Safety and Dose Confirmation Run-in Period (Part A)

We anticipate enrolling up to 14 patients with primary wAIHA or secondary wAIHA due to autoimmune disorders (e.g., SLE) in Cohort 1 of the open-label SRP (Part A) which will provide preliminary safety, tolerability, PK/PD and efficacy data in a similar wAIHA population as the population intended to be enrolled in the RCP. Up to six additional patients with secondary wAIHA due to a lymphoproliferative disease may be enrolled in Cohort 2 to provide preliminary data on a broad wAIHA population. All patients enrolled in the SRP will receive obexelimab 250 mg SC dose every seven days. During the SRP, patients will undergo assessments for efficacy, safety, PK, PD, and immunogenicity. The primary efficacy endpoint in the SRP is proportion of patients with a hemoglobin ("Hgb") ≥ 10 g/dL and ≥ 2 g/dL increase from baseline on at least 3 of 4 consecutive visits, on or after Week 12, with no use of blood transfusion or GC rescue therapy prior to attaining response. Following the conclusion of the SRP, after considering a number of factors, including whether the results of the SRP are favorable, we may meet with the FDA to agree on the final trial design, including the primary endpoint or endpoints required for the RCP and whether a patient reported outcome co-primary or key secondary endpoint will be required.

Randomized Control Period (Part B)

The decision to initiate the RCP (Part B) will be based on a number of factors, including the data collected in Cohort 1 and our discussions with the FDA. We anticipate that up to approximately 114 patients would be enrolled in the RCP, randomized 1:1 to obexelimab 250 mg or placebo SC injection every seven days over 24 weeks. If initiated, the RCP may begin once all 14 patients with primary wAIHA or secondary wAIHA due to underlying autoimmune disorder (Cohort 1) have reached Week 12 (or withdrawn from the trial). We expect that the primary efficacy endpoint in the RCP will be the proportion of patients who achieve a durable Hgb response (defined as Hgb ≥ 10 g/dL and ≥ 2 g/dL increase from baseline on at least three of four consecutive available visits), at the earliest on or after Week 12, with no use of blood transfusion or GC rescue therapy prior to attaining durable response through Week 24. Following the completion of the RCP, eligible patients will have the opportunity to enroll into the OLE Period (Part C) of the trial, in which all patients will receive obexelimab.

Safety Profile of Obexelimab

Overall, 198 subjects have received obexelimab, 158 subjects as an IV infusion at doses of up to 10 mg/kg and 40 subjects as a SC injection of up to 375 mg. The majority of TEAEs in the studies using obexelimab were mild or moderate.

The clinically important identified risk of obexelimab, defined by serious and related events, included unanticipated infusion related reactions which have not been observed for the subcutaneous injection of obexelimab. The clinically non-important identified risks of obexelimab, defined as non-serious and related events, included intravenous infusion related GI events and injection site reactions via the SC administration. The injection site reactions were of minimal clinical impact, non-serious, did not lead to study drug discontinuation, and are anticipated to occur in less than 2% of injections. The IV infusion related GI events were non-serious and were not observed with SC injection.

Serious Adverse Events

The only SAEs considered by the investigator to be related to obexelimab or placebo across the five clinical studies completed to date were: two IV infusion related reactions, one in each of two obexelimab treated patients, one venous thrombosis in an obexelimab treated patient, one herpes zoster in a placebo treated patient and a post herpetic neuralgia in a placebo treated patient.

Anti-Drug Antibodies

The development of anti-drug antibodies ("ADA") has been observed in all studies; however, the ADA response did not have an apparent effect on PK or safety parameters (i.e., accelerated clearance), with the

possible exception of one subject (in the first in human ("FIH") study) and the three subjects with hypersensitivity reactions mentioned above.

Safety Summary of Previously Completed Clinical Studies

Study XmAb5871-01

Overall, doses of up to and including 10 mg/kg obexelimab were well tolerated by healthy male subjects. GI-related TEAEs (including nausea, vomiting, abdominal pain, abdominal discomfort, epigastric discomfort and diarrhea) were the most frequently reported (14/36, 38.9%). Eight subjects (8/36, 22.2%) who had received 0.2 to 10 mg/kg obexelimab had their IV infusion temporarily interrupted as a result of the GI-related symptoms. In all cases, symptoms leading to infusion interruption were transient and subjects were able to continue the infusion after a short break without recurrence of symptoms. Symptom resolution did not require the use of concomitant medications. No infusion-related reactions or hypersensitivity reactions were observed. There were no SAEs reported. No subject was withdrawn and none self-withdrew. There was no consistent dose-response relationship with the incidence of TEAEs and no dose-limiting toxicities were observed.

Study XmAb5871-02

Among the 40 patients who received obexelimab, the most common TEAEs were vomiting (7/40, 17.5%), headache (7/40, 17.5%), nausea (6/40, 15.0%), pyrexia (4/40, 10.0%), and arthralgia (4/40, 10.0%). As in the FIH study in healthy male volunteers (Study XmAb5871-01), gastrointestinal-related TEAEs (nausea, vomiting, diarrhea) were mostly mild to moderate, resolved with interruption of infusion and did not reoccur with reinitiation of infusion.

In general, multiple doses of up to 10 mg/kg obexelimab were well tolerated in patients with RA. Two subjects experienced infusion-related reactions (both at 10.0 mg/kg), one of which was considered an SAE. The other event, associated with the first infusion, was considered of moderate severity. In both cases, the infusion was terminated, and the patients recovered without sequelae. The nature and severity of these infusion reactions were consistent with those reported for other monoclonal antibody therapies.

Study XmAb5871-03

In general, obexelimab was well tolerated in patients with IgG4-RD. The most common TEAEs were abdominal pain and nausea (4/20, 20%), vomiting (3/20, 15%), and diarrhea, chills, headache, nasal congestion, and upper respiratory tract infection (2/20, 10%). Four patients (4/20, 20%) had first dose GI symptoms of nausea, vomiting, and/or diarrhea as described previously with IV infusions. The symptoms were relieved by interrupting the infusion for a short period of time. There was one infusion-related hypersensitivity reaction that was associated with the presence of ADA, that was treated with symptomatic medications and that resolved after obexelimab was stopped. This patient recovered fully and discontinued the trial. There was one case of pneumonia accounting for two SAEs (initial and recurrence due to non-compliance with therapy) in one patient and a second patient experienced one SAE (chronic inflammation demyelinating polyradiculoneuropathy in the setting of small lymphocytic lymphoma (pre-existing)). None of the SAEs were considered to be related to obexelimab.

Study XmAb5871-04

Obexelimab was generally well tolerated in patients with SLE. The most frequently occurring TEAEs were nausea (20/52, 39%), headache (12/52, 23%), vomiting (9/52, 17%), back pain and dizziness (8/52, 15%), flushing (7/52, 14%), and pain in extremity (6/52, 12%). The majority of these events were mild and resolved. There were 8 SAEs in patients administered obexelimab, only one (infusion-related reaction) of which was considered related to study drug. Fourteen (14/52, 26.9%) patients that received obexelimab and 25 (48.1%) patients that received placebo withdrew for LOI. Adverse events led to the withdrawal of seven (7/52, 13%) obexelimab-treated patients (most of which were infusion-related reactions) and two (4%) patients that were administered placebo. Withdrawal for other reasons occurred in three patients that were administered obexelimab and eight that were administered placebo.

Study XmAb5871-05

Overall, the SC administration of obexelimab was well tolerated. The most common TEAEs across all SC dose regimens were headache and injection site reaction (3/40, 8%). The incidence of injections with injection

site erythema, induration and/or pain as a total out of all injections was 4/207 (total), or 1.9% of injections. The symptoms involved only one of the possible two or three sites injected on that day, were mild, and resolved within 24 hours.

Dosage and Administration for Obexelimab

Obexelimab has been evaluated in five completed clinical trials in which a total of 198 subjects have received obexelimab either as an IV infusion at doses of up to 10 mg/kg (n=158) or as a SC injection at does up to 375 mg (n=40). We believe these trials have demonstrated obexelimab's PK/PD and tolerability profile.

Our current ongoing and planned trials of obexelimab utilize or will utilize a fixed 250 mg self-administered SC injection dosed weekly. This dosing regimen is supported by the totality of existing clinical efficacy and safety data, PK/PD modeling, and nonclinical data. The 250 mg weekly SC dose is designed to maximize the potential for efficacy by providing maximum PD target engagement, comparable exposure and, importantly, a higher C_{trough} when compared with the 5 mg/kg IV every two weeks dosing regimen, which demonstrated clinical activity in the IgG4-RD and SLE Phase 2 trials of obexelimab. In addition, the 250 mg weekly SC dose was designed to maintain a lower C_{max} than the 5 mg/kg IV every two weeks dosing regimen to provide sufficient safety margins and an acceptable tolerability profile based on both clinical and nonclinical study data of obexelimab.

Preclinical Characterization

In vitro studies demonstrated that obexelimab has a high affinity for human CD19 and human FcγRIIb. The half-maximal effective concentration ("EC_{50}") of binding of obexelimab to a human CD19 expressing cell line is 0.3 nM, and the EC_{50} of binding of obexelimab to human primary B cells is 1.4 nM. The binding affinity of obexelimab for human FcγRIIb (8 nM) has been increased approximately 230-fold relative to human native IgG1 as a result of Fc engineering. *In vitro*, co-engagement of CD19 and FcγRIIb by obexelimab results in the inhibition of calcium mobilization upon stimulation of B cells from normal volunteers as well as in RA and SLE patients. *In vivo*, obexelimab demonstrated inhibition of an induced human B cell response to immunization with tetanus toxoid in severe combined immunodeficient mice engrafted with human peripheral blood mononuclear cells. In addition, obexelimab demonstrated disease improvement in several animal models of disease, including collagen-induced arthritis, AIHA and MS. Obexelimab has shown no antibody-dependent cellular cytotoxicity mediated B cell depletion *in vitro,* nor has there been any significant obexelimab-mediated IL-6 or TNF-α cytokine release.

Other Pipeline Programs

Beyond our lead product candidate, obexelimab, we are advancing a pipeline of clinical programs for the potential treatment of other I&I indications that we may continue to develop and ultimately commercialize with partners. Our pipeline includes two global programs, ZB002 (an anti-TNFα monoclonal antibody) and ZB004 (a CTLA-4-Ig fusion), and two regional programs, ZB001 (also known as VRDN-001, an IGF-1R monoclonal antibody), and related programs, and ZB005 (also known as DNTH103, an anti-active C1s monoclonal antibody), for which we hold the development and commercialization rights in greater China. Based on the ongoing clinical studies and clinical data generated to date, we intend to determine future potential indications in which to pursue further clinical development of these programs and ultimately, if approved, commercialization with one or more partners.

ZB002 Program (anti-tumor necrosis alpha monoclonal antibody)

ZB002 is a monoclonal antibody inhibitor of TNFα designed to have an extended half-life as compared to existing anti-TNFα therapies. ZB002 is identical to adalimumab in the TNFα-binding region of the fragment variable domain, but the Fc domain contains modifications to extend ZB002's half-life *in vivo* (Xencor's Xtend technology). Our Phase 1 SAD study demonstrated a half-life of approximately 55 days for ZB002, which we believe may allow for dosing once every four to eight weeks. In the second quarter of 2024, we initiated a Phase 1b MAD study of ZB002 in patients with rheumatoid arthritis. A head-to-head preclinical study in mice demonstrated ZB002's extended (≥ 2-fold longer) half-life over adalimumab. If the results of our

ongoing Phase 1b MAD study of ZB002 are favorable, we may seek to identify a partner to advance ZB002 in subsequent trials for potential use as a treatment for certain I&I diseases that can benefit from TNFα inhibition.

Anti-TNFα Background and Mechanism of Action

TNFα is a potent inflammatory cytokine, produced primarily by activated monocytes, macrophages and T cells, as a cell surface protein. After being activated, TNFα is released and binds to receptors on TNFα-responsive cells to enhance the inflammation and immune response to environmental stimuli such as foreign antigens. Elevated expression of TNFα has been linked to a number of I&I diseases, and inhibition of TNFα signaling has been validated as a therapeutic approach to treat several diseases. The FDA and other comparable foreign regulatory agencies have approved five anti-TNFα therapies to treat diseases, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, ulcerative colitis, hidradenitis suppurativa, and uveitis. Among those approved therapies are Remicade (infliximab), Simponi (golimumab) and Humira (adalimumab), monoclonal antibodies that target TNFα for inhibition.

Summary of Clinical Trials

We conducted a Phase 1 SAD study designed to evaluate the safety, tolerability, PK and PD profiles of ZB002 in healthy volunteers. We enrolled 48 healthy volunteers across six cohorts of varying dose levels, ranging from 20 mg to 240 mg, for the study. Eight healthy volunteers were randomized 3:1 to ZB002 or placebo, per cohort. There was one SAE of peri-anal abscess. Our Phase 1 SAD study demonstrated a half-life of approximately 55 days for ZB002, which we believe may allow for dosing once every four to eight weeks. In the second quarter of 2024, we initiated a Phase 1b MAD study of ZB002 in patients with rheumatoid arthritis. If the results of our ongoing Phase 1b MAD study of ZB002 are favorable, we will seek to identify a partner to advance ZB002 in subsequent trials and ultimately, if approved, commercialize ZB002 for potential use as a treatment for certain I&I diseases that can benefit from TNFα inhibition.

Preclinical Characterization

ZB002 has similar pharmacological characteristics to adalimumab, including TNFα binding and inhibition. The EC_{50} for *in vitro* inhibition of TNFα signaling is roughly equivalent (18.17 ng/mL for ZB002 and 14.25 ng/mL for adalimumab), and ZB002 and adalimumab inhibited TNFα-induced lethality in *in vivo* mouse models at similar rates. However, ZB002 has a higher fragment crystallizable receptor ("FcRn") binding affinity ($K_D = 6.54 \times 10^{-8}$ M) compared to adalimumab ($K_D = 1.88 \times 10^{-6}$ M), which is designed to extend ZB002's *in vivo* half-life. In the human neonatal FcRn expressed transgenic mice, the PK profile of ZB002 was found to be similar to that of adalimumab with the exception of an extended (≥ 2-fold longer) half-life (t1/2 = 9.9 hours and 4.1 hours for ZB002 and adalimumab, respectively). The subcutaneous bioavailability of ZB002 was 62.4% to 106.0% in cynomolgus monkeys, depending on the dose. Weekly subcutaneous administration of ZB002 for 13 weeks in cynomolgus monkeys demonstrated no adverse safety findings at any dose tested up to 200 mg/kg, providing an adequate therapeutic window for assessment in humans.

ZB004 Program (CTLA-4-Ig fusion)

ZB004 is a CTLA-4-Ig fusion protein designed to have an extended half-life versus existing CTLA-4-Ig fusion protein therapies. Based on the results from our ongoing Phase 1 study, we plan to evaluate the path forward for the development of ZB004 in the treatment of I&I indications.

CTLA-4-Ig Background and Mechanism of Action

ZB004 is comprised of two CTLA-4 extracellular domain substitutions and an IgG Fc region containing substitutions (Xencor's Xtend technology). This design allows for increased binding affinity to human CD80 and CD86 and FcRn. Its mechanism of action is selective inhibition of T cell co-stimulation by binding to CD80 and CD86 receptors, which blocks their interaction with CD28 on T cells.

In rheumatoid arthritis, T cells contribute to lymphoid organogenesis in the inflamed joint and neoangiogenesis, stimulate synoviocyte proliferation, and support the development of osteoclasts. CTLA-4, a protein expressed on the surface of CD4+ and CD8+ T cells, is an inhibitory receptor with high homology to

the costimulatory receptor CD28. It acts as a negative regulator of CD28-mediated activation of CD4+ and CD8+ T cells. CTLA-4-Ig fusion proteins disrupt binding of CD28 with ligand B7 molecules, CD80 and CD86, expressed on antigen-presenting cells. Inhibition of this signaling pathway results in a suppression of T cell effector function and is clinically validated by the regulatory approval of two CTLA-4-Ig therapeutics in several I&I diseases: Orencia (abatacept) and Nulojix (belatacept).

Clinical Development

We conducted a Phase 1 SAD study designed to evaluate the safety, tolerability, PK immunogenicity and PD profiles of ZB004 in healthy volunteers. Our Phase 1 SAD study enrolled 40 healthy volunteers across five cohorts of varying dose levels, ranging from 3 mg to 200 mg, with eight healthy volunteers randomized 3:1 to ZB004 or placebo, per cohort. Our Phase 1 SAD study demonstrated a half-life of approximately 17.4 days at the highest dose level of 200 mg, where CD86 receptor occupancy reached a maximum peak value of 81%, overcoming the effect of target mediated drug disposition. There were no SAEs reported.

Preclinical Characterization

ZB004 has been engineered to increase its affinity to human CD80 and CD86 by approximately six-fold compared to abatacept. ZB004 also binds with higher affinity to human FcRn which is expected to extend ZB004 half-life *in vivo*. ZB004 has shown potency by inhibiting T cell activity and cytokine release. In an *in vitro* functional inhibition assay of T cell activity, the mean half-maximal inhibitory concentration ("IC_{50}") value was 0.334 µg/mL for ZB004 (2 donors) and > 50 µg/mL for abatacept. When the inhibition of inflammation cytokine release was assessed, the IC_{50} values for interleukin 2 (IL-2) secretion driven by ZB004 or abatacept were < 0.003 µg/mL and 0.152 µg/mL, respectively. The IC_{50} values for interferon gamma secretion driven by ZB004 and abatacept were 0.0054 µg/mL and > 50 µg/mL, respectively. ZB004 has shown prophylactic efficacy in a collagen-induced arthritis disease model.

ZB004 was well tolerated in toxicology studies up to 13 weeks via subcutaneous administration in cynomolgus monkeys and rats, providing an adequate therapeutic window for assessment in humans. In addition, ZB004 has a PK profile in animals with a dose-disproportional increase in exposure. The terminal half-life parameter of ZB004 was determined at least 1.39-fold longer than that of abatacept in cynomolgus monkeys. The subcutaneous bioavailability of ZB004 was 45.4% to 72.5% for rats and 73.4% to 79.9% for cynomolgus monkeys, depending upon the doses.

ZB001, insulin-like growth factor-1 receptor (anti-IGF-1R) mAb

ZB001 is a monoclonal antibody that binds to, and is designed to act as a full antagonist of, IGF-1 receptor. This mechanism of action has been clinically and commercially validated by the only FDA product approved for the treatment of thyroid eye disease ("TED"), Tepezza (teprotumumab). TED is a debilitating condition that significantly impacts quality of life and can cause proptosis, double vision and vision loss. In October 2020, we entered into an exclusive license with Viridian, to develop, manufacture, and commercialize certain IGF-1R directed antibody products, including ZB001, for non-oncology indications in greater China. Pursuant to our agreement with Viridian, we are obligated to reimburse Viridian for certain CMC and development expenses, and pay Viridian upon achievement of development milestones and royalties on net sales. For more information on our agreement with Viridian, see the section titled "Certain Relationships and Related Party Transactions—Director Affiliations—Agreements with Viridian Therapeutics Inc."

In April 2023, we completed a Phase 1 SAD clinical study in China in healthy volunteers showing ZB001 was well tolerated when administered in doses up to 20 mg/kg. In April 2024, we completed the last patient visit in the Phase 1 MAD clinical study of ZB001 in Chinese patients with active TED. Preliminary data showed significant and rapid improvement in both signs and symptoms after 4 infusions of ZB001 in both 2 dose cohorts of 3mg/kg and 10mg/kg. All AEs were mild or moderate in severity and no SAEs were reported. Following the initial clinical development of ZB001, we intend to seek to enter into an agreement with a third party who can complete the clinical development work, obtain regulatory approval and ultimately, if approved, commercialize ZB001 and other IGF-1R antibodies pursuant to the license with Viridian in greater China.

ZB005, anti-active C1s mAb

ZB005 is a highly potent, highly selective, and human IgG4 monoclonal antibody designed to selectively bind only to the active form of C1s, a validated target in the I&I field. As a result, ZB005 may have a reduced risk of infection from encapsulated bacteria. In addition, ZB005 is engineered with YTE half-life extension technology and has a PK profile designed to support less frequent, lower dose, self-administration as a SC injection. We believe that ZB005 has the potential to yield therapeutic benefit in multiple I&I disease indications, in part due to an extended half-life and this complement protein component (C1s) inhibitor class's lack of an FDA boxed warning for serious meningococcal infections which are associated with other complement inhibitor classes (e.g., complement protein C5 inhibitor, complement protein C3 inhibitor, and complement factor B inhibitor). In June 2022, we entered into an exclusive license with Dianthus to research, develop, manufacture and commercialize monoclonal antibody antagonists targeting the human Complement C1s protein (including ZB005, also known as DNTH103) in greater China. The agreement with Dianthus entitles Dianthus to reimbursement for certain CMC and development expenses, development milestones and royalties on net sales. For more information on our agreement with Dianthus, see the section titled "Certain Relationships and Related Party Transactions—Director Affiliations—Agreement with Dianthus Therapeutics, Inc."

In August 2023, Dianthus reported data from its ongoing Phase 1 study in 52 healthy volunteers across seven dose cohorts. These data validated the extended half-life and potent classical pathway inhibition, which we believe supports a differentiated safety profile of ZB005 and the potential of ZB005 to yield therapeutic benefit in multiple I&I disease indications. Dianthus has stated that it plans to initiate a Phase 2 trial in the first quarter of 2024 with respect to myasthenia gravis.

Based on the clinical data generated to date and additional data we or Dianthus plan to generate, we intend to seek to enter into an agreement with a third party who can complete the clinical development work, obtain regulatory approval, and ultimately, if approved, commercialize ZB005 pursuant to the license with Dianthus in greater China.

License Agreements

License Agreements with Xencor

In September 2020, we entered into a license agreement (the "2020 Xencor Agreement") with Xencor, to obtain (a) an exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (b) a non-exclusive payment bearing license under certain know-how controlled by Xencor to research, develop, manufacture, market and sell three antibody product candidates (the "2020 Licensed Assets"), including ZB002 and ZB004. We subsequently relinquished rights to the third product candidate back to Xencor and that asset is no longer a 2020 Licensed Asset. Xencor obtained the rights to some of the intellectual property licensed to us pursuant to license agreements between Xencor and a third party (each such agreement, an "Upstream License Agreement"). As such, the 2020 Xencor Agreement provides that the parties agree that some of the licenses granted by Xencor to us constitute sublicenses under the Upstream License Agreements and are subject, and subordinate, to the terms and conditions of the Upstream License Agreements. As consideration for the 2020 Xencor Agreement, we issued Xencor a 15% equity interest in Zenas. The 2020 Xencor Agreement became effective in November 2020, upon Zenas' issuance of 5,041,542 shares of its Series A Preferred Stock with a fair value of $16.1 million to Xencor as initial consideration.

Under the 2020 Xencor Agreement, we are obligated to use commercially reasonable efforts to conduct all preclinical (excluding preclinical activities previously conducted by Xencor at the time the 2020 Xencor Agreement was executed), clinical and regulatory activities necessary to develop and obtain the regulatory approval of the 2020 Licensed Assets worldwide. We are further required to use commercially reasonable efforts to commercialize the 2020 Licensed Assets having regulatory approvals in certain specified countries (United States, UK, France, Germany, Italy, and Spain). We are not required to pay any development, regulatory or sales milestone payments under the 2020 Xencor Agreement. We are required to pay Xencor tiered royalties on annual net sales of successfully commercialized products utilizing the 2020 Licensed Assets. The royalty percentage rates vary by geographic areas as defined in the 2020 Xencor Agreement and range from the mid-single digits to the mid-teens. On a region-by region basis and product-by-product basis, the term during which the royalties are payable by us to Xencor is until the latest of (a) last-to-expire licensed

patent covering the product in the applicable region, (b) the expiration of regulatory exclusivity for the product in the applicable region, or (c) the twelfth anniversary of the first commercial sale of the product in the applicable region. As of the date of this prospectus, the last-to-expire patent under the 2020 Xencor Agreement will have an expiration date of December 22, 2028 for ZB002 and February 22, 2031 for ZB004, provided the latest application in each of these countries is allowed. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the products during the term of the 2020 Xencor Agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the products in the applicable region. We are obligated to reimburse Xencor for certain third-party costs as further specified under the 2020 Xencor Agreement. During the six months ended June 30, 2024, we incurred no such reimbursable costs. During the six months ended June 30, 2023, we incurred immaterial reimbursable costs. During the years ended December 31, 2023 and 2022, we incurred immaterial costs and $0.1 million of such reimbursable costs, respectively.

Under the 2020 Xencor Agreement, (a) Xencor owns all know-how and patent rights invented solely by Xencor, (b) we own all know-how and patent rights invented solely by us; and (c) Xencor and we jointly own all joint intellectual property. Subject to the license grants under the 2020 Xencor Agreement, both parties may practice the joint intellectual property for all purposes on a worldwide basis without consent of and without a duty of accounting to the other party.

Under the 2020 Xencor Agreement, during the term of the agreement and for two years thereafter, we agree we will not develop, manufacture, or commercialize a competing product for any 2020 Licensed Asset (i.e., any product that binds to the same target as such 2020 Licensed Asset). The 2020 Xencor Agreement will remain in effect, on a region-by region basis and product-by-product basis, until the expiration of all royalty payment obligations. The 2020 Xencor Agreement may be terminated by either party for the other party's uncured material breach or insolvency. Xencor may terminate the 2020 Xencor Agreement if we challenge a licensed patent. We may terminate for convenience on a country-by-country basis with advance notice to Xencor, with the notice period differing based on whether such termination right is exercised prior to or following the first commercial sale.

Upon termination, all licenses granted by Xencor to us automatically terminate. We are obligated to assign to Xencor all regulatory filings or approvals specifically related to the terminated assets or products. At Xencor's sole discretion, we are obligated to transfer (a) our rights under agreements between us and third parties that solely relate to the development, manufacture or commercialization of terminated assets or products, (b) all materials developed by us for use for commercialization of terminated assets or products and (c) any product mark for terminated assets or products.

Upon termination, if Xencor elects to continue development and commercialization of terminated assets or products, we are obligated to grant to Xencor (a) an exclusive license under certain of our patent rights and (b) a nonexclusive license under certain of our know-how, where such licenses are irrevocable, perpetual, royalty-bearing and sublicensable solely to develop, manufacture, and commercialize the terminated assets or products. In consideration for these licenses, Xencor is obligated to pay us (a) mid-single digits royalty on net sales of the terminated assets or products if Xencor commercializes such terminated assets or products and (b) low double digits percentage of all payments receives from sublicensees if Xencor sublicenses the licenses granted by us. Xencor's obligation to make payments for these licenses is, on a product-by-product basis and region-by-region basis, until last-to-expire licensed patent covering the product in the applicable region.

In May 2021, we entered into a license agreement (the "2021 Xencor Agreement") with Xencor to obtain (a) an exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (b) a non-exclusive payment bearing license under certain know-how controlled by Xencor to research, develop, manufacture, market and sell obexelimab, an antibody product candidate based on Xencor's (and its licensors') proprietary technology. In addition, Xencor granted us a non-exclusive, royalty-free, sublicensable worldwide license under the same patent and know-how rights to develop, manufacture and commercialize companion diagnostics for obexelimab. Xencor obtained the rights to some of the intellectual property licensed to us pursuant to the Upstream Agreements. As such, the 2021 Xencor Agreement provides that the parties agree that some of the licenses granted by Xencor to us constitute sublicenses under the Upstream Agreements and are subject and subordinate to the terms and conditions of the Upstream Agreements. The 2021 Xencor Agreement became effective in November 2021, upon the execution of an amendment to the 2021 Xencor Agreement and Zenas' concurrent issuance to Xencor of a warrant with a fair

value of $20.7 million to Xencor as initial consideration providing Xencor the right to acquire additional equity, such that its total equity in Zenas would be 15% of its fully diluted capitalization at the completion of our Series B financing.

Under the 2021 Xencor Agreement, we are obligated to use commercially reasonable efforts to conduct all preclinical, clinical, regulatory and other activities (excluding activities previously conducted by Xencor at the time the 2021 Xencor Agreement was executed) necessary to develop and obtain the regulatory approval of obexelimab worldwide. We are further required to use commercially reasonable efforts to commercialize obexelimab following regulatory approvals in certain specified countries (United States, UK, France, Germany, Italy, and Spain).

We were obligated to make development milestone payments of up to $10.0 million, at Xencor's option either in cash or fully-paid newly issued shares, which milestone payment was paid in Series B Preferred Shares in June 2023. We are obligated to make regulatory milestone payments up to $75.0 million. We are also obligated to make one-time sales milestone payments up to $385.0 million upon achieving milestone events of net sales in a given calendar year in the territory equal to certain threshold amounts. In addition, we are required to pay Xencor tiered royalties on annual net sales of successfully commercialized products utilizing obexelimab, with the royalty rates varying based on regions and ranging from the mid-single digits to the mid-teens. On a region-by region basis and product-by-product basis, the term during which the royalties are payable by us to Xencor is until the latest of (a) the last-to-expire licensed patent covering the product in the applicable region, (b) the expiration of regulatory exclusivity for the product in the applicable region, or (c) the twelfth anniversary of the first commercial sale of the product in the applicable region. As of the date of this prospectus, the last-to-expire patent under the 2021 Xencor Agreement will have an expiration date of October 6, 2041, provided the latest application in each of these countries is allowed. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering product during the term of the 2021 Xencor Agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the product in the applicable region.

Under the 2021 Xencor Agreement, we agree we will not research or develop obexelimab in a way that would produce a molecule that would be classified as obexelimab or an obexelimab product. In addition, during the term and for two years thereafter, we agree not to develop, manufacture, or commercialize a competing product to obexelimab (i.e., any product that binds to CD19 and incorporates FcγRIIb Technology). During the term, Xencor is obligated to refrain from developing, manufacturing, or commercializing a competing product to obexelimab as well. The non-competes do not apply to any pre-existing activity for a competing product of an acquirer, subject to customary restrictions on such activity following such acquisition.

The 2021 Xencor Agreement will remain in effect, on a region-by region basis and product-by-product basis, until the expiration of all royalty payment obligations. The 2021 Xencor Agreement may be terminated by either party for the other party's uncured material breach or insolvency. We may terminate for convenience on a country-by-country basis with advance notice to Xencor, with the notice period differing based on whether such termination right is exercised prior to or following the first commercial sale.

Upon termination, all licenses granted by Xencor to us automatically terminate. We are obligated to assign to Xencor all regulatory filings or approvals specifically related to the terminated assets or products. At Xencor's sole discretion, we are obligated to transfer (a) our rights under agreements between us and third parties that solely relate to the development, manufacture or commercialization of terminated assets or products, (b) all materials developed by us for use for commercialization of terminated assets or products; and (c) any product mark in relation to the Compound (as defined below) or the Products (as defined below).

Upon termination, if Xencor elects to continue development and commercialization of terminated assets or products, we are obligated to grant to Xencor (a) an exclusive license under certain of our patent rights, and (ii) a nonexclusive license under certain of our know-how, where such licenses are irrevocable, perpetual, royalty-bearing and sublicensable solely to develop, manufacture, and commercialize the terminated assets or products. In consideration for these licenses, Xencor is obligated to pay us (a) mid-single digits royalty on net sales of the terminated assets or products if Xencor commercializes such terminated assets or products and (b) low double digits percentage of all payments receives from sublicensees if Xencor sublicenses the licenses

granted by us. Xencor's obligation to make payments for these licenses is, on a product-by-product basis and region-by-region basis, until the last-to-expire licensed patent covering the product in the applicable region.

License Agreement with Bristol-Myers Squibb

On August 30, 2023 (the "BMS Effective Date"), we entered into a strategic license and collaboration agreement with BMS under which we provided (a) an exclusive (even as to us) license under certain of our patents and joint patents to be developed under the BMS Agreement, and (b) a non-exclusive license under certain of our know-how. The license grants are for BMS to (a) develop, manufacture (subject to our rights to be the exclusive manufacturer for BMS for a certain period of time), commercialize or otherwise exploit our proprietary CD19 x FcγRIIb antibody, obexelimab (the "Compound") and any biological product (irrespective of presentations, formulations or dosages) containing the Compound but not any of our other proprietary active ingredient (the "Product") for treatment of any disease in human or animal in the BMS Territory and (b) conduct development and manufacture of the Compound and Products outside the BMS Territory provided that the Compound and Product are solely used in the BMS Territory. We also provided BMS a non-exclusive and royalty-free license under the same patent and know-how rights for BMS to develop, manufacture, commercialize, or otherwise exploit companion diagnostics for the Compound and Products in the BMS Territory. We retain all rights to commercialize obexelimab outside of the BMS Territory.

Under the BMS Agreement, during the term of the BMS Agreement and for a certain period thereafter, BMS has agreed not to develop, manufacture, or commercialize in the BMS Territory a competing product to obexelimab. We have similarly agreed, during the term of the BMS Agreement and for a certain period thereafter, not to develop, manufacture of commercialize in the BMS Territory a product that competes with obexelimab. The non-competes do not apply to any pre-existing activity for a competing product of an acquirer, subject to customary restrictions on such activity following such acquisition.

Under the BMS Agreement, we own all intellectual property in (a) improvements and modification to our pre-existing intellectual property, irrespective of which party develops such improvements and modification, (b) any item relating solely to the Compound and Products derived from use of our pre-existing intellectual property and confidential information, irrespective of which party develops such item and (c) any item generated solely by us in relation to the BMS Agreement. With the exclusion of intellectual property allocated as our intellectual property pursuant to (a) or (b) in the foregoing, (a) BMS shall own intellectual property generated solely by BMS under this Agreement and (b) parties will jointly own all other jointly developed intellectual property.

As part of the BMS Agreement, BMS is solely responsible for conducting all development activities required to obtain regulatory approval for the Compound or Products in the BMS Territory and BMS is obligated to use commercially reasonable efforts to develop at least one Product and seek and maintain regulatory approvals for such Product in Japan and certain other jurisdictions in the BMS Territory.

The parties agreed that we will manufacture and supply and BMS will exclusively purchase all of BMS's requirements of (a) Products (and placebo) for development in the BMS Territory, subject to the terms of a separate clinical supply agreement and clinical supply quality agreement, to be executed after the BMS Effective Date and (b) finished Products for commercialization in the BMS Territory, subject to the terms of a separate commercial supply agreement and commercial supply quality agreement, to be executed within a certain number of months prior to the first regulatory approval in the BMS Territory. However, BMS may elect to manufacture the Product itself or via a third party (a) at any time after a certain period following the BMS Effective Date or (b) during such period following the BMS Effective Date if we fail to supply above a certain threshold quantity of the Product ordered in any given calendar quarter. BMS has exclusive rights to commercialize the Product in the BMS Territory and is obligated to use commercially reasonable efforts to commercialize Products in Japan and certain other jurisdictions in the BMS Territory after obtaining the applicable regulatory approvals.

Under the terms of the BMS Agreement, we have received a one-time upfront payment of $50.0 million. We are entitled to receive further separate development and regulatory milestone payments up to $79.5 million and sales milestone payments up to $70.0 million upon BMS achieving certain net sales milestones in a given calendar year in the BMS Territory.

In addition, if BMS successfully develops and commercializes the Product in the BMS Territory, BMS will pay us tiered royalties ranging from (a) the mid-teens to very-low twenties for net sales of Product in Japan and (b) high single digit to low-teens for net sales of Product in all other countries in the BMS Territory, subject to specified reductions. On a country-by-country basis, the term during which the royalties are payable to us is until the latest of (a) the last-to-expire licensed patent covering the Product, (b) the expiration of regulatory exclusivity for the Product or (c) the twelfth anniversary of the first commercial sale of the Product. As of the date of this prospectus, the last-to-expire patent under the BMS Agreement will have an expiration date of October 2, 2044, provided the latest application in each of these countries is allowed. The expected termination of the royalty obligations will depend on factors such as the filing of additional patents covering the Product during the term of the BMS Agreement, the availability and application of patent term extensions and/or expiration of regulatory exclusivity for the Product in the BMS Territory. Finally, BMS will be required to pay a portion of the costs associated with our ongoing INDIGO Trial, in which BMS is participating, as well as any other global study in which BMS elects to participate. During the year ended December 31, 2023, we recorded $4.1 million as a reduction to research and development expense for costs associated with our INDIGO Trial that will be reimbursed by BMS. During the six months ended June 30, 2024, we recorded $2.7 million as a reduction to research and development expense for costs associated with our INDIGO Trial that will be reimbursed by BMS. We recognized no revenue during the six months ended June 30, 2024 pursuant to the BMS Agreement.

The BMS Agreement will remain in effect, on a country-by-country basis, until the expiration of all royalty payment obligations, and may be earlier terminated by either party for the other party's uncured material breach or insolvency. BMS may terminate for convenience on a country-by-country basis with advance notice to us, with the notice period differing based on whether such termination right is exercised prior to or following the first commercial sale. In addition to customary events of termination, we also have a right to terminate the agreement (a) automatically upon written notice if the upstream Xencor License Agreement terminates and (b) with written notice if BMS challenges the licensed patents.

Upon termination of the BMS Agreement, all licenses granted by us to BMS will automatically terminate and BMS is obligated to cease developing, manufacturing (subject to any transition assistance) and commercializing the Compound and Products in the BMS Territory. Additionally, BMS is obligated to transfer to us all regulatory filings and regulatory approvals related to the Compound or the Products in the Field in the BMS Territory. BMS is further obligated, at our sole discretion, to assign to us (to the extent permissible) (a) BMS's rights under agreements between BMS and third parties that solely relate to the development, commercialization or manufacture of the Compound or the Products, (b) documentation relating to the commercialization of the Compound or the Products in the BMS Territory; and (c) any BMS owned marks for the Compound or the Products. BMS is obligated to provide reasonable transition supply assistance with respect to any agreement for manufacturing Compound or Products transferred to us, including manufacturing the Compound or Products for up to 18 months following termination.

Intellectual Property

We own or license patents in the United States and foreign countries that protect our products, their methods of use and manufacture, as well as other innovations important to our business, and in order to help bring new therapies to patients. We consider the overall protection of our patents, trademarks, licenses and other intellectual property rights to be of material value. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our success will, in part, depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on regulatory protection, particularly biological data exclusivity, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our products and development programs.

In the biopharmaceutical industry, a substantial portion of an innovative product's commercial value is usually realized during the period in which the product has exclusivity. A product's exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovative drug is entitled.

Patents are a key determinant of exclusivity for most pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, discovery tools, pharmaceutical formulations, biomarkers, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. The protection afforded by a patent extends for a 20-year term from its filing date, without taking into account any potential patent term adjustment or extension. The protection provided by a patent depends on the scope of its coverage and the availability of meaningful legal remedies to enforce patent claims in the country or countries where it has issued.

Market exclusivity can also be influenced by regulatory data protection ("RDP"). Many developed countries provide certain non-patent incentives for the development of medicines. For example, in the United States, EU member states, UK, Japan, and certain other countries, RDP intellectual property rights are offered to: (i) provide a time period of data protection during which a generic company is not allowed to rely on the innovator's data in seeking approval; (ii) restore patent term lost during drug development and approval; and (iii) provide incentives for research on medicines for rare diseases, or orphan drugs, and on medicines useful in treating pediatric patients. These incentives may extend a product's market exclusivity period beyond the patent term.

Patent Portfolio

As of June 30, 2024, we own or exclusively in-license 11 patent families that specifically cover our product candidates obexelimab (our CD19 x FcγRIIb antibody), ZB002 (our anti-TNFα antibody), and ZB004 (our CTLA-4-Ig fusion protein). These families include 14 issued U.S. patents, six pending U.S. applications, 119 issued foreign patents, two pending PCT applications and 24 pending foreign patent applications in Australia, Brazil, Canada, China, Europe, Eurasia, Israel, Mexico, South Africa, South Korea, Hong Kong, Japan, India, Russia and Taiwan. In addition, we own or exclusively in-license eight United States provisional patent applications, which belong to four different patent families, within the priority year. Any United States or foreign patents issued from national stage filings of our owned, or exclusively in-licensed PCT patent applications, any U.S. patents issued from our exclusively in-licensed non-provisional applications, and any United States patents or foreign patents issued from non-provisional applications we may file in connection with our provisional patent applications would be scheduled to expire on various dates from 2027 through 2045.

All expected expiration dates provided herein are based on a 20-year term, without taking into account any possible PTA or PTE and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Obexelimab

Obexelimab is a bifunctional, non-cytolytic, humanized monoclonal antibody that binds CD19 and FcγRIIb to inhibit B-lineage cell activity. As of June 30, 2024, we own or exclusively in-license from Xencor eight patent families that specifically cover the composition of matter, mechanism of action, manufacturing, biomarkers and the clinical uses of obexelimab for treating IgG4-RD, SLE, MS and wAIHA.

A first patent family specifically covers the composition of matter of obexelimab and includes six issued patents and two pending applications in the United States, and 21 issued foreign patents in Australia, Hong Kong, India, Israel and various European countries including Belgium, Denmark, France, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Monaco, Netherlands, Spain, Sweden, Switzerland, and UK. The 20-year statutory term for the patents issued in this family expires in May 2028, excluding any extension of patent term that may be available. A second patent family is directed to obexelimab's mechanism of action and includes one issued patent and one pending application in the United States, four pending applications in Canada, Europe and Japan, and 19 issued patents in Japan and European countries including Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Sweden, Turkey and UK. The 20-year statutory term for any patents issued in this family expires in June 2037, excluding any extension of patent term that may be available. A third patent family is directed to the use of biomarkers for treating autoimmune diseases (e.g., SLE) and includes one pending United States application, and 13 pending applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, Japan, South Korea, Mexico, South Africa and Taiwan. The 20-year statutory term for any patents issued in this family would

expire in October 2041, excluding any extension of patent term that may be available. A fourth patent family is directed to the clinical use of obexelimab for treating IgG4-RD, currently including a pending PCT application and a Taiwanese application. The 20-year statutory term for any patents issued in this family would expire in June 2043, excluding any extension of patent term that may be available. A fifth patent family is directed to the clinical use of obexelimab for treating wAIHA, currently including a pending PCT application and a Taiwanese application. The 20-year statutory term for any patents issued in this family would expire in April 2044, excluding any extension of patent term that may be available. A sixth patent family is directed to the clinical use of obexelimab for treating MS currently including four provisional applications. Assuming the provisional applications are converted to a non-provisional application at the 12-month from priority deadline, the 20-year statutory term for any patents issued in this family would expire in October 2044, excluding any extension of patent term that may be available. A seventh patent family is directed to the SC administration of obexelimab for treating SLE currently including one provisional application. Assuming the provisional application is converted to a non-provisional application at the 12-month from priority deadline, the 20-year statutory term for any patents issued in this family would expire in January 2045, excluding any extension of patent term that may be available. An eighth patent family is directed to the manufacturing processes for obexelimab currently including one provisional application. Assuming the provisional application is converted to a non-provisional application at the 12-month from priority deadline, the 20-year statutory term for any patents issued in this family would expire in June 2045, excluding any extension of patent term that may be available. A PTE of up to five years may be available and can be applied in one of these families as appropriate.

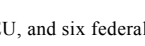
ZB002

ZB002 is an anti-TNFα monoclonal antibody with the Xtend technology modified to have an extended half-life as compared to existing anti- TNFα therapies. As of June 30, 2024, we exclusively own or in-licensed two patent families covering ZB002. A first patent family specifically covers the full-length amino acid sequences of ZB002, including three issued patents in the United States, Brazil and Japan, and four pending applications in the United States, Europe, Hong Kong and Russia. The 20-year statutory term for U.S. patents in this family expires in October 2027 and any foreign patents that are in this family are expected to expire in December 2028, excluding any extension of patent term that may be available. A second patent family is directed to the formulation and dosing of ZB002 in treating autoimmune diseases currently including two provisional applications. Assuming the provisional applications are converted to a non-provisional application at the 12-month from priority deadline, the 20-year statutory term for any patents issued in this family would expire in March 2045. A PTE of up to five years may be available and can be applied in one of these families as appropriate.

ZB004

ZB004 is a CTLA-4-Ig fusion protein with the Xtend technology modified to have an extended half-life versus existing CTLA-4-Ig fusion protein therapies. As of June 30, 2024, we exclusively in-licensed one patent family that specifically covers the composition of matter of ZB004 and related methods of use including six issued patents and one pending application in the United States, two pending foreign applications in China and Hong Kong, and 77 issued foreign patents in Australia, Canada, China, India, Japan, South Korea and European countries including Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lichtenstein, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and UK. The 20-year statutory term for the patents issued in this family expires in February 2031, excluding any extension of patent term that may be available. A PTE of up to five years may be available.

Trademark Portfolio

As of June 30, 2024, we own three federal trademark registrations for the marks  , ZENAS BIOPHARMA and  in the United States, four federal trademark registrations for the marks  ,  , ZENAS BIOPHARMA and  in the EU, and six federal trademark registrations for

the marks ZENAS BIOPHARMA, 泽纳仕 and Zenas BioPharma in China. We also own three allowed federal trademark applications for the marks , and ZENAS BIOPHARMA in the United States, one pending federal trademark application for the mark in China, two pending federal trademark applications for the mark and in the United States, and two pending federal trademark applications for the mark and in the EU.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We have engaged, and currently rely on, a single third-party CMO, WuXi Biologics, for the supply of our product candidates for use in our preclinical studies and clinical trials. Should our CMO become unavailable to us for any reason, we believe that there are a number of potential replacements, although we would incur delay and cost in identifying and qualifying such replacements.

We maintain a master services agreement with Wuxi Biologics pursuant to which it provides biologics development and manufacturing services on a per-project basis. We may terminate the master services agreement at any time for convenience in accordance with the terms of the agreement. We may also terminate the master services agreement in the event that Wuxi Biologics does not obtain or maintain any material governmental license or approval in accordance with the terms of the agreement. The agreement includes confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates. While any reduction or halt in supply from the CMO could limit our ability to develop our product candidates until a replacement CMO is found and qualified, we believe that we have sufficient supply to support our current clinical trial programs. See “Risk Factors” for additional information.

If any of our product candidates receives marketing approval, we intend to rely on third-party CMOs for commercial manufacturing. As our product candidates advance through development, we expect to enter into longer-term commercial supply agreements to fulfill and secure our production needs. We are in the process of establishing redundant manufacturing capacity for commercial drug substance and drug product at WuXi Biologics’ facilities in Europe. In addition, we are currently evaluating potential new contract manufacturing organizations not affiliated with WuXi Biologics in the United States and the EU to establish additional sources of supply for drug substance and drug product for both commercial and clinical use. We currently plan to select the additional suppliers for drug substance and drug product in the second half of 2024. For the medical device component of our product (i.e., prefilled syringe or autoinjector), we plan to utilize device assembly facilities in the United States or EU for the global supply. While the drug substances used in our product candidates are manufactured by more than one supplier, we rely on a single third-party manufacturer to manufacture and supply the drug substances, drug products, raw materials, samples, components and other materials for our product candidates. In the event it is necessary or advisable to acquire supplies from alternative sources, we might not be able to obtain them at reasonable prices, or at all. It could also require significant time and expense to transfer our manufacturing processes to another company. If we need to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards, regulations and guidelines, and we may be required to conduct additional studies.

Additionally, to adequately meet our projected manufacturing needs for commercializing obexelimab and our other product candidates, our CMOs will need to scale-up production or we will need to secure additional suppliers. Processes for producing obexelimab drug substances and drug product for commercial supply have been developed and defined. We believe the drug substance and drug product processes for obexelimab and our other product candidates are amenable to scale-up.

Sales, Marketing and Commercialization

None of our product candidates have been approved for sale in any country. We hold global development and commercialization rights to obexelimab, excluding Japan, Taiwan, South Korea, Singapore, Hong Kong

and Australia, which we have licensed to BMS. We also hold the global development and commercialization rights to ZB002 and ZB004. We hold development and commercialization rights to ZB001 and ZB005 in greater China only.

If our product candidates receive FDA approval, we intend to build our own commercialization infrastructure in the United States and Europe, to market and sell our products. For Asia and other geographies, we plan to conduct the initial clinical development work and then seek to enter into an agreement with a third party to complete the clinical development work, obtain regulatory approval, and ultimately commercialize in these territories. However, we intend to continually evaluate the economics of potentially commercializing our product candidates ourselves, if approved, versus other strategic commercialization arrangements.

We currently have no sales, marketing or commercialization capabilities and have no experience as a company performing such activities. However, we intend to build the necessary capabilities and infrastructure over time as our product candidates continue to advance through clinical development. We believe that clinical data, the size of the market opportunity and the size of the required commercial infrastructure will influence our commercialization plans and decision making.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize, if approved, will compete with existing therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition, the existence of therapeutic alternatives and the availability of coverage and reimbursement from government and other third-party payors.

Many of the companies against which we are competing, or against which we may compete 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 drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We are currently developing obexelimab for IgG4-RD, MS, SLE and wAIHA. There are currently no approved products for IgG4-RD or wAIHA. A number of products are approved for MS and two products are approved for SLE. However, there are a number of product candidates in clinical development by other companies for IgG4-RD, MS, SLE and wAIHA which may become available in the future. Potentially competitive therapies by indication fall primarily into the following groups of treatment:

IgG4-RD:

- UPLIZNA (inebilizumab-cdon), an anti-CD19 antibody being developed by Amgen Inc., for which Amgen announced its intention to file a BLA based on the results of its Phase 3 clinical trial;
- a small molecule Bruton’s tyrosine kinase (“BTK”) inhibitor in a Phase 2 clinical trial, being developed by Sanofi S.A.;
- other clinical or preclinical small molecules, biologics (including cell-based therapies), or other therapeutic modalities that may be or are being developed for IgG4-RD; and

- other therapies such as corticosteroids and immunosuppressants like cyclophosphamide and rituximab have been used off-label. While these other therapies have not been shown to be effective, and carry significant side effects, their off-label use could reduce or delay treatment in the addressable patient population for obexelimab.

MS:

- approved monoclonal antibody biologic therapies including anti-CD20 antibodies such as Ocrevus marketed by F. Hoffmann-La Roche Ltd., Kesimpta marketed by Novartis AG, Briumvi marketed by TG Therapeutics Inc., an anti-CD52 antibody Lemtrada marketed by Sanofi S.A., and an α4-integrin antibody Tysabri marketed by Biogen;
- approved non-antibody-based injectable therapies including interferon beta-1a therapies such as Avonex marketed by Biogen, Plegridy marketed by Biogen, Betaseron marketed by Bayer AG, Extavia marketed by Novartis AG, Rebif marketed by Merck KGaA, and myelin basic protein-based therapies such as Copaxone marketed by Teva Neuroscience Inc.;
- approved small molecule oral therapies including Aubagio marketed by Genzyme Corporation, Bafiertam marketed by Banner Life Sciences, Gilenya marketed by Novartis AG, Mavenclad marketed by Merck KGaA, Mayzent marketed by Novartis AG, Ponvory marketed by Janssen Pharmaceuticals, Inc., Tascenso ODT marketed by Cycle Pharmaceuticals Ltd., Tecfidera marketed by Biogen, Vumerity marketed by Biogen, and Zeposia marketed by Bristol Myers Squibb Company;
- three small molecule BTK inhibitor programs in Phase 3 development by Sanofi S.A., Novartis AG, and Hoffmann-La Roche Ltd.;
- a vidofludimus calcium program in Phase 3 development by Immunic Therapeutics Inc.;
- a small molecule selective tyrosine kinase inhibitor program in Phase 3 development by AB Science;
- an anti-CD40/CD40L antibody in a Phase 3 clinical trial being developed by Sanofi S.A;
- several Phase 2 clinical trial programs evaluating multiple targets / mechanisms of action including but not limited to BTK, M1R (muscarinic type 1 receptor), RIPK1 (receptor-interacting serine/threonine-protein Kinase 1), BLyS/APRIL, MOG (myelin oligodendrocyte glycoprotein), VAA-4 (very late antigen 4), undisclosed targets / mechanisms and allogenic, autologous, mesenchymal, and CAR-T cell therapies;
- other clinical or preclinical disease modifying small molecules, biologics, or other therapeutic modalities that may be or are being developed for MS; and
- and, approved generic and biosimilar therapies.

SLE:

- approved therapies including an anti-BLyS antibody Benlysta marketed by GSK plc., an anti-IFNAR (type I interferon receptor) antibody Saphnelo marketed by AstraZeneca plc., and a dual antagonist of BlyS and APRIL Tai'ai approved and marketed only in China, by RemeGen Co., Ltd.;
- an anti-CD40L (CD40 ligand) pegylated Fab (antigen binding fragment) program in a Phase 3 clinical trial, being developed by UCB Biopharma SRL;
- an anti-BDCA2 (blood dendritic cell antigen 2) antibody program in Phase 3 clinical trials, being conducted by Biogen Inc.;
- a dual antagonist of BLyS and APRIL program in a Phase 3 (ex-China) clinical trial, being developed by RemeGen Co., Ltd.;
- two anti-CD20 antibody programs in Phase 3 clinical trials, being developed by F. Hoffmann-La Roche Ltd. and Beijing Mabworks Biotech Co., Ltd., the latter in China only;
- a small molecule tyrosine kinase 2 ("TYK2") inhibitor in Phase 3 clinical trials, being developed by Bristol Myers Squibb Company;
- a sphingosine-1-phosphate 1 receptor modulator in Phase 3 clinical trials, being developed by Idorsia Pharmaceuticals Ltd.;

- a small molecule Janus kinase inhibitor in Phase 3 clinical trials, being developed by AbbVie Inc.;
- an anti-BAFF-R antibody program in Phase 3 clinical trials, being developed by Novartis AG;
- several Phase 2 clinical trial programs evaluating multiple targets / mechanisms of action including but not limited to TLR7/8, CD28/ICOS, CD40/CD40L, BAFF/APRIL, IL2, CRL4-CRBN, IFNB1, BTLA, FcRn, TYK2, BTK, CD22, CD32B/CD79B, CD19, CD19/CD20/BCMA-CAR T programs and undisclosed targets / mechanisms;
- other clinical or preclinical small molecules, biologics, or other therapeutic modalities that may be or are being developed for SLE; and
- other therapies such as antimalarials (e.g., hydroxychloroquine), corticosteroid, and immunosuppressants (e.g., cyclophosphamide or rituximab) have been used off-label. While these other therapies have not been shown to be effective, and carry significant side effects, their off-label use could reduce or delay treatment in the addressable patient population for obexelimab.

wAIHA:

- an anti-BAFF-R (B cell activating factor receptor) antibody program in a Phase 3 clinical trial, being developed by Novartis AG;
- an anti-FcRn (neonatal fragment crystallizable receptor) antibody program in a Phase 2/3 clinical trial, being developed by Johnson & Johnson;
- a small molecule spleen tyrosine kinase inhibitor in a Phase 2/3 clinical trial in China, being developed by HUTCHMED (China) Ltd.;
- a small molecule BTK inhibitor in a Phase 2 clinical trial, being developed by Sanofi S.A.;
- a dual monoclonal antibody antagonist of BlyS and APRIL in Phase 1/2 clinical trial by Alpine Immune Sciences, Inc;
- other clinical or preclinical small molecules, biologics, or other therapeutic modalities that may be or are being developed for wAIHA; and
- other therapies such as corticosteroid, immunosuppressants (e.g., cyclophosphamide or rituximab), intravenous immunoglobulin, and splenectomy have been used off-label. While these other therapies have not been shown to be effective, and carry significant side effects, their off-label use could reduce or delay treatment in the addressable patient population for obexelimab.

We are also developing ZB002, an anti-TNFα therapy with an extended half-life. The TNFα-binding region within the fragment variable (Fv) domain has an identical amino acid sequence to Humira (adalimumab). The fragment crystallizable (Fc) domain consists of a hybrid immunoglobulin (IgG1/2) constant region containing amino acid substitutions for extended half-life. There are 5 FDA-approved innovator anti-TNF programs for various indications including Humira marketed by AbbVie Biotechnology Ltd., Enbrel marketed by Amgen Inc., Remicade, marketed by Janssen Biotech, Inc., Simponi, marketed by Janssen Biotech, Inc., and Cimzia, marketed by UCB, Inc. In addition to these five innovator anti-TNF programs, a number of biosimilar anti-TNF programs are FDA-approved including Humira biosimilars (such as Amjevita marketed by Amgen Inc., Abrilada marketed by Pfizer Inc., Cyltezo marketed by Boehringer Ingelheim Pharmaceuticals, Inc., Hadlima Organon group of companies, Hulio marketed by Veritas Inc., Hyrimoz marketed by Sandoz Inc., Idacio marketed by Fresenius Kabi USA, LLC, Yuflyma marketed by Celltrion Healthcare Co., Ltd., and Yusimry marketed by Coherus BioSciences, Inc.).

ZB004 is a CTLA-4-Ig fusion protein with an extended half-life and potential improved potency versus existing CTLA-4-Ig fusion protein therapies. There are two marketed CTLA-4-Ig fusion protein therapies. Orencia, marketed by BMS, is FDA-approved for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and prophylaxis of acute graft versus host disease. Nulojix, marketed by BMS, is FDA-approved for prophylaxis of organ rejection in adult patients receiving a kidney transplant. One Orencia biosimilar program recently entered Phase 1 clinical development.

Government Regulation

Government authorities at the federal, state and local level in the United States and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of biological products such as those we are developing.

We, along with our CMOs, CROs and third-party vendors, will be required to satisfy these requirements in each of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes, regulations, and other regulatory requirements, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

We are currently developing product candidates that are biological products, or biologics. In the United States, where we are initially focusing our product development, the FDA regulates biologics under the FDCA and the Public Health Service Act ("PHSA"), and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. Our product candidates are early-stage and have not been approved for marketing in the United States.

An applicant seeking approval to market and distribute a new biologic in the United States must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's GLPs;
- manufacture of the drug substance and drug product in accordance with the FDA's cGMPs, along with required analytical and stability testing;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent IRB, representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials, in accordance with current Good Clinical Practice requirements ("cGCPs"), necessary to establish the safety, potency and purity of the product candidate for each proposed indication;
- preparation and submission to the FDA of a BLA, requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product and proposed labeling;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLPs and cGCPs, as applicable, and the integrity of clinical data in support of the BLA;
- payment of user fees under the Prescription Drug User Fee Act ("PDUFA"), unless exempted;
- the FDA's review and approval of the BLA, including consideration of the views of any FDA advisory committee, if applicable; and
- if approved, compliance with any post-approval requirements, including the potential requirement to implement a REMS and any post-approval studies or other post-marketing commitments required by the FDA.

Failure to comply with the applicable requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process, or post-approval process, may subject an applicant to delays in the conduct of the study or regulatory review and approval, as well as administrative or judicial sanctions or other consequences. These sanctions or consequences may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, issuance of clinical holds for planned or ongoing studies, refusal to approve pending applications, suspension or revocation of existing product licenses or approvals, issuance of warning or untitled letters, adverse publicity, product recalls, marketing restrictions, product seizures, import detentions and refusals, total or partial suspension of manufacturing or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice ("DOJ"), and other governmental entities, including state agencies.

Preclinical Studies and Investigational New Drug Application

Once a therapeutic product candidate is identified for development, it must undergo preclinical studies (also known as preclinical testing) before any testing may be conducted in humans. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animals. The conduct of preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLPs. The results of the preclinical tests, together with manufacturing information, analytical data, and plans for the proposed clinical studies, are submitted to the FDA as part of an IND. Some preclinical testing may continue after an IND is submitted.

An IND is a request for FDA authorization to administer an investigational new drug product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin. As a result, submission of an IND may or may not result in FDA authorization to begin a clinical trial, or to begin a clinical trial on the terms originally specified by the sponsor in the IND.

At any time during the initial 30-day IND review period or while clinical trials are ongoing under the IND, the FDA may impose a partial or complete clinical hold. Clinical holds may be imposed by the FDA when there is concern for patient safety, and may be a result of new data, findings, or developments in clinical, preclinical, and/or chemistry, CMC or where there is non-compliance with regulatory requirements. This order would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. A separate submission to an existing IND must also be made for each successive clinical trial conducted, and the FDA must grant permission, either explicitly or implicitly, by not objecting before each clinical trial can begin.

Human Clinical Trials

Clinical trials involve the administration of an investigational drug product to healthy volunteers or patients with the disease or condition to be treated under the supervision of qualified investigators. Clinical trials must be conducted in accordance with GCPs, which establish ethical and data integrity standards for clinical testing, as well as the requirements for informed consent.

Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

For clinical trials conducted in the United States, an IND is required, and each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. An IRB must operate in compliance with FDA regulations.

The FDA, IRB or the trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the trial is not being conducted in accordance with GCPs or IRB requirements or that research subjects or patients are being exposed to an unacceptable health risk. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or data monitoring committee. Depending on its charter, this group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, FDA may accept the results of the study in support of a BLA if the study was well-designed and conducted in accordance with GCPs, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population of healthy subjects to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and PD. In the case of some products designed to address severe or life-threatening diseases, initial human testing is often conducted in patients with the disease, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the preliminary efficacy of the product candidate for specific targeted indications and determine dose tolerance and recommended dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.
- Phase 3 clinical trials are generally undertaken to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are generally referred to as "pivotal," however, for some investigational products, Phase 2 may be considered pivotal trials if such trials are expected to provide the clinical evidence needed to support a marketing application.

In some cases, the FDA may approve a BLA for a product but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after approval. Such post-approval trials are typically referred to as confirmatory studies, or Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and verify clinical benefit for products approved under accelerated approval regulations. Failure to exercise due diligence with regard to conducting required confirmatory studies could result in withdrawal of approval for products.

While the IND is active and before approval, progress reports detailing the results of the clinical trials and preclinical studies performed since the last progress report must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and 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.

There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose information about ongoing clinical trials, including information related to the drug, patient population, phase of investigation, trial sites and investigators. Sponsors are also obligated to disclose the

results of completed clinical trials, other than Phase 1 clinical trials, within specific timeframes. Information about applicable clinical trials is published on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

During the development of a new biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Compliance with cGMPs

Concurrent with clinical trials, companies must finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the products do not undergo unacceptable deterioration over their shelf life. 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 cGMPs and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing controls for products like biologics whose attributes cannot be precisely defined. Material changes in manufacturing equipment, location, or process post-approval, may result in additional regulatory review and approval.

Review and Approval of a BLA

The results of clinical trials and preclinical studies, together with detailed information regarding the manufacturing processes, chemistry and composition of the product, the proposed labeling and other relevant information, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more specified indications. Clinical and preclinical data may come from company-sponsored trials or from a number of alternative sources, including studies initiated by investigators, and the BLA must include any negative and ambiguous results, as well as positive findings. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, and potency of the investigational product to the satisfaction of the FDA. For most BLAs, the sponsor is required to pay a substantial application user fee at the time of submission and the sponsor of an approved BLA is subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether to accept it for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and the review process may be significantly extended by FDA requests for additional information or clarification. For example, the review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional data, analysis or information that FDA deems a major amendment.

During its review of a BLA, the FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GLPs or GCPs, the FDA may approve the BLA or issue a complete response letter. Under the PHSA, the FDA may approve a BLA if it determines the product is safe, pure, and potent, and that the facility in which the product will be manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. If FDA determines the product meets these standards, it may issue an approval letter authorizing the commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. A complete response letter may require additional clinical data and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Sponsors that receive a complete response letter have one year to submit information that represents a complete response to the deficiencies identified by the FDA. The FDA will then re-review the application, taking into consideration the response, and determine whether the application meets the criteria for approval. Failure to respond to a complete response letter will serve as a withdrawal of an application. The FDA will not approve an application until issues identified in any complete response letters have been addressed.

If the FDA approves a new product, it may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use (also known as ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

After approval, if there are any modifications to the approved product, including changes in the indications, dosage forms, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the generation of additional data or the conduct of additional preclinical studies and clinical trials.

Post-Approval Regulation

Upon FDA approval of a BLA, the sponsor will be required to comply with all post-approval regulatory requirements for biologics, as well as any specific post-approval requirements that the FDA has imposed as part of the product or indication's approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information, obtain FDA approval for certain manufacturing and labeling changes, and comply with requirements concerning advertising and promotional labeling, record-keeping, and drug supply chain security. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections for compliance with ongoing regulatory requirements, including cGMPs. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control, as well as pharmacovigilance activities, to maintain compliance with cGMPs and other regulatory requirements.

A biological product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, 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, to the FDA. The FDA may perform certain confirmatory tests on lots of some products before releasing the lots for distribution. In addition, the FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products, including biological products. These regulations include, among other things, standards and regulations for direct-to-consumer advertising, communications

regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the BLA is approved. Once a BLA is approved, the sponsor can make only those claims relating to safety, efficacy, purity and potency that are in accordance with the provisions of the approved label. In the United States, healthcare professionals are generally permitted to prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those approved by the FDA. Such off-label uses are common across medical specialties. The FDA does not regulate the practice of medicine or healthcare providers' choice of treatments. However, FDA regulations do impose rigorous restrictions on manufacturers' communications of off-label uses. Additionally, promotional materials for prescription drug products must be submitted to the FDA in conjunction with their first use.

If a company, including any agent of the company or anyone speaking on behalf of the company, is found to have promoted off-label uses, the company may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services ("HHS"), as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

The FDA may withdraw product approval if compliance with regulatory requirements and standards is not maintained or if issues occur after the product reaches the market. Later discovery of previously unknown issues 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 trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include:

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

FDA Regulation of Combination Products

Certain therapeutic products are comprised of multiple FDA-regulated components, such as drugs and medical devices, that are physically combined and produced as a single entity, packaged together in a single package, or packaged separately but intended to be labeled for use together. These products are known as combination products. We expect that obexelimab and our other product candidates packaged in a prefilled

syringe or autoinjector would be subject to regulation as a combination product if consisting of a therapeutic biologic and a delivery device.

The constituent elements of such combination products would normally be subject to different FDA regulatory frameworks and regulated by different Centers at the FDA. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application; however, FDA could require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort and information. Even when a single marketing application is required for a combination product, such as a BLA for a combination biologic and device product, both FDA's Center for Biologics Evaluation and Research and FDA's Center for Devices and Radiological Health may participate in the review. If a product candidate is considered a biologic-device combination product, the sponsor will also need to comply with post-marketing regulatory requirements, including adverse event reporting and applicable portions of the FDA's Quality System regulation, applicable to combination products.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA has several programs intended to facilitate and expedite development and review of new products that are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation and priority review designation. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

The FDA may designate a product for fast track designation if it is intended for the treatment of a serious or life-threatening disease or condition, and preclinical or clinical data demonstrate the potential to address unmet medical needs for such a disease or condition. For products with fast track designation, sponsors may have more frequent interactions with the FDA, the product is potentially eligible for accelerated approval and priority review, if relevant criteria are met, and the BLA may be eligible for "rolling review," under which the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a product with fast track designation may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining sections of the BLA, and the sponsor must pay any required user fees upon submission of the first section of the BLA. The FDA's time goal for reviewing a fast track application does not begin until the last section of the application is submitted.

A product may be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The designation includes all of the fast track program features, including eligibility for rolling review. Additionally, the FDA may take certain actions to expedite the development and review of breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff managers in the review process; assigning a cross-disciplinary lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. A priority review designation is intended to direct the FDA's attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an original BLA from ten months to six months from the filing date.

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 drug qualifies for one or more of these programs, the FDA may later withdraw or rescind the designation if it decides that the drug no longer meets the conditions for qualification or decides that the time period for FDA review or approval will not be shortened.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides a meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. 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. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

The FDA's approval of a candidate product under the accelerated approval pathway is usually contingent on a sponsor's agreement to conduct post-approval confirmatory studies to verify and describe the product's clinical benefit, and the FDA may require such studies to be underway prior to approval. Failure to conduct required post-approval studies, confirm a clinical benefit during post-marketing studies may result in the FDA's withdrawal of the product from the market on an expedited basis. All promotional materials for therapeutic candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug or biologic for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. If orphan drug designation is granted by the FDA, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. After FDA grants orphan designation, the product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same indication for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, or the sponsor is unable to provide sufficient quantities.

The FDA has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or use of a product, rather than the disease or condition for which the product received orphan designation. However, in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with this position, holding that orphan-drug exclusivity blocked the FDA's approval of the same drug for all uses or indications within the same orphan-designated disease. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that the FDA intends to continue to apply its longstanding interpretation of the regulations to all matters outside of the scope of the *Catalyst* order and will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Development in Pediatric Patients

Under the Pediatric Research Equity Act of 2003, a BLA or BLA supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product 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. A sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit a Pediatric Study Plan ("PSP") that contains an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor and the FDA must reach agreement on the PSP. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted.

Biosimilars and Exclusivity

The ACA, which was signed into law in March 2010, included the BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed "reference product." Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product in any given patient, and (for products administered multiple times to an individual) that the biologic and the reference

biologic may be 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 of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity and enforceability prior to the approval of the biosimilar. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state regulated, to regulate the use of biosimilars.

U.S. Patent Term Restoration and Extension

In the United States, a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Federal and State Data Privacy and Security Laws

Under HIPAA, HHS has issued regulations to protect the privacy and security of protected health information, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 or HITECH, and their regulations, including the final omnibus rule published on January 25, 2013, also imposes certain obligations on the business associates of covered entities and their covered subcontractors that obtain protected health information in providing services to or on behalf of covered entities or business associates. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. In addition to possible federal, administrative, civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Accordingly, state attorneys general have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

Additionally, states, such as California, Virginia and Colorado have recently enacted the consumer privacy laws that grant rights to data subjects and place increased privacy and security obligations on entities handling personal data of consumers or households. While we are not currently subject to laws such as the CCPA, some observers note that the CCPA and similar legislation could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Because of the breadth of these laws and the narrowness of the statutory exceptions under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that we may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any applicable privacy or data security laws or regulations, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that we collect or otherwise process personal information, we may be subject to privacy or data protection laws that are in effect in such third countries foreign laws.

Regulation and Procedures Governing Approval of Medicinal Products in Europe

In order to market any medicinal product outside of the United States, a company must also comply with numerous and varying regulatory requirements to generate relevant data for the purpose of establishing its quality, safety and efficacy. There are specific rules governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Regardless of the product approval status in the United States, an applicant will need to obtain the necessary approvals granted by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of a medicinal product in those countries or jurisdictions.

The processes governing approval of medicinal products in the EU and UK generally adopt a similar approach to that applied in the United States. They entail satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. Data should be generated to demonstrate that a drug substance and a drug product can be manufactured and controlled according to the pre-specified quality standards. The data relating to quality, preclinical testing and clinical trials should be submitted to the relevant competent authorities in a marketing authorization application ("MAA") for regulatory review in order to determine whether a marketing authorization can be granted. Even if a marketing authorization has been granted, there is a need to obtain a pricing and reimbursement decision before a new medicinal product can be marketed and sold in the EU and/or the UK (as applicable).

Clinical Trial Approval

Pursuant to the currently applicable Regulation (EU) No 536/2014 (CTR) and Directive 2005/28/EC on GCP, an applicant must obtain approval from the national competent authority of an EU member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant can only start a clinical trial at a specific site after a research ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the CTR and corresponding national laws of the member states. All suspected unexpected serious adverse reactions to the investigational medicinal product that occur during the clinical trial have to be reported to the national competent authorities and research ethics committees of the member state where they occurred.

Pursuant to the CTR, a sponsor must submit a single application for a new clinical trial authorization through a centralized EU clinical trials portal called the Clinical Trials Information System ("CTIS"). One national competent authority (from the reporting EU member state selected by the applicant) takes the lead in validating and evaluating the application, as well as consulting and coordinating with the other concerned member states in which the clinical trial is to be conducted. If an application is rejected, it may be amended and resubmitted through CTIS. A concerned member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in that member state. By January 31, 2025, all ongoing trials approved under the CTD must comply with the CTR and information relating to such

clinical trials must be recorded in CTIS. The CTR aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the CTIS.

The UK formally left the EU on January 31, 2020, under the terms of the Agreement on the withdrawal of the UK of Great Britain and Northern Ireland from the EU and the European Atomic Energy Community (the EU-UK Withdrawal Agreement). Despite this, EU law continued to apply in the UK until the expiry of the transition period on 31 December 2020. Following the UK's departure from the EU, the UK and the EU entered into a trade and cooperation agreement ("TCA"), which includes specific provisions concerning pharmaceuticals (such as the mutual recognition of cGMP inspections of manufacturing facilities for medicinal products and cGMP documents issued), but which does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At the point that the transition period expired, the Northern Ireland Protocol, which is contained in the EU-UK Withdrawal Agreement, took effect. The Northern Ireland Protocol makes certain provisions of EU law, including several concerning medicinal products, applicable in Northern Ireland. This position has recently been revised via the Windsor Framework. Under the Windsor Framework, from January 1, 2025, all new medicinal products for the UK market will be authorized by the UK's Medicines and Healthcare products Regulatory Agency ("MHRA") (see further below).

In the UK, clinical trials of medicinal products are primarily governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended (the UK Regulations). The UK Regulations sought to implement the CTD while the UK was a member state of the EU. Since the CTR was not in force in the EU at the time when the UK exited the EU, it was not retained in UK law on exit day under the terms of the European Union (Withdrawal) Act 2018. Following a public consultation which was conducted in early 2022, the UK authorities are in the process of developing legislation which seeks to improve and strengthen the clinical trials regulatory regime in the UK. The extent to which the regulation of clinical trials in the UK will mirror the CTR is unknown at present.

Accelerated Assessment Pathways

The EU's Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and facilitates accelerated assessment of medicinal products representing substantial innovation reviewed under the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EEA or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by, for example, introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme. Many benefits accrue to sponsors of therapeutic candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, an EMA contact and rapporteur from the Committee for Human Medicinal Products ("CHMP"), or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

The UK's Innovative Licensing and Access Pathway ("ILAP") aims to accelerate the time to market of innovative medicinal products. It is open to both commercial and non-commercial applicants, who are based in the UK or global, and who are developing medicinal products which include products containing new chemical entities, biological medicinal products, new indications and repurposed medicinal products. It comprises of an Innovation Passport designation and a Target Development Profile, and provides applicants with access to a toolkit to support all stages of the design, development and approvals process. The major benefit of the ILAP scheme is that it provides applicants with opportunities for enhanced regulatory and stakeholder input during the development of their medicinal products.

Marketing Authorization

To obtain a marketing authorization for a medicinal product under the EU regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU member states (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EU.

Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the EU, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP"), covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP. The Paediatric Committee of the EMA ("PDCO"), may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population. An application for marketing authorization or a variation or a variation or a line-extension which is accompanied by the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for a six months extension of their supplementary protection certificate. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is not automatically available and is subject to the EMA or the relevant national competent authorities confirming compliance with the agreed PIP that may require an opinion to be given by the EMA's Pediatric Committee.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states, as well as the additional member states of the EEA (Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines developed by means of certain biotechnological processes (including, recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods), products designated as orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products containing a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer, HIV / AIDS, neurodegenerative disorders, diabetes, auto-immune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance which was not authorized in the EU on May 20, 2004, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. An applicant for the centralized MA must demonstrate the quality, safety and efficacy of their products to the EMA for an opinion to be adopted regarding the approvability of the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Under the centralized procedure, the CHMP established within the EMA is responsible for conducting an initial assessment of a medicinal product. The maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued ordinarily within 67 days of receipt of the EMA's recommendation. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

National marketing authorizations, which are issued by the national competent authorities of the member states of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a medicinal product has already been authorized for marketing in a member state of the EEA, this national authorization can be recognized in other member states

through the mutual recognition procedure. If the product has not received a national authorization in any member state at the time of application, it can be approved simultaneously in two or more member states through the decentralized procedure.

For the time being, under the Northern Ireland Protocol, centralized marketing authorizations continue to provide a valid basis for commercializing medicinal products in Northern Ireland. However, centralized marketing authorizations no longer provide a valid basis for the commercialization of medicinal products in Great Britain. Pursuant to the Windsor Framework, from January 1, 2025, all new medicinal products for the UK market will be authorized by the MHRA. In this regard, the MHRA will grant a single UK-wide marketing authorization for all medicinal products intended for sale in the UK, enabling medicinal products to be sold in a single pack and under a single authorization throughout the UK.

Following its departure from the EU, the UK has introduced changes to its national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, ILAP (described above) and new routes of evaluation for novel products and biotechnological products. Notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, and that EU marketing authorizations do not automatically provide a valid basis for the commercialization of medicinal products in Great Britain from January 1, 2024, applicants will be able to request the MHRA to recognize marketing authorizations granted in foreign jurisdictions (including the EU) under a new International Recognition Procedure.

Regulatory Data Protection in Europe

In the EU and the UK, new chemical entities (including both small molecules and biological medicinal products) and new biological substances approved on the basis of a complete independent data package consisting of quality, preclinical testing results and clinical trial data qualify for eight years of RDP upon grant of a marketing authorization and two years of marketing protection. Data protection prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the MAA dossier of the reference medicinal product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. During the two-year period of marketing protection, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. Even if a generic or biosimilar medicinal product is approved, it cannot be marketed until the expiration of the marketing protection. The ten-year protection period can be extended to a maximum of eleven 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 authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical or a new biological entity so that the innovator gains the prescribed period of data protection, another company may market another version of the medicinal product if such company obtained marketing authorization based on an MAA with a complete and independent data package consisting of pharmaceutical and preclinical testing results and clinical trial data.

Patent Term Extensions in the EU and Other Jurisdictions

The EU also provides for patent term extension through SPCs which aim to offset the loss of patent protection for pharmaceutical products arising from the lengthy testing and clinical trials required to obtain an MA. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a basic patent for up to five years after its originally scheduled expiration date in order to provide up to a maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains an MA for it to be placed on the market. As mentioned above, in certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained; and in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. Although SPCs are available throughout the EU, holders must apply the patent term extension on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the EU.

Orphan Drug Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a medicinal product can be designated as an orphan medicinal product by the European Commission, upon satisfactory scientific

assessment by the EMA's Committee for Orphan Medicinal Products ("COMP"), if the sponsor can establish: (1) that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, where either (i) such condition affects not more than five in ten thousand persons in the EU when the application is made, or (ii) without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment in its development, and (2) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition. In the UK, the MHRA conducts an equivalent assessment, against criteria which have been tailored for the UK population.

The COMP is required to re-assess the granted orphan designation at the time of marketing authorization grant to ensure that it continues to meet the criteria for the designation to be maintained. Otherwise, the orphan designation can be revoked. In relation to the UK, the MHRA does not grant orphan designations during the development of the medicinal product. Instead, the MHRA will decide whether the criteria are satisfied at the point of marketing authorization grant. An orphan drug designation provides a number of benefits, including fee reductions, fee waivers, protocol assistance (as a type of scientific advice specific for orphan medicinal products) and the possibility to apply for a centralized EU marketing authorization. Marketing authorization for an orphan medicinal product benefits from a ten-year period of market exclusivity. During this period of market exclusivity, the European Commission, national competent authorities of the EU member states may only grant marketing authorization to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its medicinal product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product. 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 period of marketing protection for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Following the UK's exit from the EU, the MHRA continues to apply the same orphan market exclusivity framework as the EU.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed indefinitely after five years on the basis of a reevaluation of the risk-benefit balance by the EMA, the competent authority of the authorizing member state, or the MHRA. To that end, the marketing authorization holder must provide the EMA, the relevant national competent authority, or the MHRA with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization expiry date. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission, the relevant national competent authority, or the MHRA decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any marketing authorization ceases to be valid if it is not followed by the placement of the medicinal product on the EU market (in the case of the centralized procedure), on the market of the authorizing member state (in the case of a national procedure), or the UK market (as applicable), within three years after grant of such an authorization.

Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product, and must adhere in strict compliance with the applicable EU laws, regulations and guidance. These include compliance with stringent pharmacovigilance rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, manufacture and control must also be conducted in strict compliance with cGMP requirements and comparable requirements of other regulatory bodies in the EU and UK. cGMP requirements apply to the methods, facilities and controls used in

manufacturing, processing and packing of drugs against the quality standards appropriate to the intended use of a medicinal product and as required by the marketing authorization, clinical trial authorization or product specification.

Much like the federal healthcare program anti-kickback law in the United States, 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 also prohibited in the EU and the UK. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU member states and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. Applicable law in Europe further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

Pursuant to national laws, industry codes or professional codes of conduct payments made to physicians in certain EU member states and the UK 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, or the UK (as applicable). Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU and the UK. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, which was transposed into national law in the UK via the Human Medicines Regulations 2012, the details are governed by regulations in each European jurisdiction and can differ from one country to another.

General Data Protection Regulation

The processing of personal data regarding individuals in the EU, including personal health data, is regulated by Regulation (EU) 2016/679, which took effect on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require us to change our business practices to ensure full compliance.

As of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. 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 authorities or programs, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

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. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the drug product, or will provide coverage at an adequate reimbursement rate. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval from one or more third party payors, less favorable coverage policies and reimbursement rates may be implemented in the future. Additionally, if a companion diagnostic test is developed for use with a drug product, any coverage and reimbursement for that test would be separate and apart from the coverage and reimbursement sought for such product. A lack of coverage or adequate reimbursement for such a test could adversely affect access to a drug product.

Within the U.S., third-party payors are increasingly seeking to control drug costs by examining the cost-effectiveness of new products and services in addition to their safety and efficacy; managing drug utilization and challenging the price of drugs. To obtain or maintain coverage and reimbursement for any future product, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. Third-party payors may limit coverage of product by, for example, only covering specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Some third-party payors may manage utilization of a particular product by requiring pre-approval (known as "prior authorization") for coverage of particular prescriptions (to allow the payor to assess medical necessity) or otherwise restricting coverage of a product even if used consistent with its approved indication. Manufacturers of marketed drugs may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. More generally, price concessions may need to be offered to third party payors to obtain favorable coverage or to purchasers to achieve sales. Arrangements with third party payors or purchasers may include value-based arrangements under which the amount paid for products depends on the performance of the product. Net prices for drugs may be further 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.

In addition, 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 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 medicinal 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

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for therapies

addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our product candidates profitably if and when approved for marketing. In particular, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. More generally, the ACA expanded healthcare coverage through Medicaid expansion and the implementation of the "individual mandate" for health insurance coverage.

Beyond the ACA, there have been ongoing healthcare reform efforts. Drug pricing and payment reform was a focus of the Trump administration and has been a focus of the Biden administration. For example, federal legislation enacted in 2021 eliminates the statutory cap on Medicaid drug rebate program rebates (currently set at 100% of a drug's "average manufacturer price"), effective January 1, 2024. As another example, the IRA, includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with the first list of drugs announced in 2023). The IRA changes have varying implementation dates that start in 2022. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. The focus on healthcare reform, including reform of drug pricing and payment, has continued in the wake of the IRA. For example, in 2022, subsequent to the enactment of the IRA, the Biden administration released an executive order directing the HHS to report on how the Center for Medicare and Medicaid Innovation ("CMMI") could be leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. The report was issued in 2023 and proposed various models that CMMI is currently developing which seek to lower the cost of drugs, promote accessibility and improve quality of care. Further, in December 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act (which allow the government, in specified circumstances, to grant or require a patent-holder of technology funded by the federal government to grant a license to certain third parties). The announcement was followed by publication of Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, given these actions, there can be no certainty that such rights will not be exercised in the future.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the

United States or Canada. Other states have also submitted Section 804 Importation Program ("SIP") proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 that remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results.

Other Healthcare Laws

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 that may constrain how we conduct our business, including the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Restrictions under applicable federal and state healthcare laws and regulations, some of which will apply only if and when we receive marketing approval for a product candidate, include the following:

- federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims, false statements and civil monetary penalties laws which prohibit, among other activities, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid and may be implicated if claims are submitted that result from a violation of the federal anti-kickback statute;
- HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician practitioners and teaching hospitals to the federal government for re-disclosure to the public;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and

- analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws 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 healthcare providers or marketing expenditures. Other state laws may require pharmaceutical companies to file reports relating to pricing and marketing information, and state and local laws may require registration of pharmaceutical sales representatives.

Efforts to ensure that our business arrangements with third parties 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 significant civil and criminal penalties, damages, fines, exclusion from participation in government healthcare 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.

Facilities

Our corporate headquarters is located in Waltham, Massachusetts, where we lease and occupy 11,971 square feet of office space. Our Waltham lease has a lease term of 3.3 years with total fixed payments of approximately $1.8 million over that period. The current term of our Waltham lease expires on June 30, 2025. We will seek to find new office space to occupy upon the expiration of our Waltham lease.

On June 28, 2022, we also entered into a lease agreement for 5,127 square feet of office space in Shanghai, PRC. Our Shanghai lease has a term of 3.0 years with total fixed payments of $0.8 million over that period. The current term of our Shanghai lease expires on September 9, 2025. Our Shanghai lease also includes an option to extend the term with at least six months' notice and rent set at an agreed upon market rate.

To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Employees and Human Capital Resources

As of June 30, 2024, we had 114 full-time employees, consisting of clinical, scientific, development, technical operations, regulatory, finance, legal and operational personnel. None of our employees is represented by labor unions or subject to a collective bargaining agreement. Our employees in China are subject to employment contracts which contain customary notice periods. We consider our relationship with our employees to be good.

Of our 114 full-time employees as of June 30, 2024, 14 were located in China and consisted of clinical, technical operations, regulatory, finance and human resources personnel. Our China-based employees support clinical operations and regulatory matters related to ZB001 and obexelimab in China and technical operations, with all functions in China reporting to management in the U.S. We recognize that our continued ability to attract, retain, and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- **Talent development, compensation, and retention**: Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and future employees. Our compensation program is designed to retain, motivate and attract highly qualified employees. Accordingly, we use a mix of competitive base salary, cash-based annual incentive compensation, performance-based equity compensation awards and other employee benefits.
- **Health and safety**: We value the health and safety of our employees and provide comprehensive insurance benefits, an employee assistance program, paid holidays, a personal time-off program, and other benefits which are intended to assist employees to manage their well-being.

- **Inclusion and diversity**: We are committed to efforts to increase diversity and foster an inclusive professional environment that supports our workforce.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings incidental to our business. We are not currently a party to any litigation or legal proceedings. Regardless of outcome, litigation can have an adverse impact on our reputation, financial condition and business, including by utilizing our resources and potentially diverting the attention of our management from the operation of our business.

MANAGEMENT

Executive Officers and Directors

Our executive officers and directors, their ages as of June 30, 2024, and their positions, are set forth in the following table:

Name	Age	Position(s)
Executive Officers and Employee Directors:		
Leon O. Moulder, Jr.	66	Chief Executive Officer and Chairman of the Board of Directors
Joseph Farmer	52	President and Chief Operating Officer
Jennifer Fox	53	Chief Business Officer and Chief Financial Officer
Orlando Oliveira	48	Chief Commercial Officer
Non-Employee Directors:		
Patricia Allen	62	Director
James Boylan	57	Director
Patrick Enright	62	Director
Tomas Kiselak	38	Director
Hongbo Lu, Ph.D.	53	Director
Jake Nunn	54	Director
John Orloff, M.D.	67	Director
Ting (Tim) Xiao	37	Director

Executive Officers and Employee Director

Leon O. Moulder, Jr., is our Founder, has served as our Chief Executive Officer since August 2023, and as our Chairman and a member of our board of directors since 2020. He has also been the Managing Member of Tellus BioVentures, LLC ("Tellus"), an early-stage life sciences investment fund, since March 2019. Prior to establishing Tellus, he cofounded TESARO, a fully-integrated Boston-based oncology-focused biopharmaceutical company ("TESARO"), and served as Chief Executive Officer and director from March 2010 until its acquisition by GlaxoSmithKline in January 2019. Mr. Moulder previously served as President, Chief Executive Officer and Vice Chairman of Abraxis BioScience Inc. ("Abraxis") from 2009 to 2010. Prior to Abraxis, he served as Vice Chairman of Eisai Corporation of North America following Eisai's acquisition of MGI PHARMA, where he served as President and Chief Executive Officer. This followed him serving as a member of the founding management team of Eligix Inc., a venture-stage biotech company. Mr. Moulder began his career as a clinical pharmacist followed by a 17-year career at predecessor companies of Sanofi S.A. (Nasdaq: SNY), beginning with Marion Laboratories Inc. Mr. Moulder is a Temple University Trustee and Chair of Temple University Japan. He is a Council Member for both the University of Chicago Booth School of Business and the Polsky Center for Entrepreneurship and Innovation. Mr. Moulder serves on the board of directors of Zai Lab Ltd. (Nasdaq: ZLAB) ("Zai Lab"), Helsinn Group and Trevena Inc. (Nasdaq: TRVN) and for several Tellus portfolio companies, including Dianthus (Nasdaq: DNTH). Mr. Moulder received a Pharmacy degree from Temple University and an M.B.A. from The University of Chicago Booth School of Business. We believe Mr. Moulder is qualified to serve as a director of the Company because of his extensive experience serving on other public company boards, investing in life sciences companies, and management experience at public biopharmaceutical companies.

Joseph Farmer, has served as our President and Chief Operating Officer since February 2022, and served as our Chief Business and Administrative Officer from April 2021 to February 2022. Mr. Farmer is an experienced biopharma executive with over 25 years of transactional and operational experience working with emerging biotechnology companies at all stages of development, from discovery through commercialization. Prior to joining Zenas, he served as Chief Operating Officer at Xilio Therapeutics, Inc. (Nasdaq: XLO), an immuno-oncology company, where he led the general and administrative, business

development, and business operations functions from May 2019 until March 2021. Prior to Xilio Therapeutics, he was the General Counsel and Corporate Secretary at TESARO, where he led the global legal, compliance and government affairs functions and was a key member of the leadership team from 2015 through its acquisition by GlaxoSmithKline in January 2019. He previously served as Chief Corporate Counsel at Cubist Pharmaceuticals Inc., from 2012 through its acquisition by Merck & Co. in 2015 and as General Counsel at two publicly traded companies, including AMAG Pharmaceuticals Inc., where he was also the Chief Administrative Officer. He began his career as a corporate attorney at Testa, Hurwitz & Thibeault, LLP. Mr. Farmer received his J.D. from Boston College Law School and his B.A. in economics from Boston University.

Jennifer Fox, has served as our Chief Business Officer and Chief Financial Officer since December 2023. Previously, Ms. Fox served as Chief Financial Officer at Nuvation Bio, Inc. (NYSE: NUVB), an oncology-focused biopharmaceutical company, from October 2020 until December 2023. Prior to this role, Ms. Fox served as Managing Director, Co-Head of North America Healthcare Corporate and Investment Banking Group at Citigroup from June 2015 to October 2020. From February 2006 to June 2015, Ms. Fox served as Managing Director at Deutsche Bank, and most recently also as Co-Head of Life Sciences Investment Banking Group. Prior to that, Ms. Fox served as Senior Managing Director Healthcare Investment Banking at Bear Stearns, Vice President Healthcare Investment Banking at Bank of America and Financial Analyst, Investment Banking Analyst, Associate, Vice President, Health Care Investment Banking at Prudential Vector Healthcare Group and Prudential Securities Incorporated. Ms. Fox serves on the board of directors for Apogee Therapeutics (Nasdaq: APGE), ProKidney Corp. (Nasdaq: PROK) and Life Science Cares. She has more than 25 years of experience in healthcare investment banking and has been a lead adviser to life science companies on over 125 financing and strategic transactions. Ms. Fox received B.S. degrees in Finance and Marketing from Manhattan College.

Orlando Oliveira, has served as our Chief Commercial Officer since July 2024. Prior to joining Zenas, Mr. Oliveira served as Senior Vice President, Head of International at Mirati Therapeutics (acquired by Bristol Meyers Squibb) from March 2022 to April 2024. From August 2019 to June 2021, he served as Senior Vice President, Head of International at Agios Pharmaceuticals and as Senior Vice President & General Manager of International at TESARO from August 2015 to July 2019. Mr. Oliveira has served as a member of the board of directors at OncoInvent AS, a privately held clinical-stage radiopharmaceutical company since April 2024. Mr. Oliveira received his B.S. degree in pharmaceutical studies from the Universidade de Coimbra (Portugal) and completed a post-graduate degree in Medical Marketing Management at the Instituto Universitário de Lisboa and a post-graduate degree in Cancer Biology at the University of Birmingham. He also received a Master's in Pharmaceutical Sciences and a post-graduate degree in Drug and Pharmacy Law from Universidade de Coimbra (Portugal).

Non-Employee Directors

Patricia Allen, has been a member of our board of directors since February 2024 and serves as the chair of our Audit Committee. Ms. Allen served as the Chief Financial Officer of Vividion Therapeutics, Inc., a wholly-owned and independently operated subsidiary of Bayer, from March 2021 until January 2024. From January 2013 to May 2020, Ms. Allen served as Chief Financial Officer of Zafgen, Inc., now Larimar Therapeutics Inc. Previously, from 2004 to 2011, Ms. Allen served as the Vice President of Finance, Treasurer, and Principal Financial Officer of Alnylam Pharmaceuticals, Inc., a publicly traded biotechnology company. Prior to Alnylam, Ms. Allen was at Alkermes, Inc., a publicly traded biotechnology company, most recently as the Director of Finance. She serves on the board of directors of Deciphera Pharmaceuticals, Inc. (Nasdaq: DCPH) since September 2016, and Yumanity Therapeutics, Inc., a publicly traded biotechnology company, from August 2019 until the completion of its merger in December 2022. Ms. Allen began her career as an auditor at Deloitte & Touche, LLP. Ms. Allen graduated summa cum laude from Bryant College with a B.S. in business administration. We believe that Ms. Allen is qualified to serve on our Board of Directors based on her experience in the biopharmaceutical industry, as well as her expertise in finance and accounting.

James Boylan, has served as a member of our board of directors since November 2022. Mr. Boylan has served as Chief Executive Officer of Enavate Sciences Inc., a portfolio company of Patient Square Capital, since May 2022. Previously, Mr. Boylan served as President and Head of Investment Banking of SVB Leerink, where he architected and led the transformation of Leerink Swann into an industry-leading healthcare

investment bank that was acquired by SVB Financial Group in 2019. Across his 12 years at SVB Leerink and prior 12 years as a Managing Director at Merrill Lynch, Mr. Boylan has worked with hundreds of life sciences and biotechnology companies to develop strategy and complete transactions in capital markets and mergers & acquisitions. Mr. Boylan also serves on the board of directors of CAMP4 Therapeutics Corp., Compass Therapeutics, Inc., and Immunome, Inc. Mr. Boylan earned an M.B.A. in finance from the Columbia Business School and a B.S. in finance from Lehigh University. We believe Mr. Boylan is qualified to serve as a director of the Company because of his extensive experience in the financial industry and in the life science and biotechnology space.

Patrick Enright, has served as a member of our board of directors since November 2022. Mr. Enright co-founded Longitude Capital Management Co., LLC ("Longitude Capital"), a healthcare venture capital firm, where he has served as Managing Director since 2006. Mr. Enright also has significant life sciences operations experience including serving on various senior executive positions at Valentis Inc., Boehringer Mannheim Pharmaceuticals Corp. (acquired by Roche) and Sandoz Inc. (now known as Novartis). Mr. Enright currently serves on the board of directors of Jazz Pharmaceuticals plc (Nasdaq: JAZZ), Vera Therapeutics, Inc. (Nasdaq: VERA), and numerous privately held healthcare companies. Previously, Mr. Enright was a Managing Director of Pequot Ventures, where he co-led the life sciences investment practice. Mr. Enright previously served on the boards of directors of over twenty companies, including Aimmune Therapeutics, Inc. from 2013 until its acquisition by Nestlé in 2020, Corcept Therapeutics Inc. from 2008 to 2017 and Vaxcyte, Inc. from 2015 to 2020. Mr. Enright received a B.S. in Biological Sciences from Stanford University and an M.B.A. from the Wharton School of the University of Pennsylvania. We believe Mr. Enright is qualified to serve as a director of the Company because of his experience serving on the board of directors of numerous biotechnology companies and his investment experience in the life sciences industry.

Tomas Kiselak, has served as a member of our board of directors since September 2020. He is a Managing Member at Fairmount Funds Management LLC, a healthcare investment firm he co-founded in April 2016. Prior to Fairmount, Mr. Kiselak was a managing director at RA Capital Management, LLC. Mr. Kiselak currently serves as the chairman of the board of directors of Viridian Therapeutics, Inc., and is a director for Apogee Therapeutics, Inc., Dianthus Therapeutics, Inc., Spyre Therapeutics, Inc., and several private companies. He received a B.S. in neuroscience and economics from Amherst College. We believe Mr. Kiselak is qualified to serve as a director of the Company because of his extensive healthcare and life sciences investment experience and his experience serving on the board of directors of numerous biotechnology companies.

Hongbo Lu, Ph.D., has served as a member of our board of directors since November 2022. Dr. Lu is the Managing Member of NEXTBio Capital, a newly launched biotech investment firm. Dr. Lu. has also served as a Senior Advisor of Vivo Capital LLC ("Vivo Capital"), a Palo Alto-based investment firm, since February 2024. Dr. Lu was previously a Managing Partner from December 2020 until February 2024. Prior to joining Vivo Capital, Dr. Lu served as a Managing Partner at Lilly Asia Ventures from January 2017 until December 2020 ("LAV"). Prior to her role at LAV, she was affiliated with OrbiMed Advisors from June 2011 until October 2016, lastly as its Managing Director. Dr. Lu previously served on the boards of directors of public companies including Turning Point Therapeutics, Inc. (TPTX, acquired by Bristol-Myers Squibb), Crown Bioscience Inc. (6554.TT, acquired by JSR), Avedro Inc. (AVDR, acquired by Glaukos). She currently serves on the boards of Arrowhead Pharmaceuticals (Nasdaq: ARWR, since March 2024) and Terns Pharmaceuticals Inc. (Nasdaq: TERN, since April 2020). Dr. Lu started her Wall Street career as a biotech analyst at Piper Jaffray & Co. and was involved in biotech start-up Zyomyx in the San Francisco Bay Area previously. Dr. Lu earned a Ph.D. in Bioengineering from the University of Washington, an M.B.A. from the Haas School of Business at the University of California, Berkeley, and graduated with honors from Tsinghua University. We believe Dr. Lu is qualified to serve as a director of the Company because of her experience serving on the board of directors of public and private biopharmaceutical companies and her experience in venture capital and the life sciences industry.

Jake Nunn, has served as a member of our board of directors since May 2024. Mr. Nunn has served as a Partner at SR One Capital Management, LP ("SR One") since October 2022. Prior to joining SR One, Mr. Nunn was a venture advisor at New Enterprise Associates, Inc., where he served as a partner from June 2006 until January 2019. Before this, he served as a partner and an analyst for the MPM BioEquities Fund, a life sciences fund at MPM Capital, L.P., a private equity firm from January 2001 to June 2006. Previously, he

was a healthcare research analyst and portfolio manager at Franklin Templeton Investments and an investment banker with Alex. Brown & Sons. Mr. Nunn currently serves on the board of directors of several public companies, including Regulus Therapeutics Inc., (Nasdaq: RGLS, since June 2019), Addex Therapeutics Ltd. (Nasdaq: ADXN, since June 2018) and Trevena, Inc. (Nasdaq: TRVN, since July 2013). Previously, Mr. Nunn served on the board of directors of Dermira, Inc., from May 2011 until its acquisition by Eli Lilly and Company in February 2020, Hyperion Therapeutics, Inc. until its acquisition by Horizon Pharma plc, Hexima Limited (ASX: HXL), and Oventus Medical Ltd. (ASX: OVN). Mr. Nunn received his A.B. in economics from Dartmouth College and his M.B.A. from the Stanford Graduate School of Business. He also holds the Chartered Financial Analyst designation and is a member of the CFA Society of San Francisco. We believe Mr. Nunn is qualified to serve as a director of the Company because of his experience serving on the board of directors of numerous biotechnology companies and his investment experience in the life sciences industry.

John Orloff, M.D., has served as a member of our board of directors since January 2022. Dr. Orloff has been a Venture Partner at Agent Capital LLC ("Agent Capital"), a healthcare venture capital firm, since October 2021. Prior to Agent Capital, Dr. Orloff served as Executive Vice President and Global Head of Research and Development for Alexion Pharmaceuticals Inc. from June 2017 until July 2021. Dr. Orloff also served as Global Head of Research and Development and Chief Scientific Officer at Baxalta Inc. from July 2015 until July 2016, and has held executive leadership roles with Novelion Therapeutics Inc., Baxter BioScience, Merck Serono, Novartis AG and Merck Research Laboratories. Dr. Orloff currently serves on the board of directors of publicly-traded BenevolentAI Ltd. (AMS: BAI). Prior to his work in the pharmaceutical industry, Dr. Orloff was a faculty member at the Yale University School of Medicine from 1990 until 1997. Dr. Orloff holds an undergraduate degree in chemistry from Dartmouth College and earned his M.D. from the University of Vermont, College of Medicine. Dr. Orloff also completed a fellowship in endocrinology and metabolism at Yale University School of Medicine. We believe Dr. Orloff is qualified to serve as a director of the Company because of his extensive experience in the pharmaceutical industry.

Ting (Tim) Xiao, has served as a member of our board of directors since May 2024. Mr. Xiao is currently a partner and founding team member at Delos Capital ("Delos") since its inception in 2015. Mr. Xiao also serves as the part-time, interim Chief Executive Officer of Odeon Therapeutics (Cayman) Limited (''Odeon''). Prior to Delos and Odeon, Mr. Xiao was a Senior Associate in the Investment Banking Division of Goldman Sachs from December 2010 until December 2014. Mr. Xiao began his career as an investment banker at China International Capital from July 2008 until December 2010. Mr. Xiao serves as a board member for Eccogene, Curatia Medical, Inc., STRM.Bio, Inc., OncoMyx Therapeutics, Inc. and as a board observer for Allecra Therapeutics, Atia Vision, Inc. and Rgenta Therapeutics. Mr. Xiao was previously a board member for Luqa Pharmaceuticals (acquired by China Medical System) and Clover Biopharmaceuticals (HKEx:2197). Mr. Xiao received his M.S. in Biotechnology from the Johns Hopkins University and his B.S. in Economics from Shanghai Jiao Tong University. He is also a CFA charterholder. We believe Mr. Xiao is qualified to serve as a director of the Company because of his investment experience in the life sciences industry.

Family Relationships

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

Composition of Our Board of Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of nine members with no vacancies. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors consists of nine members, each of whom was elected as a director pursuant to the board composition provisions of our Fourth Amended and Restated Shareholders Agreement (the "Shareholders Agreement") among us and our stockholders. The board appointment provisions of the Shareholders Agreement will terminate upon the completion of this offering, at which point no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Shareholders Agreement will continue to serve as directors until a successor is duly elected and qualified, or until his or her earlier resignation or removal.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our Restated Charter to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Dr. Lu and Messrs. Moulder and Xiao, and their terms will expire at the annual meeting of stockholders to be held in 2025;
- the Class II directors will be Messrs. Boylan, Enright and Kiselak, and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- the Class III directors will be Ms. Allen, Mr. Nunn and Dr. Orloff, and their terms will expire at the annual meeting of stockholders to be held in 2027.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the rules of the Nasdaq Stock Market require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent and that director nominees be selected or recommended for the board's selection by independent directors constituting a majority of the independent directors or by a nominating and corporate governance committee comprised solely of independent directors. Under the rules of the Nasdaq Stock Market, a director will only qualify as "independent" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that such person is "independent" as defined under the rules of the Nasdaq Stock Market and the rules under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Leon O. Moulder, Jr., is an "independent director" as defined under applicable rules of the Nasdaq Stock Market, including, in the case of Ms. Allen and Mr. Enright, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act and are "non-employee directors" as defined in Section 16b-3 of the Exchange Act. Our board of directors has determined that Mr. Moulder, by virtue of his position as our chief executive officer, is not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Person Transactions."

Committees of Our Board of Directors

Our board of directors will establish an audit committee, a compensation committee and a nominating and corporate governance committee prior to the listing of our common stock on the Nasdaq Global Select Market. The composition and responsibilities of each of the committees of our board of directors are

described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee will operate pursuant to a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at www.zenasbio.com prior to the listing of our common stock on the Nasdaq Global Select Market upon the completion of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Audit Committee

Our audit committee will operate under a written charter, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq Listing Rules.

The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance, procedures and 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 written periodic reports from such firm;
- pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- overseeing and periodically reviewing with our independent registered public accounting firm our compliance with all applicable requirements of the Public Company Accounting Oversight Board;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations and the steps taken to deal with such issues;
- reviewing disclosures about any significant deficiencies or material weaknesses in our internal control structures and procedures, including disclosures in our annual and quarterly reports;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding cybersecurity risks and processes for assessing, identifying and managing material risks from cybersecurity threats;
- discussing our risk management policies with management;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and approving any related person transactions;
- overseeing our guidelines and policies governing risk assessment and risk management;
- overseeing and periodically reviewing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

The members of our audit committee will be Ms. Allen and Messrs. Boylan and Enright. Ms. Allen will chair the audit committee. Our board of directors has determined that each member of our audit committee has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has also determined that Ms. Allen is an "audit committee financial expert," as defined under Item 407 of Regulation S-K.

We expect to satisfy the member independence requirements for the audit committee prior to the end of the transition period provided under the rules of the Nasdaq Stock Market and SEC rules and regulations for companies completing their initial public offering.

Compensation Committee

Our compensation committee will operate under a written charter, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq Listing Rules.

Our compensation committee's responsibilities upon completion of this offering will include:

- reviewing and establishing our overall management compensation strategy and benefits philosophy and policies, including base salary, incentive compensation and equity-based grants;
- reviewing and approving performance goals and objectives relevant to compensation of our chief executive officer and other executive officers;
- evaluating the performance of the chief executive officer and executive officers in light of their performance goals and objectives, including during executive sessions of non-employee directors, and recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors with respect to non-employee director compensation;
- reviewing, overseeing and administering our equity incentive plans, granting awards under such plan and making recommendations to the board of directors about the adoption of any new or modifying existing equity-based, cash-based, management incentive and deferred compensation plans;
- establishing and reviewing "clawback" policies that allow the recouping of incentive compensation;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and non-employee directors;
- recommending to our board of directors any stock ownership guidelines for our executive officers and non-employee directors, periodically assessing these guidelines and recommending revisions as appropriate, and monitoring individual compliance with these guidelines;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor and determining the compensation and independence of such consultant or advisor;
- preparing, if required, the compensation committee report on executive compensation for inclusion in our annual report on Form 10-K and our proxy statement in accordance with SEC rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- reviewing and approving all employment contract and other compensation, severance and change-in-control arrangements for our executive officers;
- establishing and periodically reviewing policies and procedures with respect to perquisites as they relate to our executive officers;

- reviewing the risks associated with our compensation policies and practices;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions based on guidelines developed and recommended to the compensation committee to the full board of directors;
- reviewing our strategies, initiatives and programs with respect to our culture, talent recruitment, development, and retention, employee engagement and diversity and inclusion;
- maintaining minutes of the compensation committee and reporting its actions and any recommendations to the board of directors on a periodic basis;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee will be Dr. Orloff and Messrs. Boylan and Enright. Dr. Orloff will chair the compensation committee. Our board of directors has determined that each member of the compensation committee satisfies the independence standards of the applicable rules of the Nasdaq Stock Market and the SEC.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will operate under a written charter, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that satisfies the applicable Nasdaq Listing Rules.

Our nominating and corporate governance committee's responsibilities upon completion of this offering will include:

- actively seeking and identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing a policy under which our stockholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- reviewing and recommending committee slates on an annual basis;
- recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principles applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board size, composition, leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility, including but not limited to sustainability, diversity and inclusion and environmental, social and governance initiatives;
- making recommendations to our board of directors of processes for annual evaluations of the performance of our board of directors and committees of our board of directors;
- overseeing the process for annual evaluations of our board of directors and committees of our board of directors;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- reviewing with management the company's social corporate responsibility activities, policies, and program;

- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions in the Company;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee will be Messrs. Nunn and Kiselak and Dr. Lu. Mr. Nunn will chair the nominating and corporate governance committee. Our board of directors has determined that each member of the nominating and corporate governance committee satisfies the independence standards of the applicable rules of the Nasdaq Stock Market.

Our board of directors may establish other committees from time to time.

Role of the Board of Directors in Risk Oversight

Our board of directors has, and, upon the completion of this offering, its committees will also have, an active role in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee will be responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and governance committee will be responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee will be responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors will be regularly informed through discussions from committee members about such risks.

Code of Business Conduct and Ethics

In connection with this offering, we adopted a written Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics will be posted on our website at www.zenasbio.com upon the completion of this offering. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our executive officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

EXECUTIVE AND DIRECTOR COMPENSATION

The following discussion of compensation arrangements should be read with the compensation tables and related disclosures set forth below. 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 following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

Our named executive officers for the year ended December 31, 2023, which consist of all individuals serving as our principal executive officers during 2023 and our three most highly compensated executive officers other than individuals who served as the principal executive officer during 2023, were:

- Leon O. Moulder, Jr., Founder, Chief Executive Officer and Chairman;
- Hua Mu, M.D., Ph.D., former Chief Executive Officer and former Interim Chief Medical Officer and former Head of China;
- Joseph Farmer, President and Chief Operating Officer;
- Jennifer Fox, Chief Business Officer and Chief Financial Officer; and
- Tanya Z. Fischer, M.D., Ph.D., former Head of Research and Development and Chief Medical Officer.

Effective June 29, 2023, Dr. Mu transitioned from the role of Chief Executive Officer to Head of China and Interim Chief Medical Officer, and Mr. Moulder became the Chief Executive Officer. Effective October 30, 2023, Dr. Fischer became the Head of Research and Development and took over for Dr. Mu as Chief Medical Officer. On August 20, 2024, Dr. Fischer decided to separate from the Company effective December 31, 2024, and in the interim serve as the Executive Research & Development Advisor to the Chief Executive Officer. Although Mr. Farmer is not a named executive officer for 2023, we are including his compensation information, as he is one of our key executive officers and this prospectus is the first disclosure of the compensation of our executive officers. We anticipate disclosing only the two most highly compensated executive officers, along with the principal executive officer, for future proxy disclosures of executive compensation as required under Item 402 of Regulation S-K under the Securities Act, so long as we remain an "emerging growth company" or "smaller reporting company."

Summary Compensation Table

The following table presents the compensation awarded to or earned by or paid to our named executive officers and Mr. Farmer during the year ended December 31, 2023.

Name and Principal Position	Fiscal Year	Salary ($)[1]	Bonus ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)	Total ($)
Leon O. Moulder, Jr. *Founder, Chief Executive Officer and Chairman*	2023	126,923[4]	—	2,474,587	—	—	2,601,510
Hua Mu, M.D., Ph.D. *Former Chief Executive Officer*	2023	589,950[5]	—	—	—	667,097[10]	1,257,047
Joseph Farmer *President and Chief Operating Officer*	2023	471,458	—	625,017	197,508	—	1,293,983
Jennifer Fox *Chief Business Officer and Chief Financial Officer*	2023	40,064[6]	450,000[8]	2,076,544	—	—	2,566,608
Tanya Z. Fischer, M.D., Ph.D. *Former Head of Research and Development and Chief Medical Officer*	2023	78,462[7]	254,080[9]	1,389,262	—	—	1,721,804

(1) The amounts shown include amounts that our named executive officers and Mr. Farmer earned and deferred into our retirement plan, described below under "Executive Compensation Arrangements—Retirement Plan and Other Benefits."

(2) The amounts shown in this column represent the grant date fair value of options to purchase our common stock granted to Mr. Moulder, Mr. Farmer, Ms. Fox and Dr. Fischer in fiscal year 2023, computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 12 to our consolidated financial statements included elsewhere in this prospectus.

(3) The amount shown in this column is the full annual bonus amount payable in respect of fiscal year 2023 to Mr. Farmer. Our board of directors has the discretion to determine Mr. Moulder's earned bonus for each fiscal year in which he remains eligible to participate in the Annual Bonus Plan. For fiscal year 2023, Mr. Moulder waived his bonus in advance of a meeting of the board of directors in which his annual bonus would have been discussed and determined. Our annual bonus program is described below under "Narrative to the Summary Compensation Table—Annual Performance Bonus Opportunity."

(4) Mr. Moulder commenced employment with the Company on June 29, 2023 with an annual base salary of $250,000. The reported amount reflects his prorated base salary for fiscal year 2023.

(5) The Company paid Dr. Mu at a rate based on his annual base salary of $589,950 through June 28, 2023, and then from his transition date of June 29, 2023 we paid him a base salary of $49,163 per month through his separation date of December 31, 2023.

(6) Ms. Fox commenced employment with the Company on December 4, 2023 with an annual base salary of $500,000. The reported amount reflects her prorated base salary for fiscal year 2023.

(7) Dr. Fischer commenced employment with the Company on October 30, 2023 with an annual base salary of $450,000. The reported amount reflects her prorated base salary for fiscal year 2023.

(8) The amounts reported in this column represent the $200,000 signing bonus paid to Ms. Fox in fiscal year 2023 in connection with the commencement of her employment in December 2023, and the $250,000 annual bonus payable to Ms. Fox in respect of fiscal year 2023, the full target bonus amount for the year, as was negotiated as part of Ms. Fox's employment agreement. If Ms. Fox voluntarily leaves the Company within 12 months following December 4, 2023, she must repay to the Company the $200,000 signing bonus. Additionally, Ms. Fox is eligible to receive an additional $100,000 bonus in December 2024 if she is employed with the Company at that time; however, if Ms. Fox leaves the Company between 12 months and 24 months following December 4, 2023, she must repay to the Company the additional $100,000 bonus. Our annual bonus program is described below under "Narrative to the Summary Compensation Table—Annual Performance Bonus Opportunity."

(9) The amounts reported in this column represent the $100,000 signing bonus paid to Dr. Fischer in fiscal year 2023 in connection with the commencement of her employment in October 2023, and the $154,080 annual bonus payable to Dr. Fischer in respect of fiscal year 2023, with the annual bonus calculated as though she was employed for the full fiscal year, as was negotiated as part of Dr. Fischer's employment agreement. If Dr. Fischer voluntarily leaves the Company without Good Reason (as defined in her employment agreement) within 24 months following October 30, 2023, she must repay to the Company the $100,000 signing bonus subtracted by 1/24 of the value of such signing bonus for each month that she was an employee of the Company prior to the date her employment terminates. Our annual bonus program is described below under "Narrative to the Summary Compensation Table—Annual Performance Bonus Opportunity."

(10) The amount reported in this column represents the severance earned by Dr. Mu in fiscal year 2023, which consists of salary continuation, an amount equal to his full annual target bonus, and his accrued but unused vacation, and is described below under "Executive Compensation Arrangements—Transition and Separation Agreements."

Narrative to the Summary Compensation Table

Historically, our board of directors was responsible for overseeing all aspects of our executive compensation programs. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors has determined our executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors then approved the compensation of each executive officer.

Annual Base Salary

Our board of directors approves the base salaries for our executive officers, which the board of directors initially establishes through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of such executive officer's responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Our board of directors periodically reviews our executive officers' base salaries, and adjusts the base salaries from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

Annual Performance Bonus Opportunity

For 2023, our executive officers were eligible to earn an annual cash incentive bonus (the "Annual Bonus") under our Short-Term Incentive Plan (the "Short-Term Incentive Plan") based on the achievement of pre-established performance objectives that our board of directors determines at the beginning of the fiscal year. The Annual Bonuses are based on both our performance and the executive officer's individual performance

when determining the amount of the Annual Bonus paid to the executive officer. In addition, our board of directors may reduce the Annual Bonus, including to zero, if the executive officer is not in compliance with our policies, guidelines and applicable laws. The Annual Bonus target amount is based on a percentage of the executive officer's annual base salary. If the minimum Company performance objectives are not met, then no Annual Bonus payments will be made. The Annual Bonus is capped at 150% of the executive officer's target bonus, in the event that our performance objectives exceed the targeted goals. Furthermore, an executive officer must be employed at the time of the payment of the Annual Bonus in order to be eligible for and to earn the Annual Bonus.

For 2023, each of Dr. Mu, Mr. Farmer, Ms. Fox and Dr. Fischer, had a target bonus equal to 60%, 50%, 50% and 40% of their base salary, respectively. Mr. Moulder is eligible to participate in the Short-Term Incentive Plan; however, he and the Company agreed that his bonus would not be subject to the target bonus percentage in the Short-Term Incentive Plan. Instead, our board of directors has the discretion to determine his earned bonus for each fiscal year in which he remains eligible to participate in the Short-Term Incentive Plan. For fiscal year 2023, Mr. Moulder waived his bonus in advance of a meeting of the board of directors in which his annual bonus would have been discussed and determined. Because Dr. Mu's employment terminated before the date of payment, he is ineligible to receive the Annual Bonus for 2023; however, pursuant to Dr. Mu's Separation Agreement, described in more detail below under "Executive Compensation Arrangements—Transition and Separation Agreements," he is entitled to receive a payment equal to the amount of his target bonus for 2023. The terms of Ms. Fox's and Dr. Fischer's Annual Bonus were in each of their employment agreements, which were negotiated prior to their hire date. Ms. Fox's employment agreement provides that she will receive her full target bonus amount for the 2023 fiscal year. Dr. Fischer's employment agreement provides that her Annual Bonus for 2023 will be calculated as though she was employed for the full fiscal year.

The corporate performance goals the board of directors established for fiscal year 2023 related to regulatory, clinical and development goals, as well as operational objectives. In February 2024, our board of directors determined that the fiscal year 2023 corporate goals were achieved at 82% overall, and as a result, approved Annual Bonuses for Mr. Farmer and Dr. Fischer, as reflected, respectively, in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table and the "Bonus" column of the Summary Compensation Table above. Our board of directors also approved the Annual Bonus for Ms. Fox, as reflected in the "Bonus" column of the Summary Compensation Table above.

Equity-Based Incentive Awards

Our equity award program is the primary vehicle for offering long-term incentives to our executive officers. We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have used stock option grants and restricted stock awards for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees. Grants to our executive officers and other employees are made at the discretion of our board of directors and are not made at any specific time period during a year.

In July 2023, in connection with his commencement of employment, we granted Mr. Moulder an option to purchase 308,069 shares of our common stock. The option has an exercise price of $9.30 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in June 2024 on the first anniversary of the vesting commencement date and the balance vesting monthly in substantially equal installments over the following 36 months, subject to Mr. Moulder's continued service with us through each vesting date.

In July 2023, we granted Mr. Farmer an option to purchase 77,737 shares of our common stock. The option has an exercise price of $9.30 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in July 2024 on the first anniversary of the vesting commencement date and the balance vesting monthly in substantially equal instalments over the following 36 months, subject to Mr. Farmer's continued service with us through each vesting date.

In October 2023, in connection with her commencement of employment, we granted Dr. Fischer an option to purchase 172,749 shares of our common stock. The option has an exercise price of $10.51 per share

and is subject to a four-year vesting schedule, with 25% of the shares vesting in October 2024 on the first anniversary of the vesting commencement date and the balance vesting monthly in substantially equal installments over the following 36 months, subject to Ms. Fischer's continued service with us through each vesting date.

In December 2023, in connection with her commencement of employment, we granted Ms. Fox an option to purchase 230,332 shares of our common stock. The option has an exercise price of $11.90 per share and is subject to a four-year vesting schedule, with 25% of the shares vesting in December 2024 on the first anniversary of the vesting commencement date and the balance vesting monthly in substantially equal installments over the following 36 months, subject to Ms. Fox's continued service with us through each vesting date. Additionally, upon any equity financing event through December 31, 2024 (including an initial public offering), Ms. Fox is entitled to receive an additional grant of an option to purchase a certain number of shares of our common stock such that Ms. Fox maintains at least 1.5% ownership of our outstanding shares on an as-converted basis.

Outstanding Equity Awards as of December 31, 2023

The following table presents the outstanding equity awards held by each named executive officer and Mr. Farmer as of December 31, 2023.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested ($)[1]
Leon O. Moulder, Jr.	—	308,069[6]	9.30	7/17/2033	—	—
	—	—	—	—	753[10]	12,801
Hua Mu, M.D., Ph.D.	116,447[2]	—	3.48	5/19/2031	—	—
	134,054[3]	—	9.30	12/13/2032	—	—
	—	—	—	—	21,172[11]	359,924
Joseph Farmer	42,344[4]	21,172	3.48	5/19/2031	—	—
	40,308[5]	120,924	9.30	12/13/2032	—	—
		77,737[7]	9.30	7/17/2033	—	—
Jennifer Fox	—	230,332[8]	11.90	12/18/2033	—	—
Tanya Z. Fischer, M.D., Ph.D.	—	172,749[9]	10.51	10/29/2033	—	—

(1) The market value of the restricted stock awards was determined based on the initial public offering price of $17.00 per share.

(2) Represents the vested portion of an option to purchase 158,791 shares of our common stock granted on May 20, 2021, which vested as to 40% of the underlying shares on April 15, 2022, with the remaining 60% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Dr. Mu's continued service with us through each vesting date. The unvested portions of Dr. Mu's stock option grants as of December 31, 2023 were forfeited in July 2023 in connection with his transition out of the chief executive officer role and his termination of employment on December 31, 2023.

(3) Represents the vested portion of an option to purchase 536,218 shares of our common stock granted on December 14, 2022, which vested as to 25% of the underlying shares on December 14, 2023, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Dr. Mu's continued service with us through each vesting date. The unvested portions of Dr. Mu's stock option grants as of December 31, 2023 were forfeited in July 2023 in connection with his transition out of the chief executive officer role and his termination of employment on December 31, 2023.

(4) Represents the vested portion of an option to purchase 63,516 shares of our common stock granted on May 20, 2021, which vested as to 25% of the underlying shares on April 1, 2022, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Mr. Farmer's continued service with us through each vesting date.

(5) Represents the vested portion of an option to purchase 161,232 shares of our common stock granted on December 14, 2022, which vested as to 25% of the underlying shares on December 14, 2023, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Mr. Farmer's continued service with us through each vesting date.

(6) Represents an option to purchase 308,069 shares of our common stock granted on July 18, 2023, which vests as to 25% of the underlying shares on June 29, 2024, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Mr. Moulder's continued service with us through each vesting date.

(7) Represents an option to purchase 77,737 shares of our common stock granted on July 18, 2023, which vests as to 25% of the underlying shares on July 18, 2024, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Mr. Farmer's continued service with us through each vesting date.

(8) Represents an option to purchase 230,332 shares of our common stock granted on December 19, 2023, which vests as to 25% of the underlying shares on December 4, 2024, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Ms. Fox's continued service with us through each vesting date.

(9) Represents an option to purchase 172,749 shares of our common stock granted on October 30, 2023, which vests as to 25% of the underlying shares on October 30, 2024, with the remaining 75% of the underlying shares vesting monthly in substantial equal installments over the following 36 months, generally subject to Dr. Fischer's continued service with us through each vesting date.

(10) Represents the unvested portion of an award of shares subject to certain restrictions for the purchase of 4,520 shares of our common stock granted on August 21, 2020, which restrictions lapsed as to 25% of the shares on August 3, 2021, with the restrictions lapsing as to the remaining 75% of the shares in substantially equal installments over the following 36 months, generally subject to Mr. Moulder's continued service with us through each vesting date.

(11) Represents restricted stock held by Dr. Mu, which was repurchased for $0 on January 16, 2024, in accordance with the Restricted Stock Repurchase Agreement by and between Dr. Mu and the Company, dated January 1, 2024.

Except for Dr. Mu as described below under "Executive Compensation Arrangements—Transition and Separation Agreements," we did not materially modify any outstanding equity awards held by our named executive officers or Mr. Farmer in 2023.

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2024 Plan the terms of which are described below under the subsection titled "Executive Compensation Arrangements—Equity Incentive Plans—2024 Equity Incentive Plan."

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to the disclosure of executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Executive Compensation Arrangements

Employment Agreements

We entered into amended and restated employment agreements with certain of our executive officers, including our currently employed named executive officers, which will govern the terms of their employment with us. Pursuant to their amended and restated employment agreements, Messrs. Moulder and Farmer and Ms. Fox are entitled to an annual base salary of $500,000, $500,000 and $500,000, respectively. In addition, Messrs. Moulder and Farmer and Ms. Fox are each eligible to earn an annual bonus at a target amount of 50% of their annual base salaries, subject to the achievement of performance objectives determined by our board of directors for the fiscal year.

In addition, Ms. Fox's amended and restated employment agreement includes the repayment of her $200,000 signing bonus paid in fiscal year 2023 if she leaves the Company on or prior to December 4, 2024 and she is eligible to receive an additional $100,000 bonus in December 2024 if she is employed with the Company at that time; however, if Ms. Fox is paid the $100,000 bonus and leaves the Company on or prior to December 4, 2025, then she must repay to the Company the additional $100,000 bonus.

Under the terms of the amended and restated employment agreements, Messrs. Moulder and Farmer and Ms. Fox are each eligible to receive severance benefits as follows: (i) in connection with a termination of employment by the Company without cause (except in connection with death or disability) or a resignation for good reason that does not occur three months prior to, on or within 12 months following a change of control, then (a) Mr. Moulder would be eligible to receive twelve months of base salary continuation and reimbursement of Consolidated Omnibus Budget Reconciliation Act premiums ("COBRA Premium Reimbursement") for up to twelve months, and (b) each of Mr. Farmer and Ms. Fox would be eligible to

receive up to nine months of base salary continuation and nine months of COBRA Premium Reimbursement; and (ii) in connection with a termination of employment by the Company without cause (except in connection with death or disability) or a resignation for good reason that occurs three months prior to, on or within 12 months following a change of control, then (a) Mr. Moulder would be eligible to receive 18 months of base salary continuation, 18 months of COBRA Premium Reimbursement, 150% of his target bonus for the year employment terminates, and full vesting of all outstanding equity awards, and (b) each of Mr. Farmer and Ms. Fox would be eligible to receive 12 months of base salary continuation, 100% of his or her target bonus for the year employment terminates, 12 months of COBRA Premium Reimbursement and full vesting of all outstanding equity awards. The receipt of severance benefits for any of the executive officers is conditioned upon the executive officer executing a general release of claims and complying with his or her restrictive covenant obligations and returning company property. The terms "cause," "good reason," "change in control" and "disability" have the meanings set forth in the applicable employment agreement.

Each of the amended and restated employment agreements contain restrictive covenants and each of Messrs. Moulder and Farmer and Ms. Fox has agreed not to solicit our employees, independent contractors, customers, vendors, suppliers or other business partners during and for one year following his or her termination of employment, and has also agreed to a perpetual confidentiality covenant, an assignment of intellectual property covenant and a perpetual non-disparagement covenant.

Prior to this offering, we entered into an employment agreement with Dr. Fischer, which governed the terms of her employment with us. Pursuant to her employment agreement, Dr. Fischer is entitled to an annual base salary of $450,000, and is eligible to earn an annual bonus at a target amount of 40% of her annual base salary, subject to the achievement of performance objectives as our board of directors determines for the fiscal year. Upon joining us in fiscal 2023, Dr. Fischer received a one-time signing bonus of $100,000, which she is required to repay to us if she voluntarily leaves the Company without good reason on or prior to October 30, 2025. The repayment amount is calculated by subtracting by 1/24 of the value of Dr. Fischer's signing bonus for each month that she was an employee of the Company prior to the date her employment terminates.

Under the terms of Dr. Fischer's employment agreement, she is eligible to receive severance benefits as follows: (i) in connection with a termination of employment by the Company without cause (except in connection with her death or disability) that does not occur within 12 months following a change of control, then she is eligible to receive six months of base salary continuation and reimbursement of COBRA Premium Reimbursement for up to six months; and (ii) in connection with a termination of employment by the Company without cause (except in connection with her death or disability) or a resignation for good reason that occurs within 12 months following a change of control, then Dr. Fischer would be eligible to receive 12 months of base salary continuation, up to 12 months of COBRA Premium Reimbursement, 100% of her target bonus for the year employment terminates, and full vesting of all outstanding equity awards. The receipt of her severance benefits is conditioned upon Dr. Fischer executing a general release of claims, complying with her restrictive covenant obligations and returning company property. The terms "cause," "good reason," "change in control," and "disability" have the meanings set forth in the applicable employment agreement.

Dr. Fischer's employment agreement also contains restrictive covenants following her termination of employment containing a one-year non-solicitation of employees and a three-year non-disparagement of the Company or its directors, officers, stockholders, agents and/or employees. Upon her employment with the Company, Dr. Fischer also entered into a "Confidentiality and Proprietary Rights Agreement" with us regarding the confidentiality of certain information and her assignment of certain information and inventions to us.

On August 20, 2024, Dr. Fischer decided to transition from her role as the Company's Head of Research & Development and Chief Medical Officer, effective as of December 31, 2024, and in the interim serve as Executive Research & Development Advisor to the Chief Executive Officer of the Company. A description of Dr. Fischer's Transition and Separation Agreement with the Company is described under "Executive Compensation Arrangements—Transition and Separation Agreements."

Transition and Separation Agreements

In connection with Dr. Mu's transition from the role of Chief Executive Officer to Head of China and Interim Chief Medical Officer, we entered into a transition and separation agreement with him, dated June 29,

2023 (the "Mu Separation Agreement"). Dr. Mu stepped down as our Chief Executive Officer effective as of June 28, 2023, and transitioned to Head of China and Interim Chief Medical Officer on June 29, 2023 (the "MuTransition Date") through his separation date of December 31, 2023 (the "Mu Separation Date"), which period of time from the Mu Transition Date through the Mu Separation Date is referred to as the "Mu Transition Period". Pursuant to the terms of the Mu Separation Agreement, Dr. Mu received a base salary of $49,163 per month during the Mu Transition Period. Additionally, Dr. Mu received payment for accrued but unused vacation up to the Mu Separation Date. Dr. Mu's release of claims became effective on January 12, 2024, following the Mu Separation Date, accordingly, Dr. Mu became eligible to receive (i) an amount equal to six months of his pre-transitional annual base salary paid as continuation of salary for a period of six months (totaling $294,975), (ii) subsidized COBRA premiums until the earlier of 12 months following the Mu Separation Date or the date upon which he commences employment that provides him with substantially similar group health benefits, and (iii) an amount equal to his target annual bonus for 2023 paid in a lump sum of the gross amount of $353,970. In addition, we agreed to extend the exercise period of his vested stock options outstanding at the Mu Separation Date until the sooner of 12 months following the date of this offering or 18 months following the Mu Separation Date, but in no event later than the term of his option.

In connection with Dr. Fischer's transition from the role of Head of Research & Development and Chief Medical Officer to Executive Research & Development Advisor to the Chief Executive Officer of the Company, we entered into a transition and separation agreement with her, dated August 20, 2024 (the "Fischer Separation Agreement"). Dr. Fischer stepped down as our Head of Research & Development and Chief Medical Officer effective August 20, 2024 (the "Fischer Transition Date") and in the interim will serve as Executive Research & Development Advisor to the Chief Executive Officer of the Company through her separation date of December 31, 2024 (the "Fischer Separation Date"), which period of time from the Fischer Transition Date through the Fischer Separation Date is referred to as the "Fischer Transition Period". Pursuant to the terms of the Fischer Separation Agreement, Dr. Fischer will continue to receive a base salary of $19,687.50 on a semi-monthly basis and remain eligible to participate in the Company's standard benefit plans during the Fischer Transition Period. Following the Fischer Separation Date, Dr. Fischer will be eligible to receive (i) an amount equal to six months of her pre-transitional annual base salary paid as continuation of salary for a period of six months (totaling $236,250), (ii) subsidized COBRA premiums until the earlier of six months following the Fischer Separation Date or the date upon which she commences employment that provides her with substantially similar group health benefits, and (iii) an amount equal to her target annual bonus for 2024 paid in a lump sum of the gross amount of $189,000 (the "Cash Separation Payments"). In addition, we agreed to accelerate the vesting of 25% of the total number of shares of Company common stock subject to the stock option granted to her on May 9, 2024, representing 375,000 shares, subject to any adjustment based on any stock split, reverse split or other recapitalization of the Company (collectively with the Cash Separation Payments, the "Separation Benefits"). Further, we agreed to extend the exercise period of her vested stock options outstanding at the Fischer Separation Date for an additional thirty (30) days than provided under the applicable equity documents to the extent any lock-up period restricts her ability to exercise her options following her Fischer Separation Date, and such extension shall not to exceed the ten-year term of her option. If Dr. Fischer is involuntarily terminated without Cause, as defined in the Fischer Separation Agreement, during the Fischer Transition Period, she will be eligible to receive the Separation Benefits and will be eligible to receive (i) her base salary from the date of termination through the Fischer Separation Date (the "Early Termination Period"), and (ii) the same COBRA subsidy that she is eligible to receive after her Separation Date (on the same terms as the COBRA subsidy after the Separation Date) for the number of whole calendar months during the Early Termination Period. Dr. Fischer's receipt of the Separation Benefits is contingent on Dr. Fischer agreeing to a release of claims in favor of the Company.

Retirement Plan and Other Benefits

Our executive officers also are eligible to participate in our employee benefit plans, in each case on the same basis as of all our other employees. These employee benefit plans include medical, dental, vision, short- and long-term disability and life and accidental dismemberment insurance plans. We pay a portion of the premiums for the medical, dental, vision and life and accidental death and dismemberment insurance for all of our employees, including our executive officers. We generally do not provide perquisites or personal benefits to our executive officers. Our employee benefit plans include a defined contribution retirement plan, which is a tax-qualified retirement plan under Section 401(k) of the Code (the "401(k) Plan"). The 401(k) Plan provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees

may elect to defer up to 100% of their eligible compensation into the 401(k) Plan on a pretax basis or through the Roth component of the 401(k) Plan on an after-tax basis, up to annual limits prescribed by the Code.

Equity Incentive Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2024 Equity Incentive Plan

Our board of directors has adopted the 2024 Plan in connection with this offering. Following this offering, instead of granting equity incentive awards under the 2020 Plan, we will grant our equity incentive awards under our 2024 Plan.

Administration. Our compensation committee will administer our 2024 Plan, and will have the authority to interpret our 2024 Plan and any awards granted under it, determine eligibility for and grant awards, determine the exercise price, base value from which appreciation is measured or purchase price, if any, applicable to any award, determine, modify, accelerate or waive the terms and conditions of any award, determine the form of settlement of awards, prescribe forms, rules and procedures relating to our 2024 Plan and awards and otherwise do all things necessary or desirable to carry out the purposes of our 2024 Plan or any award. Our board of directors may at any time act in the capacity of the administrator of our 2024 Plan (including with respect to such matters that are not delegated to our compensation committee). Our compensation committee (or our board of directors) may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members (or one or more other members of our board of directors), may delegate to one or more of our officers the power to grant awards to the extent permitted by law and may delegate to employees and other persons the day-to-day tasks as it determines is appropriate. As used in this summary, the term "Administrator" refers to our compensation committee, our board of directors or any of either of its authorized delegate(s), as applicable.

Eligibility. Our employees, directors, consultants and advisors are eligible to participate in our 2024 Plan. Only individuals who are providing direct services to us or our subsidiaries on the date of grant of the award will be eligible to receive stock options, and stock appreciation rights, or SARs. Furthermore, only our employees or employees of our subsidiaries will be eligible to receive stock options intended to be incentive stock options, or ISOs.

Authorized Shares. Subject to adjustment as described below, the maximum number of shares of our common stock that we may issue in satisfaction of awards under our 2024 Plan will be the number of shares of our common stock equal to 12% of shares issued and outstanding as of immediately following the consummation of the offering not to exceed 5,657,830 shares (the "initial share pool"), plus the number of shares of our common stock available for issuance under the 2020 Plan as of the effective date of the 2024 Plan, plus the number of shares subject to outstanding awards under the 2020 Plan that would again be available for issuance under the 2020 Plan upon the occurrence of certain events with such number of shares automatically increasing on January 1 of each year beginning in 2025 and continuing through and including 2034, by the lesser of (i) five percent of the number of shares outstanding as of such January 1, and (ii) the number of shares that our board of directors determines on or prior to such January 1. Up to the total number of shares from our initial share pool may be issued in satisfaction of ISOs. The collective amount of shares available for issuance under our 2024 Plan is the "Share Pool". We will not reduce the Share Pool by (i) any shares of stock withheld by us in payment of the exercise price or purchase price of an award or in satisfaction of tax withholding requirements or (ii) any shares underlying any portion of an award that is settled in cash or that expires, becomes unexercisable, terminates or is forfeited to or repurchased by us without the issuance (or retention, in the case of restricted or unrestricted stock) of shares. Any substitute awards, as described below, will be in addition to, and not reduce, the Share Pool.

Shares that may be delivered under our 2024 Plan may be authorized but unissued shares, treasury shares or previously issued shares acquired by us.

Director Limits. The awards granted under our 2024 Plan to non-employee directors will be consistent with the terms of our non-employee director compensation policy, but any limitations provided in such policy do not apply to any compensation granted or paid for services other than as a director, including as a consultant or advisor to the Company or a subsidiary.

Types of Awards. Our 2024 Plan provides for the grant of stock options, SARs, restricted and unrestricted stock and stock units, performance awards and other awards that are convertible into or otherwise based on our common stock. Dividend equivalents may also be provided in connection with awards under our 2024 Plan.

- *Stock Options and SARs*. The Administrator may grant stock options, including ISOs, and SARs. A stock option is a right entitling the holder to acquire shares upon payment of the exercise price, which the Administrator determines on the grant date of the stock option. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price per share of all stock options, and the base value of all SARs, must equal at least 100% of the fair market value per share of our common stock on the date of grant. The term of a stock option or SAR may not exceed ten years. An ISO granted to a participant who owns more than 10% of the total combined voting power of all classes of our stock on the date of grant, or any subsidiary corporations, may not have a term in excess of five years and must have an exercise price of at least 110% of the fair market value per share of our common stock on the date of grant. The participant may pay for the exercise price by cash or check, or as the Administrator permits (i) by remitting shares that the participant owns; (ii) through net exercise; (iii) through a broker-assisted cashless exercise program; or (iv) by other means acceptable to the Administrator.
- *Restricted and Unrestricted Stock and Stock Units.* The Administrator may grant awards of stock, stock units, restricted stock and restricted stock units. A stock unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted stock unit is a stock unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted stock are shares subject to restrictions requiring that they be forfeited, redelivered or offered for sale to us if specified performance or other vesting conditions are not satisfied.
- *Performance Awards.* The Administrator may grant performance awards, which are awards subject to the achievement of performance criteria.
- *Other Share-Based Awards.* The Administrator may grant other awards that are convertible into or otherwise based on shares, subject to such terms and conditions as it determines.
- *Substitute Awards.* The Administrator may grant substitute awards which may have terms and conditions that are inconsistent with the terms and conditions of our 2024 Plan. A substitute award is an award granted under our 2024 Plan in substitution for one or more equity awards of an acquired company that are converted, replaced or adjusted in connection with the acquisition.

Vesting; Terms of Awards. The Administrator determines the terms and conditions of all awards granted under our 2024 Plan, including the time or times an award vests or becomes exercisable, the terms and conditions on which an award remains exercisable and the effect of termination of a participant's employment or service on an award. The Administrator may at any time accelerate the vesting or exercisability of an award.

Transferability of Awards. Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

Effect of Covered Transactions. In the event of a covered transactions (including the consummation of a consolidation, merger or similar transaction, the sale of all or substantially all of our assets or shares of our common stock, our dissolution or liquidation or such other transaction that the Administrator determines is

a covered transaction), the Administrator may, with respect to outstanding awards, provide for any or a combination of the following:

- The assumption, substitution or continuation of an award (or any portion thereof) by the acquiror or surviving entity;
- A cash payment in respect of an award (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any; and/or
- The acceleration of exercisability or delivery of shares in respect of an award, in full or in part.

The Administrator will determine the terms and conditions as it deems appropriate with respect to each award, and does not have the obligation to treat all awards the same, in connection with a covered transaction. Except as the Administrator may otherwise determine, each award will automatically terminate or be forfeited immediately upon the consummation of the covered transaction, other than awards that are assumed or that continue following the covered transaction.

Adjustment Provisions. In the event of a change in our capital structure that constitutes an equity restructuring, including a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other changes in our capital structure, the Administrator will make appropriate adjustments to the maximum number of shares that may be delivered under our 2024 Plan, the number and kind of securities subject to individual awards, and the exercise or purchase prices (or base values) of, outstanding awards and any other provisions affected by such event.

Clawback. The Administrator may provide that any outstanding award, the proceeds of any award or shares acquired under any award and any other amounts received in respect of any award or shares acquired under any award will be subject to forfeiture and disgorgement to us, with interest and other related earnings, if (i) the participant is not in compliance with (a) any provision of our 2024 Plan or any award, (b) any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant, or (c) any company policy, such as our insider trading policy or our clawback policy, or (ii) otherwise required by law or Nasdaq listing standards.

Amendments and Termination. The Administrator may at any time amend our 2024 Plan or any outstanding award and may at any time terminate our 2024 Plan as to future grants. Except as expressly provided in our 2024 Plan, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent (unless the Administrator expressly reserved the right to do so in our 2024 Plan or at the time the award was granted). The Administrator will condition any amendments to our 2024 Plan upon shareholder approval to the extent required by applicable law or Nasdaq Listing Rules.

2020 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, the 2020 Plan in October 2020. The 2020 Plan was most recently amended in May 2024. No further awards will be made under the 2020 Plan following the completion of this offering.

Authorized Shares. Subject to certain capitalization adjustments, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2020 Plan will not exceed 4,424,044 shares. The maximum number of shares of our common stock that the plan administrator may issue pursuant to the exercise of ISOs under our 2020 Plan is 4,424,044 shares. No shares will be issued under the 2020 Plan after the effective date of our 2024 Plan. The shares of common stock underlying any awards that are (i) forfeited, (ii) canceled, (iii) reacquired by the Company prior to vesting, (iv) satisfied without the issuance of stock or otherwise terminated (other than by exercise), and (v) that are withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, will again become available for issuance under the 2020 Plan up to the effective date of our 2024 Plan, then any shares that again become available for issuance under the 2020 Plan will do so under our 2024 Plan.

Plan Administration. The 2020 Plan is administered by our board of directors or a committee appointed by it (the plan administrator). The plan administrator has full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to accelerate the

time at which a stock award may be exercised or vest, to amend the 2020 Plan and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan.

Types of Awards. The 2020 Plan allows for the grant of nonqualified stock options, restricted stock, unrestricted stock, SARs, and restricted stock unit awards to our employees, officers, directors, consultants and advisors and those of our subsidiary corporations, and for the grant of ISOs to our employees and to any employees of our subsidiaries.

- *Stock Options and SARs*. The exercise price per share of all stock options, and the base value of all SARs, must equal at least 100% of the fair market value per share of our common stock on the date of grant. The term of a stock option or SAR may not exceed ten years. An ISO granted to a participant who owns more than 10% of the total combined voting power of all classes of our stock on the date of grant, or any subsidiary corporations, may not have a term in excess of five years and must have an exercise price of at least 110% of the fair market value per share of our common stock on the date of grant. The plan administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or certain other property or other consideration acceptable to the plan administrator. After a participant's termination of service, the participant generally may exercise his or her stock options, to the extent vested as of such date of termination, during a period of 90 days after termination of service. If a termination of service is due to death or disability, the option generally will remain exercisable, to the extent vested as of such date of termination, until the one-year anniversary of such termination of service. However, in no event may an option be exercised later than the expiration of its term. If a termination of service is for cause (as defined in an applicable award agreement), the stock option automatically expires upon the date of the termination of service.
- *Restricted Stock*. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeitures provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the plan administrator.
- *Unrestricted Stock*. Unrestricted stock awards 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.
- *Restricted Stock Units*. A restricted stock unit is an award that covers a number of shares of our common stock that may be settled upon vesting in cash, by the issuance of the underlying shares or a combination of both. The plan administrator determines the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include specified performance criteria and/or continued service to us) and the form and timing of payment.

Changes to Capital Structure. In the event of certain changes in our capitalization, the exercise prices of and the number of shares subject to outstanding awards, and the purchase price of and the numbers of shares subject to outstanding awards will be proportionately adjusted, subject to any required action by our board of directors or stockholders.

Covered Transactions. The 2020 Plan provides that upon the effectiveness of a "covered transaction," as defined in the 2020 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2020 Plan. To the extent that awards granted under the 2020 Plan are not assumed or continued or substituted by acquirer or the successor entity, and except as the plan administrator may otherwise determine, all stock options and all other awards granted under the 2020 Plan shall automatically terminate. In addition, upon a covered transaction, the plan administrator may provide for a cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any. Additionally, the plan administrator may resolve, in its sole discretion, to subject any payments in respect of awards to any escrow, holdback, earn-out or similar provisions in the transaction agreements as such provisions apply to holders of our common stock. Upon a covered transaction, the plan administrator may also provide for the acceleration of exercisability or delivery of shares in respect of any award, in full or in part.

Transferability. Except as the plan administrator may otherwise determine, the 2020 Plan generally does not allow for the transfer or assignment of awards other than by will or by the laws of descent and distribution.

Plan Amendment or Termination. The plan administrator may amend or terminate the 2020 Plan at any time and for any reason, however, the Company will obtain stockholder approval if required by applicable law. After the effective date of the 2024 Plan, no additional awards will be granted under the 2020 Plan. However, the 2020 Plan will continue to govern the terms and conditions of the outstanding awards granted under it.

2024 Employee Stock Purchase Plan

Our board of directors has adopted the Zenas BioPharma, Inc. 2024 Employee Stock Purchase Plan in connection with this offering. We intend that our ESPP qualify as an "employee stock purchase plan" under Section 423 of the Code.

Administration. Our compensation committee will administer our ESPP and will have the discretionary authority to interpret our ESPP, determine eligibility under our ESPP, prescribe forms, rules and procedures relating to our ESPP and otherwise do all things necessary or desirable to carry out the purposes of our ESPP. Our compensation committee may delegate its authority under the ESPP to a sub-committee comprised of one or more of its members, to member of our board of directors, or to our officers or employees to the extent permitted by applicable law. As used in this summary, the term "Administrator" refers to our compensation committee, or to the persons or groups that our compensation committee delegated its authority to under our ESPP.

Shares Subject to our ESPP. The aggregate number of shares of our common stock available for purchase under our ESPP will be the number of shares of our common stock equal to one percent of the shares of common stock issued and outstanding as of immediately following the consummation of this offering, with such number of shares automatically increasing on January 1 of each year beginning in 2025 and continuing through and including 2034, by the lesser of (i) one percent of the number of shares outstanding as of such January 1, and (ii) the number of shares that our board of directors determines on or prior to such January 1, up to a maximum of 1,000,000 shares in the aggregate per year. The number of shares available for purchase under our ESPP is the "ESPP Pool," which ESPP Pool is subject to adjustment, as described below. Shares that we may deliver to a participant under our ESPP may be authorized but unissued shares, treasury shares or previously issued shares that we acquired. If any right to purchase shares under our ESPP expires or terminates for any reason, the shares subject to the expired or terminated right will return to and be added to the ESPP Pool.

Eligibility. Our ESPP limits participation to our employees (i) whose customary employment with us or one of our subsidiaries, as applicable, is for more than five months per calendar year, (ii) who customarily work 20 hours or more per week and (iii) who satisfy the requirements set forth in our ESPP. Employees of our subsidiaries that are designated as a participating entity and who fulfill the criteria described in the prior sentence may also participate in our ESPP. The Administrator may establish additional or other eligibility requirements, or change the requirements described in this paragraph, to the extent consistent with Section 423 of the Code. Any employee who owns (or under the statutory attribution rules deemed to own) shares possessing five percent or more of the total combined voting power or value of all classes of shares of us or our subsidiaries, if any, will not be eligible to participate in our ESPP. Employees who are citizens or residents of a jurisdiction outside of the U.S. will not be eligible to participate in our ESPP if participation is prohibited under the laws of that jurisdiction or if compliance with the laws of that jurisdiction would cause our ESPP to violate the requirements of Section 423 of the Code. Employees of a "designated subsidiary" (as defined in the ESPP) may be eligible to participate even if their customary employment is less than twenty (20) hours per week and/or five (5) months per calendar year, to the extent required by applicable law, or any lesser number of hours per week and/or number of months in any calendar year established by the Administrator (if required under applicable law) or employees of a designated subsidiary under the Non-423 Component (as defined in the ESPP).

General Terms of Participation. Our ESPP allows eligible employees to purchase shares during specified six month offering periods. During each offering period, eligible employees will be able to purchase shares on the last business day of the offering period. A participant may purchase a maximum of 25,000 shares with respect to any offering period (or such other number as the Administrator may prescribe). No participant will be permitted to purchase shares under our ESPP that exceeds $25,000 in fair market value for the calendar year, as determined in accordance with Section 423 of the Code.

The purchase price of each share issued under our ESPP at the end of the offering period will be 85% (or such other percentage as specified by the Administrator) of the lesser of: (a) the fair market value of a share on the first day of the offering period, and (b) the fair market value of a share on the last business day of the offering period.

The Administrator may, without shareholder approval, change the commencement and exercise dates of offering periods, the purchase price, the duration of any offering periods and other terms of our ESPP.

Participants in our ESPP will pay for shares purchased under our ESPP through payroll deductions unless otherwise provided by the Administrator under a sub-plan or separate offering for a non-U.S. subsidiary. Participants may elect to authorize payroll deductions between 1% and 15% of the participant's eligible compensation each payroll period.

Transfer Restrictions. For participants who have purchased shares under our ESPP, the shares may not be transferred, sold, pledged or alienated, other than by will or by the laws of descent and distribution, for three months following the date on which such shares were purchased, or such other period as the Administrator may decide.

Adjustments. In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure that constitutes an equity restructuring, the Administrator will make appropriate adjustments to the aggregate number and type of shares available for purchase under our ESPP, the number and type of shares available to purchase, the maximum number and type of shares purchasable and/or the purchase price per share.

Corporate Transactions. In the event of a corporate transaction, which may be a sale of substantially all of our common stock or assets, a merger, consolidation or similar transaction, or an acquisition of us by another entity, the Administrator may (i) provide that a participant's rights under our ESPP will be assumed or substituted for participation in the acquiror's or successor corporation's ESPP, if the Company is merged with or acquired by another corporation, (ii) cancel participants' rights under our ESPP and have the accumulated payroll deduction of participants returned to the participants, or (iii) terminate the offering period on or before the date of the proposed corporate transaction.

Amendments and Termination. The Administrator has the discretion to amend our ESPP to any extent and in any manner it may deem advisable. However, any amendment that would be treated as the adoption of a new plan for purposes of Section 423 of the Code will require shareholder approval. The Administrator may suspend or terminate our ESPP at any time.

Clawback Policy

In connection with this offering, our board of directors adopted the Company's Policy for Recoupment of Incentive Compensation ("Clawback Policy"), which is designed to comply with Section 10D-1 of the Exchange Act and the applicable Nasdaq Listing Rules. The Clawback Policy requires us to recoup incentive-based compensation received by each current or former officer of the Company subject to Section 16 of the Exchange Act (each a "covered officer"), including each named executive officer, if the Company is required to prepare an accounting restatement due to its material noncompliance with any financial reporting requirement under the securities laws. The Clawback Policy generally applies to all cash-based or equity-based incentive compensation, bonus and/or awards that a covered officer receives that is or was based, wholly or in part, upon the attainment of any financial reporting measure during the three completed fiscal years occurring immediately prior to the date that the Company is required to prepare a restatement. However, the Clawback Policy does not apply to compensation, bonus and/or award that was received on or before the date our common stock is first listed.

Stock Option Grants in Connection with this Offering

In connection with this offering, Messrs. Moulder and Farmer and Ms. Fox will be granted options to purchase 1,486,000, 206,000 and 155,000 shares of our common stock, respectively. The grant date will be the same date as this offering. The options granted to Messrs. Moulder and Farmer and Ms. Fox will vest as to 25% of the shares on the first anniversary of the option's vesting commencement date and the remainder of the shares will vest in equal monthly installments over the following 36 months, in each case, generally subject

to continued employment through the applicable vesting date. Each of the options will have an exercise price per share equal to the initial public offering price in this offering.

Non-Employee Director Compensation

The following table presents the compensation awarded to or earned by or paid to all individuals who served as non-employee directors during the year ended December 31, 2023. Mr. Moulder's compensation for the year ended December 31, 2023 is included in the Summary Compensation Table above and the accompanying narrative description; he did not receive any compensation in connection with his service as a member of our board of directors.

Name[1]	Option Awards ($)[4]	Total ($)
James Boylan[2]	—	—
Patrick Enright[2]	—	—
Tomas Kiselak[2]	—	—
Hongbo Lu, Ph.D.[2]	—	—
Marietta Wu, M.D., Ph.D.[2]	—	—
John Orloff, M.D.[3]	80,102	80,102

(1) Ms. Allen became a director in February 2024 and Messrs. Nunn and Xiao became directors in May 2024 and therefore did not receive any compensation during the year ended December 31, 2023.

(2) Messrs. Boylan, Enright and Kiselak, and Drs. Lu and Wu, have not received compensation in respect of their service as members of our board of directors. As of May 2024, Dr. Wu ceased to be a member of our board of directors.

(3) As of December 31, 2023, Dr. Orloff has options to purchase 17,274 shares of our common stock. Dr. Orloff received a grant to purchase 5,758 shares of our common stock on March 11, 2022 and a grant to purchase 11,516 shares of our common stock on February 21, 2023.

(4) The amount shown in this column represents the grant date fair value of an option to purchase 11,516 shares of our common stock granted to Dr. Orloff which remained outstanding at the end of fiscal year 2023, computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 12 to our consolidated financial statements included elsewhere in this prospectus.

Outstanding equity awards held by our non-employee directors are subject to the terms of our 2020 Plan, as described in the section titled "Executive Compensation Arrangements—Equity Incentive Plans—2020 Equity Incentive Plan."

In connection with this offering, Messrs. Boylan, Enright, Kiselak, Nunn, and Xiao and Dr. Lu will each be initially granted options to purchase 37,000 shares of our common stock. The options granted to our non-employee directors will vest in equal annual installments over three years, beginning on the first anniversary of the option's vesting commencement date, in each case, generally subject to continued service through the applicable vesting date. Additionally, Mr. Orloff and Ms. Allen will each be granted options to purchase 18,500 shares of our common stock. The options granted to Mr. Orloff and Ms. Allen will vest as to 100% of the shares subject to the option on the first anniversary of the option's vesting commencement date, subject to continued service through such date. Each of the options will have an exercise price per share equal to the initial public offering price in this offering and the grant date for each of the options will be the same date as this offering.

Post-IPO Non-Employee Director Compensation Policy

In connection with this offering, we adopted a non-employee director compensation policy which covers non-employee members of our board of directors. The following summary describes the material terms of the non-employee director compensation policy.

Under the non-employee director compensation policy and following this offering, each covered non-employee director's compensation will consist of a cash retainer and an equity incentive award. The aggregate value of all compensation payable, the cash retainer and equity award value combined, for our lead independent director and for each non-employee director for his or her first year of service will not exceed $1,000,000 annually, and to each of our other non-employee directors will not exceed $750,000 annually. The

non-employee director compensation for Fiscal Year 2024 and for future years until our board of directors modifies the non-employee director compensation policy is described below.

The cash retainer will be as follows:

- each covered non-employee director will receive an annual cash retainer of $40,000 (and an additional cash retainer of $30,000 for the lead independent director);
- each covered non-employee director who is a member of the audit committee will receive an additional annual cash retainer of $7,500 ($15,000 for the audit committee chair);
- each covered non-employee director who is a member of the compensation committee will receive an additional annual cash retainer of $5,000 ($10,000 for our compensation committee chair); and
- each covered non-employee director who is a member of the nominating and corporate governance committee will receive an additional annual cash retainer of $4,000 ($8,000 for the nominating and corporate governance committee chair).

The equity incentives will be as follows:

- each covered non-employee director, who was not first elected or appointed during the applicable fiscal year, will annually be granted a stock option to purchase 18,500 shares of our common stock; and
- each covered non-employee director who is first elected or appointed to our board of directors after the completion of this offering will be granted a stock option to purchase 37,000 shares of our common stock.

The stock options granted to our non-employee directors will have a per share exercise price equal to the closing price of a share of our common stock on the date of grant (or if no closing price is reported on that date, the closing price on the immediately preceding date on which a closing price was reported) and will expire not later than ten years after the date of grant. The annual stock options granted to our covered non-employee directors will vest as to 100% of the shares underlying the stock option on the earlier of the one-year anniversary of the date of grant or the day prior to the next annual meeting for a non-employee director who resigns his or her position as a member of our board of directors, subject to the director's continued service on our board of directors. The stock option granted to a covered non-employee director upon his or her initial election to our board of directors will vest as to one-third of the shares underlying the stock option on each of the first three anniversaries of the date of grant, subject to such director's continued service on our board of directors through the applicable vesting dates.

All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the non-employee director. For the calendar quarter during which this offering occurs, all annual cash retainers will be prorated based on the number of calendar days the non-employee director was a member of our board of directors following this offering.

Each director is entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee on which he or she serves.

Limitations on Liability and Indemnification

Our Restated Charter, which will become effective immediately prior to the completion of this offering, will contain provisions that limit the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Restated Charter will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our Restated Bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our Restated Bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these Restated Charter and Restated Bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our Restated Charter and Restated Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Plans

Our directors, officers and key employees may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a summary of transactions since January 1, 2021, to which we have been a party in which the amount involved exceeded the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus captioned "Executive and Director Compensation." We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions with unrelated third parties.

Private Placements

Warrant to Xencor, Inc.

In May 2021, we entered into the 2021 Xencor Agreement pursuant to which Xencor agreed to grant us a license to develop, manufacture and commercialize obexelimab. In consideration of the license, we agreed to issue to Xencor a certain number of shares of our convertible preferred stock (the "Xencor Equity Consideration") concurrently with a future equity financing transaction. We also agreed to make certain milestone payments upon the achievement of certain development, regulatory and sales milestones. Xencor holds more than 5% of our capital stock. See the section titled "Business—License Agreements—License Agreements with Xencor, Inc." for further information on the material terms of our license agreement with Xencor.

In November 2021, we amended the 2021 Xencor Agreement and, pursuant to such amendment, we issued to Xencor the Xencor Warrant, in lieu of the issuance of the Xencor Equity Consideration. In November 2022, the Xencor Warrant was exercised for 14,441,793 shares of our Series B Preferred Stock. Each 8.6831 shares of our Series B Preferred Stock will convert into one share of our common stock immediately prior to the completion of this offering, giving effect to adjustments to the conversion ratio in connection with the 1-for-8.6831 reverse stock split of our common stock effected on September 5, 2024.

Convertible Promissory Notes

In November 2021, we entered into the 2021 Notes, in an aggregate principal amount of $58.0 million. Each 2021 Note had a maturity date of May 19, 2023 and accrued interest at a rate of 8.0% per annum. The terms of the 2021 Notes provided for automatic conversion into shares of our convertible preferred stock upon a qualified financing and optional conversion upon a non-qualified financing. The following table summarizes the 2021 Notes purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock:

Purchaser	Aggregate Principal Amount of Convertible Notes ($)
Tellus BioVentures, LLC[1]	5,000,000
Entities affiliated with Fairmount Funds Management LLC[2]	5,000,000
Xencor, Inc.	5,000,000
Quan Venture Fund II, L.P.[3]	3,000,000

(1) Mr. Moulder, our chief executive officer and a member of our board of directors, is the Managing Member of Tellus BioVentures, LLC and as a result may be deemed to share voting and investment power with respect to the shares held by Tellus BioVentures, LLC. Tellus BioVentures, LLC holds more than 5% of our capital stock.

(2) Mr. Kiselak, a member of our board of directors, serves as Managing Member and Founder of Fairmount Funds Management LLC and as a result may be deemed to share voting and investment power with respect to the shares held by Fairmount Funds Management LLC and its affiliates. Entities related to Fairmount Funds Management LLC hold an aggregate of more than 5% of our capital stock.

(3) Dr. Wu, a member of our board of directors until May 2024, is Managing Director of Quan Capital, an entity affiliated with Quan Venture Fund II, L.P., and as a result may be deemed to share voting and investment power with respect to the shares held by Quan Venture Fund II, L.P. Quan Venture Fund II, L.P. holds more than 5% of our capital stock.

In November 2022, all of the 2021 Notes were converted in connection with the issuance and sale of our Series B Preferred Stock into an aggregate of 37,471,107 shares of our Series B Preferred Stock at a conversion price representing a 30% discount to the Series B Preferred Stock purchase price (the "Conversion Discount"). Each 8.6831 shares of our Series B Preferred Stock will convert into one share of our common stock immediately prior to the completion of this offering, giving effect to adjustments to the conversion ratio in connection with the 1-for-8.6831 reverse stock split of our common stock effected on September 5, 2024.

In connection with the issuance of the 2021 Notes, we also entered into a side letter with Xencor (the "Xencor Side Letter"), agreeing that any shares of convertible preferred stock issued in connection with the conversion of Xencor's 2021 Note would have certain preferred rights substantially similar to those provided to other preferred stockholders of ours. The Xencor Side Letter will terminate upon the completion of this offering.

Series B Preferred Stock Financing

In November 2022, we entered into a Series B Preferred Stock subscription agreement pursuant to which we issued an aggregate of 77,052,632 shares of our Series B Preferred Stock at a purchase price of $2.38666 per share. Where applicable, the payment of the purchase price consisted of or included the conversion of the 2021 Notes at the Conversion Discount and the exercise of the Xencor Warrant at an exercise price of $0.0001 per share. Each 8.6831 shares of our Series B Preferred Stock will convert into one share of our common stock immediately prior to the completion of this offering, giving effect to adjustments to the conversion ratio in connection with the 1-for-8.6831 reverse stock split of our common stock effected on September 5, 2024. The following table summarizes the Series B Preferred Stock issued to our directors, executive officers and beneficial holders of more than 5% of our capital stock:

Purchaser	Shares of Series B Preferred Stock	Aggregate Purchase Price of Shares Purchased ($)	Aggregate Price of Shares Converted ($)
Enavate Sciences[1]	10,474,889	24,999,999	
Longitude Venture Partner IV, L.P.[2]	6,284,933	14,999,999	
Entities affiliated with Fairmount Funds Management LLC[3]	6,163,236	7,000,000	5,000,000
Vivo Innovation Funds II Holdings, L.P.[4]	4,189,955	9,999,998	
Tellus BioVentures LLC[5]	3,230,268		5,000,000
Xencor, Inc.	17,672,061		5,000,000
Quan Venture Fund II, L.P.[6]	1,938,160		3,000,000
Leon O. Moulder, Jr.	418,996	1,000,001	

(1) Mr. Boylan, a member of our board of directors, serves as Chief Executive Officer of Enavate Sciences, an entity affiliated with Zebra Aggregator, LP, and as a result may be deemed to share voting and investment power with respect to the shares held by Zebra Aggregator, LP. Zebra Aggregator, LP holds more than 5% of our capital stock.

(2) Mr. Enright, a member of our board of directors, serves as a Managing Director and Founder of Longitude Capital and as a result may be deemed to share voting and investment power with respect to the shares held by Longitude Capital and its affiliates. Entities related to Longitude Capital hold an aggregate of more than 5% of our capital stock.

(3) Mr. Kiselak, a member of our board of directors, serves as Managing Member and Co-Founder of Fairmount Funds Management LLC and as a result may be deemed to share voting and investment power with respect to the shares held by Fairmount Funds Management LLC and its affiliates. Entities related to Fairmount Funds Management LLC hold an aggregate of more than 5% of our capital stock.

(4) Dr. Lu, a member of our board of directors, is a former Partner of Vivo Capital, an entity affiliated with Vivo Innovation Fund II Holdings, L.P.

(5) Mr. Moulder, our chief executive officer and a member of our board of directors, is the Managing Member of Tellus BioVentures, LLC and as a result may be deemed to share voting and investment power with respect to the shares held by Tellus BioVentures, LLC. Tellus BioVentures, LLC holds more than 5% of our capital stock.

(6) Dr. Wu, a member of our board of directors until May 2024, is Managing Director of Quan Capital, an entity affiliated with Quan Venture Fund II, L.P., and as a result may be deemed to share voting and investment power with respect to the shares held by Quan Venture Fund II, L.P. Quan Venture Fund II, L.P. holds more than 5% of our capital stock.

In April 2023, the Company incurred a $10.0 million development milestone pursuant to the 2021 Xencor Agreement. Xencor elected to receive payment in the form of the Company's Series B Preferred Stock and the Company issued 4,189,955 shares of Series B Preferred Stock as payment for the development milestone in June 2023 at a purchase price of $2.38666 per share.

Series C Preferred Stock Financing

In May 2024, we entered into a Series C Preferred Stock subscription agreement pursuant to which we issued an aggregate of 116,275,239 shares of our Series C Preferred Stock, including 12,284,686 shares of Series C Preferred Stock issued upon the conversion of the BMS Note, at a purchase price of $1.72131 per share. The payment of the purchase price included the conversion of the BMS Notes at the Conversion Discount. Each 8.6831 shares of our Series C Preferred Stock will convert into one share of our common stock immediately prior to the completion of this offering, giving effect to adjustments to the conversion ratio in connection with the 1-for-8.6831 reverse stock split of our common stock effected on September 5, 2024. The following table summarizes the Series C Preferred Stock issued to our directors, executive officers and beneficial holders of more than 5% of our capital stock:

Purchaser	Shares of Series C Preferred Stock	Aggregate Purchase Price of Shares Purchased ($)	Aggregate Price of Shares Converted ($)
Entities affiliated with SR One Capital Management, LP[(1)]	23,238,113	39,999,996	
Delos Capital Fund III, LP[(2)]	8,714,293	15,000,000	
BMS	12,284,686		20,000,000[(6)]
Entities affiliated with New Enterprise Associates (NEA)	12,490,486	21,499,998	
Norwest Venture Partners XVI, LP	12,490,486	21,499,998	
Enavate Sciences[(3)]	14,523,821	24,999,998	
Entities affiliated with Longitude Capital[(4)]	11,619,057	19,999,999	
Entities affiliated with Fairmount Funds Management LLC[(5)]	2,614,287	4,499,998	

(1) Mr. Nunn, a member of our board of directors, serves as a Partner of SR One. Entities related to SR One hold an aggregate of more than 5% of our capital stock.

(2) Mr. Xiao, a member of our board of directors, serves as a Partner and founding team member of Delos Capital, an entity affiliated with Delos Capital Fund III, LP.

(3) Mr. Boylan, a member of our board of directors, serves as Chief Executive Officer of Enavate Sciences, an entity affiliated with Zebra Aggregator, LP, and as a result may be deemed to share voting and investment power with respect to the shares held by Zebra Aggregator, LP. Zebra Aggregator, LP holds more than 5% of our capital stock.

(4) Mr. Enright, a member of our board of directors, serves as a Managing Director and Founder of Longitude Capital and as a result may be deemed to share voting and investment power with respect to the shares held by Longitude Capital and its affiliates. Entities related to Longitude Capital hold an aggregate of more than 5% of our capital stock.

(5) Mr. Kiselak, a member of our board of directors, serves as Managing Member and Co-Founder of Fairmount Funds Management LLC and as a result may be deemed to share voting and investment power with respect to the shares held by Fairmount Funds Management LLC and its affiliates. Entities related to Fairmount Funds Management LLC hold an aggregate of more than 5% of our capital stock.

(6) Excludes $1,145,753 of accrued interest on the BMS Note that, together with $20.0 million of principal amount of the BMS Note, was converted into shares of Series C Preferred Stock.

Shareholders Agreement

We are party to the Shareholders Agreement with our stockholders. Pursuant to the terms of the Shareholders Agreement, we granted these stockholders certain information rights and the right to participate in future stock issuances, which rights terminate upon this offering. The Shareholders Agreement also grants these stockholders certain registration rights. See the section titled "Description of Capital Stock —Registration Rights" for additional information regarding these registration rights. Other provisions of the Shareholders Agreement will terminate upon completion of this offering.

Director Affiliations

Some of our directors are affiliated with and, prior to the completion of this offering, have served on our board of directors as representatives of entities which beneficially own or owned 5% or more of our voting securities, as indicated in the table below:

Director	Affiliated Stockholder
Leon O. Moulder, Jr.	Tellus BioVentures LLC
James Boylan	Enavate Sciences LP
Patrick Enright	Longitude Venture Partners IV, L.P.
Tomas Kiselak	Fairmount Funds Management LLC
Hongbo Lu, Ph.D.	Vivo Capital
Jake Nunn	SR One Capital Management, LP

Agreement with Dianthus Therapeutics Inc.

In September 2020, we entered into an option agreement (the "Dianthus Option Agreement") with Dianthus pursuant to which we obtained an exclusive option to negotiate and enter into exclusive license agreements with Dianthus for the rights to research, develop, manufacture, market and sell products related to either or both of two antibody product candidates based on Dianthus' proprietary technology. Upon execution of the Dianthus Option Agreement, we issued 18,063 shares of our common stock to Dianthus at par as initial consideration.

In October 2021, we notified Dianthus of our intention to exercise our option to acquire the rights to ZB005 pursuant to the Dianthus Option Agreement, which resulted in a $1.0 million milestone payment to Dianthus.

Pursuant to the Dianthus Option Agreement, we were required to reimburse Dianthus for a specified percentage of certain third-party costs which Dianthus incurred in its initial discovery and development activities related to each of the two options, and were incurred from the date we notified Dianthus of our exercise of an option through the earlier of: (i) execution of a license agreement between Dianthus and us or (ii) our written notice to Dianthus that we are terminating license negotiations regarding an option. To date, we have only exercised our option with respect to the ZB005 program, and as a result we have only reimbursed Dianthus with respect to costs associated with the ZB005 program. During the six months ended June 30, 2024 and 2023, we recognized $2.8 million and $2.0 million of research and development expense related to the Dianthus Option Agreement, respectively. Additionally, during the years ended December 31, 2023 and 2022, we recognized $3.0 million and $6.9 million of research and development expense related to the Dianthus Option Agreement, respectively.

The Dianthus Option Agreement may be considered a related party transaction because during fiscal year 2023 Tellus beneficially owned more than 5% of our capital stock, had a seat on our board of directors and was also a 10% or greater stockholder of Dianthus and Mr. Moulder was a member of the board of directors of Dianthus. The Dianthus Option Agreement was negotiated on an arm's-length basis and on terms that we believe are no less favorable than would have been reached with an unrelated third party.

Agreements with Viridian Therapeutics Inc.

In October 2020, we entered into a license agreement (the "Viridian License Agreement") with Viridian pursuant to which we licensed technology comprising certain materials, patent rights and know-how from Viridian. Upon execution of the Viridian License Agreement, we issued Viridian 38,707 shares of our common stock.

Since February 2021, we have entered into several letter agreements with Viridian pursuant to which Viridian agreed to assist us with certain development activities, including manufacturing (the "2021 Viridian Letter Agreements"). In May 2022, we entered into a Manufacturing Development and Supply Agreement with Viridian (the "Viridian Manufacturing Agreement") pursuant to which Viridian will manufacture and supply, or Viridian will have manufactured and supplied, clinical drug product for developmental purposes. In

January 2024, we entered into a letter agreement with Viridian (the "2024 Viridian Letter Agreement" and, together with the Viridian License Agreement, the 2021 Viridian Letter Agreements and the Viridian Manufacturing Agreement, the "Viridian Agreements"), pursuant to which we agreed to support Viridian with its Phase 3 Thrive-2 and Global Safety trials in China by initiating and managing the studies. In July 2024, the parties agreed to cease further activities under the 2024 Viridian Letter Agreement. The Viridian Agreements provide for reimbursement of certain CMC and development expenses, development milestones, and royalties on net sales. Under the terms of the Viridian Agreements, Viridian granted us an exclusive license to develop, manufacture, and commercialize certain IGF-1R directed antibody products for non-oncology indications in the area of greater China. During each of the six months ended June 30, 2024 and 2023, we recognized $0.1 million of research and development expense related to the Viridian Agreements, respectively. Additionally, during the years ended December 31, 2023 and 2022, we recognized an immaterial amount and $1.3 million of research and development expense related to the Viridian Agreements, respectively. Pursuant to the 2024 Viridian Letter Agreement, Viridian has agreed to reimburse our costs incurred, including a full-time equivalent rate for services rendered, with reimbursements being recorded as a reduction of research and development expenses. Such amounts have been and are expected to be immaterial.

The Viridian Agreements may be considered related party transactions because Fairmount beneficially owns more than 5% of our capital stock, has a seat on our board of directors and is also a 10% or greater stockholder of Viridian and has two seats on the board of directors of Viridian. The Viridian Agreements were negotiated on an arm's-length basis and on terms that we believe are no less favorable than would have been reached with an unrelated third party.

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors' and officers' liability insurance. We also maintain a general liability insurance policy which covers certain liabilities of directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Related Person Transactions Policy

Our board of directors has adopted a written related person transaction policy, effective upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds in any fiscal year the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years and a related person had, has or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked with considering all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2024, as adjusted to reflect the conversion of all preferred stock into common stock prior to the completion of this offering and the sale of common stock offered by us in this offering, for:

- each person who we know beneficially owns more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a "beneficial" owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

Percentage ownership of our common stock before this offering is based on 26,557,087 shares of our common stock outstanding as of June 30, 2024, prior to the completion of this offering, and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering. Percentage ownership of our common stock after this offering is based on shares of our common stock outstanding as of June 30, 2024, after giving effect to the transactions as described above and our issuance of shares of our common stock in this offering. The table below excludes any purchases that may be made in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of June 30, 2024 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 1000 Winter Street, North Building, Suite 1200, Waltham, MA 02451.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or Greater Stockholders:			
Xencor, Inc.[1]	3,098,380	11.7%	7.8%
Enavate Sciences[2]	2,879,006	10.8%	7.2%
Entities affiliated with SR One[3]	2,676,245	10.1%	6.7%
Entities affiliated with Longitude Capital[4]	2,061,934	7.8%	5.2%
Tellus BioVentures LLC[5]	1,652,039	6.2%	4.2%
Entities affiliated with Fairmount Funds Management LLC[6]	1,592,806	6.0%	4.0%
Entities affiliated with New Enterprise Associates[7]	1,438,481	5.4%	3.6%
Norwest Venture Partners XVI, LP[8]	1,438,482	5.4%	3.6%
Bristol-Myers Squibb Company[9]	1,414,781	5.3%	3.6%
Directors and Named Executive Officers:			
Leon O. Moulder, Jr[10]	1,903,047	7.1%	4.8%
Hua Mu, M.D., Ph.D[11]	282,259	1.1%	0.7%
Jennifer Fox	—	—%	—%
Tanya Z. Fischer, M.D., Ph.D[12]	—	—%	—%

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Patricia Allen	—	—%	—%
James Boylan[2]	—	—%	—%
Patrick Enright[4]	—	—%	—%
Tomas Kiselak[6]	—	—%	—%
Hongbo Lu, Ph.D	—	—%	—%
Jake Nunn[3]	—	—%	—%
John Orloff, M.D[13]	7,676	—%	—%
Ting (Tim) Xiao	—	—%	—%
All executive officers and directors as a group (12 persons)[14]	2,051,886	7.7%	5.1%

(1) Consists of 3,098,380 shares of common stock held by Xencor. Xencor has sole voting and dispositive power over the shares, and no individual or other entity is deemed to hold any beneficial ownership in the shares. The principal business address of Xencor is 465 North Halstead Street, Suite 200 Pasadena, California 91107.

(2) Consists of 2,879,006 shares of common stock held by Zebra Aggregator, LP ("Zebra"), a limited partnership affiliated with Enavate Sciences. Enavate Sciences GP, LLC ("Enavate GP") is the general partner of Zebra. Voting, investment and dispositive power with respect to the shares held by Zebra are made collectively by the managers of Enavate GP: Jim Momtazee, Laura Furmanski, Neel Varshney and James P. Boylan, a member of our Board. Mr. Boylan disclaims beneficial ownership of such securities. The address is 1209 Orange Street, Wilmington, New Castle, Delaware 19801.

(3) Consists of (i) 1,505,388 shares of common stock held by SR One Capital Fund II Aggregator, L.P. ("SR One Fund"), (ii) 669,061 shares of common stock held by SR One Capital Opportunities Fund I, LP ("SR One Capital Opportunities"), and (iii) 501,796 shares of common stock held by AMZL, LP ("AMZL"). SR One Capital Partners II, LP, is the general partner of SR One Fund. SR One Capital Opportunities Partners I, LP, is the general partner of SR One Capital Opportunities. SR One Capital SMA Partners, LP is the general partner of AMZL. SR One Capital Management, LLC, or SR One Capital Management, is the general partner of SR One Capital Partners II, LP, SR One Capital Opportunities Partners I, LP, and SR One Capital SMA Partners, LP. Simeon George, MD, is the Manager of SR One Capital Management, LP. SR One Capital Partners II, LP, SR One Capital Management, LP, and Simeon George, MD share voting and dispositive power with respect to the shares directly held by SR One Fund. SR One Capital Opportunities Partners I, LP, SR One Capital Management, LP, and Simeon George, MD share voting and dispositive power with respect to the shares directly held by SR One Capital Opportunities. SR One Capital SMA Partners, LP, SR One Capital Management, LP, and Simeon George, MD share voting and dispositive power with respect to the shares directly held by AMZL. Jake Nunn is a Partner at SR One Capital Management, LP, an entity affiliated with SR One Fund, SR One Capital Opportunities, and AMZL, and a member of our board of directors, and has no voting or dispositive power with respect to any of the above referenced shares and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein. The address for these entities is 985 Old Eagle School Road, Suite 511, Wayne, PA 19087.

(4) Consists of (i) 1,727,404 shares of common stock held by Longitude Venture Partners IV, L.P. ("LVPIV") and (ii) 334,530 shares of common stock held by Longitude Prime Fund, L.P. ("LPF"). Longitude Capital Partners IV, LLC ("LCPIV") is the general partner of LVPIV and may be deemed to have voting, investment and dispositive power with respect to these securities. Longitude Prime Partners, LLC ("LPP") is the general partner of LPF and may be deemed to have voting, investment and dispositive power with respect to the securities held by LPF. Juliet Tammenoms Bakker and Patrick G. Enright, a member of our Board, are the managing members of LCPIV and LPP and may each be deemed to share voting, investment and dispositive power with respect to these securities. Each of LCPIV, LPP, Ms. Bakker and Mr. Enright disclaims beneficial ownership of such securities except to the extent of their respective pecuniary interests therein. The address for these individuals and entities is 2740 Sand Hill Road, 2nd Floor, Menlo Park, California 94025.

(5) Consists of 1,652,039 shares of common stock held by Tellus. Leon O. Moulder, Jr. is the Managing Member of Tellus and may be deemed to have sole voting and dispositive power over the shares held by Tellus. Mr. Moulder is our chief executive officer and Chairman of our board of directors. Mr. Moulder disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein. The principal business address of Tellus is 10520 Trevi Isle Way, Miromar Lakes, FL 33913.

(6) Consists of 1,592,806 shares of common stock held by Fairmount Healthcare Fund II LP ("Fund II"). Fairmount Funds Management LLC ("Fairmount") serves as investment manager for Fund II. Fund II has delegated to Fairmount the sole power to vote and the sole power to dispose of all securities held in Fund II's portfolio. Because Fund II has divested itself of voting and investment power over the securities it holds and may not revoke that delegation on less than 61 days' notice, Fund II disclaims beneficial ownership of the securities it holds. The general partner of Fairmount is Fairmount Funds Management GP LLC ("Fairmount GP"). As managing members of Fairmount GP, Peter Harwin and Tomas Kiselak may be deemed to have voting and investment power over the shares held by Fund II. Fairmount, Fairmount GP, Peter Harwin and Tomas Kiselak disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address of the entities listed is 200 Barr Harbor Drive, Suite 400, West Conshohocken, PA 19428.

(7) Consists of (i) 1,437,478 shares of common stock held by NEA 18 Venture Growth Equity, L.P ("NEA 18 VGE") and (ii) 1,003 shares of common stock held of record by NEA Ventures 2024, L.P. ("Ven 2024"). NEA Partners 18 VGE, L.P. ("NEA Partners 18 VGE") is the sole general partner of NEA 18 VGE. NEA 18 GP VGE, LLC ("NEA 18 VGE LLC") is the sole general partner of NEA Partners 18 VGE. Ali Behbahani, Carmen Chang, Anthony A. Florence, Jr., Mohamad Makhzoumi, Edward T. Mathers, Scott D. Sandell, Paul E. Walker and Rick Yang are the managers of NEA 18 VGE LLC. The shares held directly by Ven 2024 are indirectly held by Karen Welsh, the general partner of Ven 2024. The address for these entities and Sandell is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093. The address for Behbahani, Chang, Makhzoumi, Walker and Yang is 2855 Sand Hill Road, Menlo Park, CA 94025. The address for Florence and Mathers is 104 5th Avenue, New York, NY 10011.All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their pecuniary interest therein.

(8) Consists of 1,438,482 shares held of record by Norwest Venture Partners XVI, LP ("NVP XVI"). Genesis VC Partners XVI, LLC ("Genesis XVI") is the general partner of NVP XVI, and NVP Associates, LLC ("NVP Associates") is the managing member of Genesis XVI. Each of Jeffrey Crowe and Jon E. Kossow, who are co-chief executive officers of NVP Associates, may be deemed to share voting and dispositive power over the shares held by NVP XVI. Each of Genesis XVI, NVP Associates and Messrs. Crowe and Kossow disclaims beneficial ownership of the securities held by NVP XVI, except to the extent of its or his pecuniary interest therein. The address for each of these entities and individuals is c/o 1300 El Camino Real, Suite 200, Menlo Park CA 94025.

(9) Consists of 1,414,781 shares of common stock held by BMS. BMS has sole voting and dispositive power over the shares, and no individual or other entity is deemed to hold any beneficial ownership in the shares. The principal business address of BMS is Route 206 & Province Line Road, Princeton, New Jersey 08543.

(10) Consists of (i) 161,155 shares of common stock held directly, (ii) 1,652,039 shares of common stock held by Tellus and (iii) 89,853 shares of common stock underlying outstanding stock options exercisable within 60 days of June 30, 2024. Mr. Moulder is the Managing Member of Tellus and may be deemed to have sole voting and dispositive power over the shares held by Tellus. Mr. Moulder disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.

(11) Consists of (i) 31,758 shares of common stock held directly and (ii) 250,501 shares of common stock underlying outstanding stock options exercisable within 60 days of June 30, 2024. Effective December 31, 2023, Dr. Mu separated from the Company.

(12) On August 20, 2024, Dr. Fischer decided to transition from the Company effective December 31, 2024, and in the interim serve as the Executive Research & Development Advisor to the Chief Executive Officer.

(13) Consists of 7,676 shares of common stock underlying outstanding stock options exercisable within 60 days of June 30, 2024.

(14) Consists of (i) 161,155 shares of common stock held directly, (ii) 238,692 shares of common stock underlying outstanding stock options exercisable within 60 days of June 30, 2024 and (iii) 1,652,039 shares of common stock held by Tellus.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our Restated Charter and Restated Bylaws as they will be in effect prior to the consummation of this offering are summaries and are qualified in their entirety by reference to our Restated Charter and Restated Bylaws that will be in effect prior to the consummation of this offering. Copies of these documents are filed as exhibits to the registration statement of which this prospectus is a part.

General

Following the completion of this offering, our authorized capital stock will consist of 175,000,000 shares of common stock, with a par value of $0.0001 per share, and 25,000,000 shares of preferred stock, with a par value of $0.0001 per share, all of which preferred stock will be undesignated.

As of June 30, 2024, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, there were 26,557,087 shares of our common stock outstanding (including 1,507 shares of unvested restricted common stock), held by 48 stockholders of record, and no shares of preferred stock outstanding.

Common Stock

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 majority of the votes cast by the stockholders entitled to vote on the election, except in the case of a contested election, in which case the election shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. 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 any series of preferred stock that we may designate and issue in the future.

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. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, 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.

Preferred Stock

Under the terms of our Restated Charter that will be in effect prior to the consummation of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has 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 our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the completion of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of June 30, 2024, options to purchase 4,270,097 shares of our common stock were outstanding, 894,713 of which were vested and exercisable as of that date. For additional information regarding the terms of our 2020 Plan, see the sections titled "Executive and Director Compensation—Equity Incentive Plan—2020 Equity Incentive Plan."

Registration Rights

Our Shareholders Agreement grants the parties thereto certain registration rights in respect of the "registrable securities" held by them, which securities include (i) the shares of our common stock issuable or issued upon conversion of shares of our convertible preferred stock; and (ii) any common stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clause (i) above. The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Shareholders Agreement, we will pay all expenses relating to such registrations, including the fees of one counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Shareholders Agreement includes customary indemnification and procedural terms.

Holders of 26,557,087 shares of our common stock, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, will be entitled to such registration rights pursuant to the Shareholders Agreement. These registration rights will expire on the earlier of (i) such time after this offering as Rule 144, or another similar exemption under the Securities Act, is available for the sale of all of such holder's shares without limitation during a three-month period without registration and (ii) the third anniversary of the consummation of this offering.

Demand Registration Rights

At any time beginning six months after the effectiveness of the registration statement of which this prospectus forms a part, the holders of at least 25% of the registrable securities then outstanding may request that we file a registration statement on Form S-1, if the aggregate offering price of the registrable securities requested to be registered would exceed $20 million.

Once we are eligible to use a registration statement on Form S-3 for a period of at least twelve months, any holder of the registrable shares then outstanding may request that we file a registration statement on Form S-3 with respect to such holders' registrable securities then outstanding.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the Shareholders Agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-4 or S-8, these holders will be entitled to notice of the registration and will have fifteen days to request the inclusion of their registrable securities in the registration subject to certain limitations. If a holder decides not to include all or any of their registrable securities in the registration, such holder shall nonetheless have the right to include any registrable securities in any subsequent registration, on the same terms and conditions.

Anti-takeover Effects of Our Restated Charter and Our Restated Bylaws

Our Restated Charter and Restated Bylaws, which will be in effect prior to the consummation of this offering, will contain certain provisions that are intended to enhance the likelihood of continuity and stability

in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Classified board. Our Restated Charter will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board of directors. Our Restated Charter will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have nine directors.

Action by written consent; special meetings of stockholders. Our Restated Charter will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our Restated Charter and the Restated Bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of our board of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require our board of directors to call a special meeting.

Removal of directors. Our Restated Charter will provide that our directors may be removed only for cause by the affirmative vote of at least a majority of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board of directors.

Advance notice procedures. Our Restated Bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the Restated Bylaws will not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the Restated Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Supermajority approval requirements. The DGCL generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our Restated Charter and bylaws will provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors will be required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our Restated Charter and Restated Bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but unissued shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum. Our Restated Charter will provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if, and only if, the Court of Chancery of the State of Delaware dismisses

a Covered Claim (as defined above) for lack of subject matter jurisdiction, any other state or federal court in the State of Delaware that does have subject matter jurisdiction) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for Covered Claims. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our Restated Charter will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Restated Charter will provide that any person or entity purchasing or otherwise acquiring any interest in the shares of capital stock of the Company will be deemed to have notice of and consented to these choice-of-forum provisions and waived any argument relating to the inconvenience of the forums in connection with any Covered Claim.

The choice of forum provisions to be contained in our Restated Charter may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions to be contained in our Restated Charter are inapplicable or unenforceable if they are challenged in a proceeding or otherwise, which could cause us to incur additional costs associated with resolving such action in other jurisdictions. See the section titled "Risk Factors—Risks Related to This Offering and Our Common Stock—Our Restated Charter will designate the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees."

Section 203 of the DGCL

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the corporation's board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 150 Royall Street, Canton, Massachusetts 02021.

The Nasdaq Global Select Market Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "ZBIO".

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled "Executive and Director Compensation—Limitations on Liability and Indemnification."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See the section titled "Risk Factors—Risks Related to This Offering and Our Common Stock —A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well." Furthermore, although our common stock has been approved for listing on Nasdaq, we cannot assure you that there will be an active public trading market for our common stock.

Upon the completion of this offering, based on the number of shares of our common stock outstanding as of June 30, 2024 (including 1,507 shares of unvested restricted common stock), after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, we will have an aggregate of 39,792,381 shares of our common stock outstanding (or 41,777,675 shares of our common stock if the underwriters exercise in full their over-allotment option). Of these shares of our common stock, all of the 13,235,294 shares sold in this offering (or 15,220,588 shares if the underwriters exercise in full their over-allotment option) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately 26,557,087 shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed, among other things and subject to certain exceptions, not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Morgan Stanley & Co. LLC and Jefferies LLC.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see the section titled "Underwriters."

After the date of the initial public filing of the prospectus, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell (subject to the lock-up agreement referred to above, if applicable) in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 397,924 shares (or 417,777 shares if the underwriters exercise their over-allotment option in full) of our common stock immediately after this offering; or
- the average weekly trading volume in shares of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

An "affiliate" is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with an issuer. Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us (as well as the lock-up agreement referred to above, if applicable). If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and shares of our common stock issued or issuable under our incentive plans. We expect to file the registration statement covering shares offered pursuant to our

incentive plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the completion of this offering, the holders of 26,557,087 shares of our common stock or their transferees, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2024 into an aggregate of 24,978,715 shares of our common stock immediately prior to the completion of this offering, will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See the section titled "Description of Capital Stock—Registration Rights" for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our common stock by Non-U.S. Holders (defined below). This summary does not purport to be a complete analysis of all the potential tax considerations relevant to Non-U.S. Holders of our common stock. This summary is based upon the Code, the Treasury regulations promulgated or proposed thereunder and administrative and judicial interpretations thereof, all as of the date hereof and all of which are subject to change at any time, possibly on a retroactive basis.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). For purposes of this summary, a "Non-U.S. Holder" means a beneficial owner of common stock that for U.S. federal income tax purposes is not classified as a partnership and is not:

- an individual who is a citizen or resident of the United States;
- a corporation or any other organization taxable as a corporation for U.S. federal income tax purposes, 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 included in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships or other pass-through entities for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- persons who hold common stock that constitutes "qualified small business stock" under Section 1202 of the Code, or "Section 1244 stock" under Section 1244 of the Code;
- persons who acquired our common stock in a transaction subject to the gain rollover provisions of the Code (including Section 1045 of the Code);
- persons that acquired our common stock pursuant to the exercise of warrants or conversion rights under convertible instruments;

- persons who have elected to mark securities to market;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of persons treated as its partners for U.S. federal income tax purposes will generally depend upon the status of the partner and the activities of the partnership. Partnerships and other entities that are classified as partnerships for U.S. federal income tax purposes and persons holding our common stock through a partnership or other entity classified as a partnership for U.S. federal income tax purposes are urged to consult their own tax advisors.

There can be no assurance that the IRS will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain a ruling from the IRS with respect to the U.S. federal income tax consequences to a Non-U.S. Holder of the purchase, ownership or disposition of our common stock.

THIS SUMMARY IS FOR GENERAL INFORMATION ONLY AND IS NOT INTENDED TO BE TAX ADVICE. NON-U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAXATION, STATE, LOCAL AND NON-U.S. TAXATION AND OTHER TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK.

Distributions of Our Common Stock

We do not currently expect to make distributions with respect to our common stock. If we make a distribution of cash or property with respect to our common stock, any such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent of our current and accumulated earnings and profits, if any, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will constitute a return of capital and will first reduce the holder's adjusted tax basis in our common stock, but not below zero. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock." Any such distribution would also be subject to the discussion below under the section titled "—Additional Withholding and Reporting Requirements."

Dividends paid to a Non-U.S. Holder generally will be subject to a 30% U.S. federal withholding tax unless such Non-U.S. Holder provides us or our agent, as the case may be, with the appropriate IRS Form W-8, such as:

- IRS Form W-8BEN or W-8BEN-E (or successor form) certifying, under penalties of perjury, a reduction in withholding under an applicable income tax treaty, or
- IRS Form W-8ECI (or successor form) certifying that a dividend paid on our common stock is not subject to withholding tax because it is effectively connected with a trade or business in the United States of the Non-U.S. Holder (in which case such dividend generally will be subject to regular graduated U.S. tax rates as described below).

The certification requirement described above must be provided to us or our agent prior to the payment of dividends and must be updated periodically. The certification also may require a Non-U.S. Holder that provides an IRS form or that claims treaty benefits to provide its U.S. taxpayer identification number. Special certification and other requirements apply in the case of certain Non-U.S. Holders that hold shares of our common stock through intermediaries or are pass-through entities for U.S. federal income tax purposes.

Each Non-U.S. Holder is urged to consult its own tax advisor about the specific methods for satisfying these requirements. A claim for exemption will not be valid if the person receiving the applicable form has actual knowledge or reason to know that the statements on the form are false.

If dividends are effectively connected with a trade or business in the United States of a Non-U.S. Holder (and, if required by an applicable income tax treaty, are attributable to a permanent establishment maintained by such Non-U.S. Holder in the United States), the Non-U.S. Holder, although exempt from the withholding tax described above (provided that the certifications described above are satisfied), generally will be subject to U.S. federal income tax on such dividends on a net income basis in the same manner as if it were a resident of the United States. In addition, if a Non-U.S. Holder is treated as a corporation for U.S. federal income tax purposes, the Non-U.S. Holder may be subject to an additional "branch profits tax" equal to 30% (unless reduced by an applicable income treaty) of its earnings and profits in respect of such effectively connected dividend income.

Non-U.S. Holders that do not timely provide us or our agent with the required certification, but which are eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty, may obtain a refund or credit of any excess amount withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under the section titled "—Additional Withholding and Reporting Requirements," in general, a Non-U.S. Holder will not be subject to U.S. federal income tax or withholding tax on gain realized upon such holder's sale, exchange or other taxable disposition of shares of our common stock, unless (1) such Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition, and certain other conditions are met, (2) we are or have been a "United States real property holding corporation," as defined in the Code (a "USRPHC"), at any time within the shorter of the five-year period preceding the disposition and the Non-U.S. Holder's holding period in the shares of our common stock, and certain other requirements are met, or (3) such gain is effectively connected with the conduct by such Non-U.S. Holder of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by such Non-U.S. Holder in the United States).

If the first exception applies, the Non-U.S. Holder generally will be subject to U.S. federal income tax at a rate of 30% (or at a reduced rate under an applicable income tax treaty) on the amount by which such Non-U.S. Holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition. If the third exception applies, the Non-U.S. Holder generally will be subject to U.S. federal income tax with respect to such gain on a net income basis in the same manner as if it were a resident of the United States and a Non-U.S. Holder that is a corporation for U.S. federal income tax purposes may also be subject to a branch profits tax with respect to any earnings and profits attributable to such gain at a rate of 30% (or at a reduced rate under an applicable income tax treaty).

With respect to the second exception, generally, a corporation is a USRPHC only if the fair market value of its U.S. real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not, and do not anticipate becoming, a USRPHC. Even if we became a USRPHC, a Non-U.S. Holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as USRPHC so long as our common stock is regularly traded on an established securities market at any time during the calendar year in which the disposition occurs and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our common stock at any time during the shorter of the five year period ending on the date of disposition and the holder's holding period.

Additional Withholding and Reporting Requirements

The Foreign Account Tax Compliance Act, Sections 1471 through 1474 of the Code, and related Treasury Regulations, together with other Treasury Department and IRS guidance issued thereunder, and intergovernmental agreements, legislation, rules and other official guidance adopted pursuant to such intergovernmental agreements (commonly referred to as "FATCA") impose a U.S. federal withholding tax of 30% on certain payments, including dividends paid on our common stock, paid to (1) a "foreign financial institution" (as defined under FATCA) unless such institution furnishes proper documentation (typically on IRS Form W-8BEN-E) evidencing either (i) an exemption from FATCA withholding, (ii) its compliance (or deemed compliance) with specified due diligence, reporting, withholding and certification obligations under

FATCA or (iii) residence in a jurisdiction that has entered into an intergovernmental agreement with the United States relating to FATCA and compliance with the diligence and reporting requirements of the intergovernmental agreement and local implementing rules; or (2) a "non-financial foreign entity" (as defined under FATCA) that does not furnish proper documentation, typically on IRS Form W-8BEN-E, evidencing either (i) an exemption from FATCA or (ii) adequate information regarding substantial United States beneficial owners of such entity (if any). An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements.

The IRS and the Department of Treasury have issued proposed regulations on which taxpayers may rely providing that these withholding rules will not apply to the gross proceeds of a sale or other disposition of shares of our common stock. Prospective investors should consult their own tax advisors regarding the effect of FATCA on their ownership and disposition of our common stock.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions on our common stock paid to the holder and the tax withheld, if any, with respect to the distributions. Non-U.S. Holders may have to comply with specific certification procedures (such as the provision of a properly completed W-8BEN or W-8BEN-E) to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%, with respect to dividends on our common stock. Dividends paid to Non-U.S. Holders subject to the U.S. withholding tax, as described above under the section titled "—Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Prospective investors should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them, including the availability of and procedure for obtaining an exemption from backup withholding.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or, in which the Non-U.S. Holder is incorporated, under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and Jefferies LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares of our common stock indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	4,963,235
Jefferies LLC	3,507,353
Citigroup Global Markets Inc.	2,977,941
Guggenheim Securities, LLC	1,786,765
Total	13,235,294

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below. The offering of the shares of common stock by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $0.714 per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives. In addition, we have requested that the underwriters make issuer directed allocations in the aggregate of 1,123,528 shares of our common stock to certain investors.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,985,294 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 1,985,294 shares of our common stock.

		Total	
	Per Share	No Exercise	Full Exercise
Public offering price	$17.00	$224,999,998	$258,749,996
Underwriting discounts and commissions to be paid by us	$ 1.19	$ 15,750,000	$ 18,112,500
Proceeds, before expenses, to us	$15.81	$209,249,998	$240,637,496

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $5.2 million. We have also agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to $40,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the trading symbol "ZBIO".

We and all of our directors and officers and the holders of substantially all of our outstanding shares of common stock or securities convertible into our common stock have agreed that without the prior written consent of Morgan Stanley & Co. LLC and Jefferies LLC on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the "restricted period"):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- submit or file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Jefferies LLC on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph do not apply to us with respect to:

- the shares of common stock to be sold to the underwriters;
- the issuance by us of shares of common stock upon the exercise of an option or warrant or the conversion or settlement of a security outstanding on the date of this prospectus that is described herein;
- grants of options, restricted stock or other equity awards and the issuance of shares of common stock or securities convertible into or exercisable for shares of common stock (whether upon the exercise of stock options or otherwise) to employees, officers, directors, advisors, or consultants of us pursuant to the terms of a plan as described in this prospectus, provided that we shall cause each recipient of such grant to execute and deliver to the representatives a lock-up agreement if such recipient has not already delivered one;
- the filing of a registration statement on Form S-8 to register shares of common stock issuable pursuant to any employee benefit plans, qualified stock option plans or other employee compensation plans, described in this prospectus;
- shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, or the entrance into an agreement to issue shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, in connection with (i) the acquisition by us or any of our subsidiaries of the securities, business, property or other assets of another person or entity, including pursuant to an employee benefit or equity-based compensation plan or agreement assumed by us or any of our subsidiaries in connection with such acquisition or (ii) joint ventures, licensing arrangements, commercial relationships or other strategic transactions; provided that the aggregate number of shares of common stock issued or issuable pursuant to this clause shall not exceed ten percent of the total number of shares of common stock issued and outstanding immediately following this offering; and provided further, that the recipients of any such shares of common stock issued pursuant to this clause during the restricted period described above shall enter into a lock-up agreement on or prior to such issuance; or

- facilitating the establishment of a trading plan on behalf of a stockholder, officer or director of our pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, *provided* that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

The restrictions on transfers or other dispositions by our directors, officers and securityholders described above do not apply to:

- transactions relating to shares of common stock or other securities acquired in this offering or in open market transactions after the pricing of this offering;
- transfers of shares of common stock or any other securities (i) as a bona fide gift or for bona fide estate planning purposes, (ii) to an immediate family member of the holder or to any trust for the direct or indirect benefit of the holder or an immediate family member of the holder, (iii) to any corporation, partnership, limited liability company, investment fund, trust or other entity of which the holder and the immediate family of the holder are the legal and beneficial owner of all of the outstanding equity securities or similar interests, or (iv) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or an immediate family member of the holder; *provided* that in the case of any transfer or distribution pursuant to this provision, (A) each donee, distributee or transferee shall sign and deliver a lock-up agreement, (B) no filing under Section 16(a) of the Exchange Act or other public announcement, reporting a reduction in beneficial ownership of shares of common stock, shall be voluntarily made during the restricted period, (C) other than in the case of preceding clauses (i) and (iv), no filing under Section 16(a) of the Exchange Act or other public announcement, reporting a reduction in beneficial ownership of shares of common stock, shall be required during the restricted period (other than a required filing on Schedule 13D, 13F or 13G) and, to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers pursuant to clauses (i) and (iv) of this paragraph, such filing shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in clause (i) or clause (iv) hereof, respectively, and (D) such transfer shall not involve a disposition for value;
- transfers of shares of common stock or any other securities to a charitable organization or educational institution in a transaction not involving a disposition for value; *provided* that in the case of any transfer or distribution pursuant to this provision, (A) each transferee shall sign and deliver a lock-up agreement and (B) no filing under Section 16(a) of the Exchange Act or other public announcement, reporting a reduction in beneficial ownership of shares of common stock, shall be voluntarily made during the restricted period and, to the extent a Form 4 or Form 5 filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers made pursuant to this provision, such filing shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this provision;
- if the holder is a corporation, partnership, limited liability company, trust or other business entity, (i) transfers or distributions of shares of common stock or any other securities to current or former general or limited partners, managers or members, stockholders, other equityholders or direct or indirect affiliates (within the meaning of Rule 405 under the Securities Act) of the undersigned, or to the estates of any of the foregoing or (ii) transfers or distributions to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the holder or affiliates of the holder (including, for the avoidance of doubt, where the holder is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership); *provided* that, in the case of any transfer or distribution pursuant to this provision, (A) each distributee or transferee shall sign and deliver a lock-up agreement, and (B) such transfer shall not involve a disposition for value;
- the transfer of shares of common stock or any other securities to us to satisfy any tax, including estimated tax, remittance, or other payment obligations of the holder arising in connection with a vesting event of our securities, upon the settlement of restricted stock units or the payment due for the

exercise of options (including a transfer to us for the "net" or "cashless" exercise of options) or other rights to purchase our securities, in all such cases pursuant to equity awards granted under a stock incentive plan or other equity award plan of ours described herein; *provided*, that any remaining shares of common stock or securities convertible into common stock received upon such vesting, settlement or exercise shall be subject to the terms of the lock-up agreement; and *provided further*, that no filing under Section 16(a) of the Exchange Act or other public announcement, reporting a reduction in beneficial ownership of shares of common stock, shall be voluntarily made during the restricted period and, to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers made pursuant to this provision, such filing shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this provision, including that (i) the securities remain subject to the terms of the lock-up agreement and (ii) that no securities were sold by the holder;

- the establishment or amendment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock; *provided* that (i) such plan does not provide for the transfer of common stock during the restricted period, and (ii) to the extent a filing under Section 16(a) of the Exchange Act or other public announcement is required or voluntarily made during the restricted period by or on behalf of such director, officer or securityholder or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period and any such filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this provision;
- the transfer of shares of common stock or any other securities that occurs by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement or other court order; *provided* that (i) the transferee shall sign and deliver a lock-up agreement, and (ii) to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers made pursuant to this provision, such filing shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this provision;
- transfers to us in connection with the repurchase of common stock in connection with the termination of such director, officer or securityholder's employment with us pursuant to contractual agreements with us as in effect as of the date of this prospectus and described herein; *provided* that no filing under Section 16(a) of the Exchange Act or other public announcement, reporting a reduction in beneficial ownership of shares of common stock, shall be voluntarily made during the restricted period and, to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers made pursuant to this provision, such filing shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this provision;
- the conversion of shares of the Company's convertible preferred stock into shares of common stock as described in this prospectus; *provided* that, in each case, such shares shall continue to be subject to the restrictions on transfer set forth in the lock up agreement;
- the transfer of shares of common stock or any other securities pursuant to a bona fide third- party tender offer, merger, consolidation or other similar transaction that is approved by our board of directors, made to all holders of common stock involving a change of control; *provided* that, in the event that the change of control is not completed, the common stock owned by the holder shall remain subject to the restrictions contained in the lock up agreement; or
- transfers with the prior written consent of Morgan Stanley & Co. LLC and Jefferies LLC on behalf of the underwriters.

Morgan Stanley & Co. LLC and Jefferies LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by

exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in

accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each Member State of the EEA (each, a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation;

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

United Kingdom

Each underwriter has represented and agreed that:

(i) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 ("FSMA") received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(ii) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the UK.

No shares have been offered or will be offered pursuant to the offering to the public in the UK prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the UK at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA;

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

This prospectus is only for distribution to and directed at: (i) in the UK, persons having professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and high net worth entities falling within Article 49(2)(a) to (d) of the Order; (ii) persons who are outside the UK; and (iii) any other person to whom it can otherwise be lawfully distributed, or all such persons together, Relevant Persons. Any investment or investment activity to which this prospectus relates is available only to and will be engaged in only with Relevant Persons, and any person who is not a Relevant Person should not rely on it.

Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the securities were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to

a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(i) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor;

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to us, the offering, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offering of shares will not be supervised by, the Swiss Financial Market Supervisory Authority , and the offering of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the shares.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring the shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions, or the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Ropes & Gray LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Cooley LLP, New York, New York.

EXPERTS

The consolidated financial statements of Zenas BioPharma, Inc. as of December 31, 2023 and 2022, and for each of the years then ended, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, an 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.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto.

Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is www.sec.gov.

Upon the effectiveness of the registration statement, we will be subject to the informational requirements of the Exchange Act and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be accessed at the SEC's website referenced above. We also intend to make this information available on the investor relations section of our website, which is located at www.zenasbio.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Zenas BioPharma, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements for the Years Ended December 31, 2023 and 2022:

Unaudited Condensed Consolidated Financial Statements for the Six Months Ended June 30, 2024 and 2023:

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Zenas BioPharma, Inc. (formerly Zenas BioPharma Cayman Limited)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Zenas BioPharma, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' deficit and cash flows for each of the years then ended, 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 the years then ended, 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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.
Boston, Massachusetts
May 15, 2024, except for Note 18(C), as to which the date is September 6, 2024

Zenas BioPharma, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash	$ 56,857	$ 67,209
Prepaid expenses and other current assets	2,947	1,235
Total current assets	59,804	68,444
Property and equipment, net	193	253
Operating lease right-of-use assets, net	821	1,548
Restricted cash	86	86
Other assets	7,276	4,248
Total assets	$ 68,180	$ 74,579
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable (includes $21 and $1,934 owed to related parties, respectively)	$ 5,396	$ 5,815
Accrued expenses (includes $404 and $3,672 owed to related parties, respectively)	17,306	19,437
Operating lease liabilities, current	556	715
Total current liabilities	23,258	25,967
Operating lease liabilities, non-current	257	812
Convertible notes, at fair value	20,300	—
Total liabilities	43,815	26,779
Commitments and contingencies (Note 15)		
Convertible preferred stock:		
Series Seed convertible preferred stock, par value $0.0001 per share; 1,785,714 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation preference of $1,000 as of December 31, 2023	956	956
Series A convertible preferred stock, par value $0.0001 per share; 17,589,380 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation preference of $56,071 as of December 31, 2023	55,840	55,840
Series B convertible preferred stock, par value $0.0001 per share; 81,242,587 and 77,052,632 shares authorized, issued and outstanding as of December 31, 2023 and 2022, respectively; liquidation preference of $193,898 as of December 31, 2023	193,290	183,290
Stockholders' deficit:		
Common stock, par value $0.0001 per share; 175,000,000 and 403,572,274 shares authorized as of December 31, 2023 and 2022, respectively; 1,576,854 and 1,549,275 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Additional paid-in capital	4,645	1,034
Accumulated other comprehensive income (loss)	37	(41)
Accumulated deficit	(230,403)	(193,279)
Total stockholders' deficit	(225,721)	(192,286)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 68,180	$ 74,579

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

Zenas BioPharma, Inc.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Revenue:		
Collaboration revenue	$ 50,000	$ —
Total revenue	50,000	—
Operating expenses:		
Research and development (includes $3,041 and $8,149 from related parties, respectively)	60,033	61,689
General and administrative (includes $8 and $103 from related parties, respectively)	17,114	13,510
Acquired in-process research and development	10,000	1,000
Total operating expenses	87,147	76,199
Loss from operations	(37,147)	(76,199)
Other income (expense), net:		
Fair value adjustments to convertible notes	(300)	(29,876)
Fair value adjustments to warrant liability	—	(13,268)
Other income, net	624	61
Total other income (expense), net	324	(43,083)
Loss before income taxes	(36,823)	(119,282)
Income tax provision	(301)	—
Net loss attributable to common stockholders	$ (37,124)	$ (119,282)
Net loss per share attributable to common stockholders−basic and diluted	$ (24.25)	$ (79.94)
Weighted-average common stock outstanding−basic and diluted	1,531,178	1,492,161
Comprehensive loss:		
Net loss attributable to common stockholders	(37,124)	(119,282)
Other comprehensive income (loss):		
Foreign currency translation adjustment	78	(41)
Comprehensive loss	$ (37,046)	$ (119,323)

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

Zenas BioPharma, Inc.

Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Convertible Preferred Stock						Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
	Series Seed		Series A		Series B							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	1,785,714	$ 956	17,589,380	$ 55,840	—	$ —	1,549,275	$ —	$ 297	$ —	$ (73,997)	$ (73,700)
Issuance of Series B convertible preferred stock, net of issuance costs of $608	—	—	—	—	25,139,732	59,391	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, upon conversion of debt	—	—	—	—	37,471,107	89,431	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, upon exercise of warrant	—	—	—	—	14,441,793	34,468	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	737	—	—	737
Net loss	—	—	—	—	—	—	—	—	—	—	(119,282)	(119,282)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	(41)	—	(41)
Balance at December 31, 2022	1,785,714	$ 956	17,589,380	$ 55,840	77,052,632	$ 183,290	1,549,275	$ —	$ 1,034	$ (41)	$ (193,279)	$ (192,286)
Issuance of Series B convertible preferred stock as payment of Xencor milestone, net of issuance costs of $0	—	—	—	—	4,189,955	10,000	—	—	—	—	—	—
Exercises of common stock options	—	—	—	—	—	—	27,579	—	116	—	—	116
Stock-based compensation expense	—	—	—	—	—	—	—	—	3,495	—	—	3,495
Net loss	—	—	—	—	—	—	—	—	—	—	(37,124)	(37,124)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	78	—	78
Balance at December 31, 2023	1,785,714	$ 956	17,589,380	$ 55,840	81,242,587	$ 193,290	1,576,854	$ —	$ 4,645	$ 37	$ (230,403)	$ (225,721)

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

Zenas BioPharma, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (37,124)	$ (119,282)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	10,000	1,000
Depreciation expense	113	78
Stock-based compensation expense	3,495	737
Change in fair value of convertible notes	300	29,876
Change in fair value of warrant liability	—	13,268
Non-cash lease expense	726	704
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,349)	(4,461)
Accounts payable	(418)	1,090
Accrued expenses	(3,558)	12,055
Operating lease liabilities	(714)	(717)
Net cash used in operating activities	(30,529)	(65,652)
Cash flows from investing activities:		
Product candidate license acquisitions and development milestones	—	(2,000)
Purchases of property and equipment	(17)	(198)
Net cash used in investing activities	(17)	(2,198)
Cash flows from financing activities:		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	59,391
Proceeds from issuance of convertible notes	20,000	—
Proceeds from exercise of stock options	116	—
Net cash provided by financing activities	20,116	59,391
Effect of exchange rate changes on cash and restricted cash	78	(41)
Net decrease in cash and restricted cash	(10,352)	(8,500)
Cash and restricted cash at beginning of period	67,295	75,795
Cash and restricted cash at end of period	$ 56,943	$ 67,295
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained under operating lease arrangements	$ —	$ 2,179
Issuance of Series B convertible preferred stock from conversion of notes	$ —	$ 89,431
Issuance of Series B convertible preferred stock upon exercise of warrants	$ —	$ 34,468
Deferred offering costs in accrued expenses	$ 1,388	$ —
Purchases of property and equipment in accrued expenses	$ 39	$ —
Disposal of property and equipment	$ 7	$ —
Reconciliation of cash and restricted cash:		
Cash	$ 56,857	$ 67,209
Restricted cash	86	86
Total cash and restricted cash	$ 56,943	$ 67,295

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

Zenas BioPharma, Inc.

Notes to Consolidated Financial Statements

1. Nature of Business

Organization

Zenas BioPharma, Inc. ("Zenas" or the "Company") was incorporated in November 2019 as Zenas BioPharma (Cayman) Limited, an exempted company incorporated in the Cayman Islands with limited liability, and commenced operations in 2020. On August 2, 2023, the Company (then known as Zenas BioPharma (Cayman) Limited ("Zenas Cayman")) de-registered from the Cayman Islands and registered by way of continuation in the State of Delaware. Zenas is a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies for patients in need. The Company's primary focus is to transform the lives of patients with unmet medical needs by developing and commercializing immune-based therapies. The Company has in-licensed and is developing several product candidates for the treatment of various auto-immune and rare diseases. The Company is headquartered in Waltham, Massachusetts and operates in one segment, which is the business of acquiring and developing immune-based therapies for potential commercialization.

On December 27, 2019, Zenas formed Zenas BioPharma (HK) Limited ("Zenas HK"), a wholly owned subsidiary established in Hong Kong. On July 30, 2020, Zenas formed Zenas BioPharma (USA) LLC ("Zenas US"), a wholly owned subsidiary of Zenas. On November 11, 2021, Zenas HK formed Shanghai Zenas Biotechnology Co. Limited ("Zenas China"), a wholly foreign-owned enterprise of Zenas HK established in Shanghai, China. On November 15, 2023, Zenas formed Zenas Biopharma Securities Corporation, a wholly owned subsidiary of Zenas, which was incorporated as a Massachusetts Security Corporation.

Since its inception, the Company has devoted its efforts principally to research and development and raising capital. The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, completing preclinical studies and clinical trials, obtaining regulatory approval for product candidates, market acceptance of products, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, and the ability to raise additional capital to fund operations. The Company's revenues to date have been generated from payments received under the Company's license agreement with Bristol-Myers Squibb Company ("BMS") (see Note 8). The Company has not generated any revenue from product sales since inception, and its product candidates currently under development will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization.

Redomicile

On August 2, 2023, Zenas Cayman de-registered from the Cayman Islands and registered by way of continuation in the State of Delaware, whereby the Company filed a Certificate of Domestication to incorporate in the State of Delaware (the "Redomicile") under the name of Zenas BioPharma, Inc. In connection with the Redomicile, (i) the existing holders of convertible preferred stock and ordinary stock holders of Zenas Cayman exchanged their shares of Zenas Cayman for the same number and classes of common stock and convertible preferred stock of the Company on a one-to-one basis, with rights identical to the exchanged shares of Zenas Cayman; and (ii) all outstanding stock awards of Zenas Cayman under the Zenas BioPharma (Cayman) Limited 2020 Equity Incentive Plan (the "2020 Plan") exercisable for ordinary stock, became outstanding awards of the Company, exercisable for common stock, with no other changes to the underlying terms of the awards.

Upon completion of the Redomicile and name change, the historical consolidated financial statements of Zenas Cayman became the historical consolidated financial statements of Zenas BioPharma, Inc. For the period ended December 31, 2022, the ordinary stock is referred to as common stock throughout the consolidated financial statements and related footnotes for consistency with the presentation as of December 31, 2023. There was no impact on the consolidated financial statements as a result of the Redomicile and name change.

Zenas BioPharma, Inc.

Notes to Consolidated Financial Statements (Continued)

1. Nature of Business (Continued)

Going Concern

The Company has incurred operating losses and negative cash flows since its inception, including net losses of $37.1 million and $119.3 million in the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the Company had an accumulated deficit of $230.4 million. The Company has not generated any product revenue since inception and has relied on its ability to fund its operations through collaboration arrangements, private equity and convertible debt financings. Management expects operating losses and negative operating cash flows to continue for the foreseeable future as it continues its research and development efforts, advances its product candidates through preclinical and clinical development, enhances its platforms and programs, expands its product pipeline, seeks regulatory approval, prepares for commercialization, hires additional personnel, protects its intellectual property and grows its business. As the Company continues to incur losses, transitioning to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and the generation of sufficient revenues to support its cost structure.

The Company expects that its existing cash of $56.9 million as of December 31, 2023, together with the $179.0 million of gross proceeds from the Series C convertible preferred stock financing ("Series C Preferred Stock") in May 2024 (see Note 18), will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date these consolidated financial statements were available to be issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company will need additional financing to support its continuing operations and to pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of private equity financings, debt financings or other capital sources, including collaborations with other companies or other strategic transactions and licensing agreements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed could have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the completion of an IPO, the Company's outstanding convertible preferred stock will convert into shares of common stock (see Note 10).

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts, transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, and related disclosures. The Company bases its estimates on historical experience, known trends and other market- specific factors or other relevant factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis using such factors and adjusts those estimates and assumptions as facts and circumstances dictate. Actual results may differ from those estimates or

2. Summary of Significant Accounting Policies (Continued)

assumptions. Significant estimates in these consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation and valuations of common stock, convertible debt, and warrants.

Segment and Geographic Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's focus is acquiring, developing and commercializing safer and more effective immune-based therapies. The Company's chief operating decision maker, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. As the Company has one reportable segment, all required segment financial information is presented in the consolidated financial statements. As of December 31, 2023 and 2022, the Company's long-lived assets held outside of the United States were immaterial.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash on deposit. The Company maintains its cash at high-quality and accredited financial institutions in amounts that could exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company has no financial instruments with off-balance-sheet risk of loss. Since inception, the Company has not held any cash equivalents.

Significant Suppliers

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs, including preclinical and clinical studies and testing. In particular, the Company relies on a single manufacturer, and expects to continue to rely on a single or small number of manufacturers to supply it with its requirements for the drug product related to these programs. These programs could be adversely affected by a significant interruption in the supply of drug substance and drug product.

Foreign Currency

A subsidiary's functional currency is the currency of the primary economic environment in which the subsidiary operates; normally, that is the currency of the environment in which a subsidiary primarily generates and expends cash. In making the determination of the appropriate functional currency for a subsidiary, the Company considers cash flow indicators, local market indicators, financing indicators and the subsidiary's relationship with both the parent company and other subsidiaries. For subsidiaries that are primarily a direct and integral component or extension of the parent entity's operations, the U.S. dollar is the functional currency.

For each foreign subsidiary with a functional currency other than the U.S. dollar, assets and liabilities are translated at current exchange rates at the balance sheet date. Expense items are translated at average currency exchange rates in effect during each period. Adjustments resulting from the translation of these subsidiaries' financial statements into U.S. dollars are excluded from the determination of net loss and are recorded in accumulated other comprehensive loss, a separate component of stockholders' deficit. For foreign subsidiaries with the U.S. dollar as the functional currency, monetary assets and liabilities are re-measured into U.S. dollars at current exchange rates at the balance sheet date. Nonmonetary assets and liabilities are re-measured into U.S. dollars at historical exchange rates. Expense items are translated at average currency exchange rates in effect during each period.

2. Summary of Significant Accounting Policies (Continued)

Realized and unrealized foreign currency transaction gains and losses are recorded in other (non-operating) income or expense in the consolidated statements of operations and comprehensive loss. Realized foreign currency transaction gains and losses were immaterial for each of the years ended December 31, 2023 and 2022.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original or remaining maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits. Since inception, the Company has not held any cash equivalents.

Restricted Cash

Restricted cash consists of cash held as collateral for a letter of credit the Company issued as a security deposit for its lease of office space in Waltham, MA.

Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.

As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

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

Level 2— Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3— Unobservable inputs for the asset or liability (i.e. supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgement. Accordingly, the degree of judgement exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. There were no changes to the valuation methods utilized by the Company during the years ended December 31, 2023 and 2022.

Impairment of long-lived assets

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of an asset's book value to the estimated undiscounted future net cash flows that the asset is expected to generate. If the estimated future undiscounted net cash flows are less than the book value, the asset is considered impaired, and the impairment loss to be recognized in income is measured as the amount by which the book value of the asset exceeds its fair

2. Summary of Significant Accounting Policies (Continued)

value, which is measured based on the estimated discounted future net cash flows that the asset is expected to generate. There were no impairment losses recognized during the years ended December 31, 2023 and 2022.

Deferred Offering Costs

The Company capitalizes legal, professional accounting and other third-party fees that are directly associated with the planned IPO as other non-current assets until the IPO is consummated. After consummation of the IPO, these costs will be recorded in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. If the Company terminates its plan for an IPO, any costs deferred will be expensed immediately. As of December 31, 2023, the Company had $1.4 million in deferred offering costs, which were included in other assets and accrued expenses. No deferred offering costs were recorded as of December 31, 2022.

Collaboration Revenue

The Company enters into license and collaboration arrangements with third parties, under which the Company licenses or may license rights to certain of the Company's product candidates and performs research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, clinical, regulatory and commercial sales milestone payments, and royalties on net sales of licensed products.

One of the Company's collaboration agreements is a strategic license and collaboration agreement with BMS (see Note 8), under which the Company licenses rights to obexelimab in Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia.

At contract inception, the Company analyzes its collaboration and license arrangements to assess whether such arrangements are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, the Company first determines which units of the collaboration are deemed to be within the scope of ASC 808 and which units of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

Contracts are considered to be collaborative arrangements when they satisfy the following criteria defined in ASC 808: (i) the parties to the contract must actively participate in the joint operating activity and (ii) the joint operating activity must expose the parties to the possibility of significant risks and rewards, based on whether or not the activity is successful. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. Payments received from or made to a partner that are the result of a collaborative relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction or increase to research and development expense, respectively.

For the units of account within the scope of ASC 606, to determine the appropriate amount of revenue to be recognized for the arrangements, 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; (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.

2. Summary of Significant Accounting Policies (Continued)

The promised goods or services in the Company's arrangements typically consist of a license to the Company's intellectual property and research and development services. The Company provides options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. 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 potential payment and the likelihood that the payments will be received. 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 often include development and regulatory milestone payments that are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Due to the uncertainty of research and development and regulatory based milestones that are not within the control of the Company, payment becomes probable upon achievement. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and clinical milestones 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, which would affect research collaboration revenue in the period of adjustment. Any amounts due to the Company but not received as of period-end will be recorded to other current assets.

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 any of the Company's collaboration arrangements.

The Company allocates the transaction price based on the estimated standalone selling price. 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 including a reasonable margin. 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.

Research and Development Expenses

Research and development costs include (i) employee-related expenses, including salaries, benefits, and stock- based compensation expense; (ii) external research and development expenses incurred under arrangements

2. Summary of Significant Accounting Policies (Continued)

with third parties, such as CRO agreements and consultants; (iii) costs associated with preclinical activities and (iv) lab supplies, lab expenses and an allocation of rent, depreciation, and infrastructure. Costs incurred in connection with research and development activities are expensed as incurred.

Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data, such as patient enrollment or clinical site activations, provided by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable. The Company monitors each of these factors and adjusts estimates accordingly. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Asset Acquisitions and Acquired In-Process Research and Development Expense

The Company accounts for acquisitions of assets or a group of assets that do not meet the definition of a business as asset acquisitions based on the cost to acquire the asset or group of assets, which include certain transaction costs. In an asset acquisition, the cost to acquire is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recorded in an asset acquisition. Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in process research and development ("IPR&D"). Acquired IPR&D that has no alternative future use as of the acquisition date is recognized as IPR&D expense as of the acquisition date. The Company will recognize additional IPR&D expenses in the future if and when the Company becomes obligated to make contingent milestone payments under the terms of the agreements by which it acquired the IPR&D assets. The Company classifies payments made for the acquisition of IPR&D assets, whether capitalized or expensed, as investing activities on its statement of cash flows.

Contingent consideration in the form of milestone payments related to IPR&D with no alternative future use are charged to expense when the related milestone is achieved and becomes payable. For the year ended December 31, 2023, the Company recognized $10.0 million of IPR&D expense in connection with the consideration due under the 2021 Xencor Agreement (see Note 9). For the year ended December 31, 2022, the Company recognized $1.0 million of IPR&D expense in connection with the consideration due under the Viridian Agreement (see Note 9).

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. Comprehensive loss consists of net loss and other comprehensive loss. During the years ended December 31, 2023 and 2022, the Company's only element of other comprehensive loss was foreign currency translation adjustments.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use lease assets ("ROU assets"), current portion of lease obligations and long-term lease obligations on the Company's consolidated balance sheet. Assets subject to finance leases are included in property and equipment, and the related lease obligation is included in other current liabilities and other long-term liabilities on the Company's consolidated balance sheet. Lease assets are tested for impairment in the same manner as

2. Summary of Significant Accounting Policies (Continued)

long-lived assets used in operations. Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense, while expense for financing leases is recognized as depreciation expense (classified as an operating expense) and interest expense (classified as a non-operating expense) using the effective interest method. The Company has elected the short-term lease recognition exemption for short-term leases, which allows the Company not to recognize lease liabilities and ROU assets on the consolidated balance sheet for leases with an original term of twelve months or less.

ROU assets represent the Company's right to use an underlying asset for the lease term, and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding ROU assets are initially recognized based on the present value of lease payments over the expected remaining lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. Certain adjustments to the ROU asset may be required for items such as incentives received from the lessor. The interest rate implicit in lease contracts is typically not readily determinable. Therefore, the Company utilizes its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the fixed rate at which the Company could borrow, on a collateralized basis, the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the ROU assets for straight-line rent expense, or any incentives received and remeasures the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date. The Company generally accounts for non-lease components together with lease components. The Company expenses variable payments included in a lease arrangement as such expenses are incurred.

Income Taxes

The Company accounts for income taxes in accordance with ASC Topic 740, *Accounting for Income Taxes*, 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 financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all deferred tax assets will not be realized.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by prescribing a "more likely than not" threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. There are no unrecognized tax benefits included in the Company's consolidated balance sheets as of December 31, 2023 and 2022. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. The Company has not recognized interest or penalties related to uncertain tax positions in its consolidated statements of operations and comprehensive loss since inception.

Stock-Based Compensation

The Company grants stock-based awards to employees, non-employee consultants and members of its board of directors (the "Board"). Stock-based compensation is recognized as expense for each stock-based award based on its estimated fair value. The Company's share-based payments include stock options and grants of common stock. The value of the award is recognized as expense on a straight-line basis over the requisite service period, and expense is adjusted for pre-vesting forfeitures in the period in which the forfeitures occur. Stock-based compensation expense is classified in the accompanying consolidated 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 recipients service payments are classified.

2. Summary of Significant Accounting Policies (Continued)

The Company determines the fair value of each restricted stock award ("RSA") at its grant date based on the estimated fair value of the Company's common stock on that date as determined by the Board. The Company determines the fair value of each stock option award at its grant date using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions. The Board determines the fair value of the Company's common stock, taking into consideration its most recently available third-party valuations of common stock and as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the grant date. The Company has historically been a private company and lacks company-specific historical and implied volatility information. The Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of representative companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. 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.

Convertible Preferred Stock

The Company has classified convertible preferred stock as temporary equity (between liabilities and stockholders deficit) in the accompanying consolidated balance sheet because it could become redeemable due to certain change in control clauses that are outside of the Company's control. The convertible preferred stock is not redeemable, except in the event of a deemed liquidation event (see Note 10, "Convertible Preferred Stock"). Because the occurrence of a deemed liquidation event is not currently probable, the carrying values of the convertible preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would be made only when a deemed liquidation event becomes probable.

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. Net loss per share attributable to common stockholders is calculated 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 convertible preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. Net loss attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the 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 per share 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 the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if

2. Summary of Significant Accounting Policies (Continued)

their effect is antidilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2023 and 2022.

Recently Issued Accounting Pronouncements

The Jumpstart Our Business Startups Act of 2012 ("JOBS Act") permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. As an emerging growth company ("EGC"), the Company has elected to take advantage of this extended transition period for certain new accounting standards, and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts the Company from having to provide an auditor attestation of internal controls over financial reporting under Sarbanes-Oxley Act Section 404(b).

In November 2023, the Financial Accounting Standard Board ("FASB") issued Accounting Standard Update ("ASU") 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures*, which is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses. The standard is effective for the Company beginning in fiscal year 2024, with early adoption permitted. The amendments should be applied retroactively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of ASU 2023-07 on the consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures*. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for the Company beginning in fiscal year 2025, with early adoption permitted. The Company does not expect to early adopt the new standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2023-09 on the consolidated financial statements and related disclosures.

3. Fair Value Measurement

The Company had no assets or liabilities utilizing fair value measurements as of December 31, 2022. The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

		December 31, 2023			
Description	**Balance Sheet Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Liabilities:					
BMS Note	Non-current liability	$ —	$ —	$ 20,300	$ 20,300
		$ —	$ —	$ 20,300	$ 20,300

During the years ended December 31, 2023 and 2022, there were no transfers between levels. The Company uses the carrying amounts of its prepaid expenses and other current assets, accounts payable and accrued expenses to approximate their fair value due to the short-term nature of these amounts.

Warrant Liability

In connection with the 2021 Xencor Agreement, the Company issued a warrant to Xencor (the "Xencor Warrant") that entitled Xencor to receive a number of shares of the Company's convertible preferred stock in the Company's next "Qualified Financing" as defined in the Xencor Warrant.

3. Fair Value Measurement (Continued)

The Company concluded that the warrant should be liability classified and accounted for at fair value pursuant to ASC Topic 480, *Distinguishing Liabilities from Equity*, as it is exercisable into shares that are redeemable outside of the control of the Company. The fair value of the warrant at issuance was determined to be $20.7 million. The Company reassessed the fair value of the Xencor Warrant at each reporting period up to and immediately prior to settlement or exercise and recorded the change in fair value as a component of other income (expense), net in the Company's consolidated statements of operations and comprehensive loss. The Xencor Warrant was exercised in full in November 2022. Immediately prior to the exercise of the warrant, the Company reassessed the fair value, which was determined to be $34.5 million. For the year ended December 31, 2022, the Company recorded $13.3 million of expense as a result of the change in fair value of the Xencor Warrant.

Convertible Notes

2021 Notes

In November 2021, the Company issued and sold an aggregate of $58.0 million of convertible promissory notes (the "2021 Notes") to several investors, pursuant to a Note Purchase Agreement with each investor (see Note 7). In November 2022, concurrently with the issuance and sale of the Company's Series B convertible preferred stock ("Series B Preferred Stock"), which was deemed to be a "Qualified Financing" as defined in the agreements governing the 2021 Notes, all of the outstanding principal plus accrued interest of the 2021 Notes was automatically converted into an aggregate of 37,471,107 shares of Series B Preferred Stock. Prior to the conversion, the 2021 Notes bore interest at a rate of 8.0% per annum, with a maturity date of May 19, 2023. Conversion into shares of preferred stock was mandatory upon the Company's issuance of a new class or series of its preferred stock which is senior to the Company's Series A convertible preferred stock ("Series A Preferred Stock") as approved by the Board and the holders of Series A Preferred Stock, with aggregate gross proceeds of a specified amount (excluding conversion of the 2021 Notes or any other convertible securities).

Pursuant to ASC Topic 825, *Fair Value Measurement*, the Company elected to record the 2021 Notes at fair value upon issuance and at every subsequent reporting date (until the 2021 Notes are converted, repaid or otherwise settled). The 2021 Notes qualified for the fair value option because no component of the 2021 Notes was required to be recorded as a component of stockholders' deficit. As the Company elected the fair value option for the 2021 Notes, it did not accrue interest expense, as the fair value of the 2021 Notes included consideration of the 8.0% interest element. The Company recorded any change in fair value of the 2021 Notes as a component of other income (expense), net in its consolidated statements of operations and comprehensive loss.

The Company recorded a $29.9 million change in fair value for the 2021 Note as a component of other income (expense), net in the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2022.

BMS Note

In August 2023, the Company entered into a $20.0 million convertible promissory note agreement with BMS (the "BMS Note") in connection with its strategic license and collaboration agreement with BMS (the "BMS Agreement") (see Note 8). The BMS Note contains various conversion features including mandatory conversion upon the occurrence of a qualified financing event, IPO, reverse merger, or special purpose acquisition company transaction and conversion at the option of BMS upon the occurrence of a non-qualified financing event. If the Company issues and sells its convertible preferred stock to accredited investors with total gross proceeds equal to at least $70.0 million (a "BMS Qualified Financing"), the outstanding principal and accrued interest of the BMS Note shall automatically convert into equity securities sold in the BMS Qualified Financing at a conversion price equal (i) to the outstanding principal and accrued interest under the BMS Note divided by (ii) the lowest cash price paid per equity security. Similarly, automatic conversion of the

3. Fair Value Measurement (Continued)

BMS Note upon an IPO would result in a conversion price equal to (i) the outstanding principal and accrued interest under the BMS Note divided by (ii) the price per share listed in the registration statement to be paid by the investors for the Company's common stock. The Company elected the fair value option to account for the BMS Note. Changes in fair value are recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

The BMS Note is classified as a liability on the Company's consolidated balance sheet and was initially recorded at fair value. The fair value of the BMS Note was estimated based on significant inputs not observable in the market, representing a Level 3 measurement within the fair value hierarchy. The Company used a scenario-based analysis to incorporate estimates and assumptions concerning the Company's prospects and market indications into a model to estimate the fair value of the BMS Note. The most significant estimates and assumptions used as inputs were those concerning the timing and probability of possible scenarios for conversion or settlement of the BMS Note and the discount rate. The Company will subsequently remeasure the fair value of the BMS Note at each reporting period.

The Company recorded a $0.3 million change in fair value for the BMS Note as a component of other income (expense), net in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2023.

The table below presents changes in the Company's liabilities with significant unobservable inputs (Level 3 liabilities) during the years ended December 31, 2023 and 2022 (in thousands):

	Convertible notes	Warrant liability
Balance as of December 31, 2021	$ 59,555	$ 21,200
Change in fair value	29,876	13,268
Issuance of Series B Preferred Stock in exchange for 2021 Notes	(89,431)	—
Issuance of Series B Preferred Stock upon exercise of warrants	—	(34,468)
Balance as of December 31, 2022	$ —	$ —
Issuance of BMS Note	20,000	—
Change in fair value	300	—
Balance as of December 31, 2023	$ 20,300	$ —

4. Other Assets

Other assets consisted of the following (in thousands):

	December 31,	
	2023	2022
Prepaid clinical expenses	$ 5,788	$ 4,122
Deferred offering costs	1,388	—
Other	100	126
Total other assets	$ 7,276	$ 4,248

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2023	2022
Employee compensation and benefits	$ 5,122	$ 4,331
External research, development and manufacturing expenses	9,398	14,375
Professional and consultant fees	2,379	629
Income taxes payable	301	—
Other	106	102
Total accrued expenses	$ 17,306	$ 19,437

6. Leases

On September 8, 2021, Zenas US entered into a lease agreement for office space in Waltham, Massachusetts (the "Waltham Lease"), commencing on March 1, 2022. The Waltham Lease was classified as an operating lease, and has a lease term of 3.3 years with total fixed payments of approximately $1.8 million over that period. Zenas US has an irrevocable letter of credit agreement for the benefit of its landlord for the Waltham Lease in the amount of $0.1 million.

On June 28, 2022, Zenas China entered into a lease agreement for office space in Shanghai, China (the "Shanghai Lease"), commencing on September 10, 2022. The Shanghai Lease was classified as an operating lease, and has a lease term of 3.0 years with total fixed payments of $0.8 million over that period, and an option to extend the lease term for an additional three years. Zenas China's exercise of the option to extend the lease term was not considered reasonably certain as of the execution of the lease.

The Company recognizes monthly operating lease expense on a straight-line basis over the term of the lease as general and administrative expenses in the consolidated statements of operations and comprehensive loss. Variable lease expense relates primarily to office lease common area maintenance, insurance, and property taxes, is expensed as incurred, and is excluded from the calculation of the lease liabilities and right-of-use-assets. Variable lease expense for the years ended December 31, 2023 and 2022 was $0.1 million and less than $0.1 million respectively.

Supplemental balance sheet information related to operating lease assets and liabilities was as follows (in thousands):

	December 31,	
	2023	2022
Operating lease assets	$ 821	$ 1,548
Operating lease liabilities	$ 813	$ 1,527
Weighted average remaining term in years	1.6	2.5
Weighted average discount rate used to measure lease liabilities	18.39%	18.32%

For the years ended December 31, 2023 and 2022, the total lease cost for operating leases (recorded in general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss) was $0.9 million and $0.7 million, respectively.

6. Leases (Continued)

Maturities of the operating lease liabilities as of December 31, 2023 are as follows (in thousands):

December 31, 2023	Amount
2024	$ 813
2025	438
Total future minimum lease payments	1,251
Less: imputed interest	(438)
Total operating lease liabilities	$ 813

There were no right-of-use assets obtained under new operating lease arrangements during the year ended December 31, 2023. During the year ended December 31, 2022, the amount of right-of-use assets obtained under new operating lease arrangements was $2.2 million. Cash paid for lease liabilities (included in cash flows used in operating activities in the consolidated statements of cash flow) was $0.9 million and $0.7 million for the years ended December 31, 2023 and 2022, respectively.

7. Convertible Notes

On November 19, 2021, the Company issued the 2021 Notes in the principal amount of $58.0 million. In November 2022, concurrently with the issuance and sale of the Company's Series B Preferred Stock, which was deemed to be a "Qualified Financing" as defined in the agreements governing the 2021 Notes, all of the outstanding principal plus accrued interest of the 2021 Notes was automatically converted into an aggregate of 37,471,107 shares of Series B Preferred Stock. Prior to the conversion, the 2021 Notes bore interest at a rate of 8.0% per annum, with a maturity date of May 19, 2023. Conversion into shares of preferred stock was mandatory upon a Qualified Financing, which is defined as the Company's issuance of a new class or series of its preferred stock which is senior to the Company's Series A Preferred Stock as approved by the Board and the holders of Series A Preferred Stock, with aggregate gross proceeds of a specified amount (excluding conversion of the 2021 Notes or any other convertible securities).

In August 2023, concurrently with the execution of the BMS Agreement (see Note 8), the Company issued the BMS Note in the principal amount of $20.0 million. The BMS Note has a stated interest rate of 8.5% per annum and a maturity date of August 30, 2026. Upon the occurrence a qualified financing, which is an event in which the Company issues and sells its convertible preferred stock to accredited investors with total gross proceeds equal to at least $70.0 million, the outstanding principal and accrued interest of the BMS Note shall automatically convert into the equity securities sold in the qualified financing at a conversion price equal to (i) the outstanding principal and accrued interest under the BMS Note divided by (ii) the lowest cash price paid per equity security.

The Company elected to record the BMS Note at fair value upon issuance and to subsequently remeasure the fair value at every reporting date (until the BMS Note is converted, repaid or otherwise settled). The Company records any change in fair value to the BMS Note as a component of other income (expense), net in its consolidated statements of operations and comprehensive loss. Refer to Note 3 above for the fair value of the BMS Note.

8. Collaboration Revenue

In August 2023, the Company entered into a license agreement with Bristol-Myers Squibb (the "BMS Agreement"), under which the Company granted BMS an exclusive license to (i) develop, manufacture (subject to the Company's rights to be the exclusive manufacturer for BMS for a certain period of time), commercialize or otherwise exploit obexelimab and any biological product (irrespective of presentations, formulations or dosages) containing obexelimab but not any of the Company's other proprietary active ingredient (the "BMS Product") into Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia (collectively, the "BMS

8. Collaboration Revenue (Continued)

Territory") and (ii) develop and manufacture obexelimab and the BMS Product outside the BMS Territory provided that obexelimab and the BMS Product are solely used in the BMS Territory.

Pursuant to the BMS Agreement, BMS paid the Company a one-time non-refundable upfront cash payment of $50.0 million. The Company is entitled to receive further separate development and regulatory milestone payments from BMS up to approximately $79.5 million. The Company is also entitled to receive one-time sales milestone payments up to $70.0 million upon BMS achieving certain net sales milestones in a given year in the BMS Territory. The Company is also eligible to receive tiered high single-digit to low double-digit royalties on net sales in the BMS Territory, subject to specified reductions.

The Company will continue to perform and oversee the ongoing Phase 3 Clinical Study of obexelimab in the IgG4-RD indication and BMS will participate in the performance of the study. BMS also has the right to participate in other global clinical studies that the Company chooses to perform. Pursuant to such global studies, including the IgG4-RD study, the Company and BMS have defined roles with specified activities assigned to each party in their respective jurisdictions. These activities are overseen by a joint steering committee, which has equal representation of the parties. BMS will fund their pro rata share of the total global study costs up to a specified percentage of the patients enrolled in the study from the BMS Territory. Should the percentage of patients from the BMS Territory fall below the specified percentage, BMS's funding would proportionately decrease. BMS is responsible for the development and commercialization of obexelimab within the BMS Territory, including the performance of any local studies within its jurisdiction that it chooses to perform, while the Company retains responsibility for the development and commercialization for the remainder of the world. The Company is responsible for manufacturing the clinical supply and commercial supply of obexelimab, each at cost plus single-digit margin.

The Company evaluated the BMS Agreement to determine whether it is a collaborative arrangement in the scope of ASC 808. The Company concluded that the BMS Agreement is a collaborative arrangement under ASC 808 as both parties are active participants in the global clinical trial and are exposed to significant risks and rewards of those activities. The Company determined that the BMS Agreement contained two material components: (i) the license granted to BMS to develop, manufacture and commercialize obexelimab within the BMS Territory, and related activities in the BMS Territory, including manufacturing and (ii) the global development of obexelimab, which at execution, solely relates to the ongoing Phase 3 clinical trial for IgG4-RD. The Company used the criteria specified in ASC 606 to determine whether the components of the BMS Agreement are performance obligations to a customer and concluded that BMS is the Company's customer for the license and related activities in the BMS Territory under ASC 606. The global development activities under the agreement do not represent a transaction with a customer and reimbursement payments received by the Company for global development activities are accounted for as a reduction of the related research and development expenses. The Company recorded $4.1 million as a reduction to research and development expense during the year ended December 31, 2023, with $1.3 million included in prepaid expenses and other current assets on the Company's consolidated balance sheet as of December 31, 2023.

The Company evaluated the license and related activities under ASC 606 as these transactions are considered transactions with a customer, and identified four material promises at the outset of the BMS Agreement, which consists of (1) the exclusive license, (2) the initial technology transfer, (3) clinical manufacturing supply related to development in the BMS Territory and (4) commercial manufacturing supply related to commercialization within the BMS Territory. The Company determined that the exclusive license and initial technology transfer were not distinct from each other, as the exclusive license has limited value without the corresponding technology transfer. As such, for the purposes of ASC 606, the Company determined that the two material promises, the exclusive license and the initial technology transfer, should be combined into one distinct performance obligation. The Company further evaluated the material promise associated with the clinical manufacturing supply and the commercial manufacturing supply, within the BMS Territory, concluding that because BMS is not obligated to purchase any minimum amount, the clinical manufacturing supply and commercial manufacturing supply represent a purchase option and not a performance obligation.

8. Collaboration Revenue (Continued)

The Company further concluded that the customer option is not priced at a significant and incremental discount at the execution of the arrangement and therefore does not represent a material right. Therefore, each of the clinical and commercial manufacturing activities were excluded as performance obligations at the outset of the arrangement.

The transaction price of the BMS Agreement was determined to be $50.0 million, which consisted of the upfront cash payment, and was allocated to the one combined performance obligation. The other potential consideration, which includes development, regulatory and sales milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestones were not deemed probable of achievement and were therefore fully constrained. The Company issued the BMS Note in connection with the BMS Agreement, and the BMS Note was recorded at fair value separate from the transaction price of the BMS Agreement (see Note 3). The Company reevaluates the transaction price at the end of each reporting period as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company adjusts its estimate of the transaction price, and any addition to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.

The Company evaluated the license under ASC 606 and concluded that the license is a functional intellectual property license. The Company determined that BMS benefited from the license along with the initial technology transfer at the time of transfer, and therefore the related performance obligation is satisfied at a point in time. The Company satisfied the performance obligation through delivery of the license and initial technology transfer prior to December 31, 2023 and recognized the upfront payment of $50.0 million as revenue during the year ended December 31, 2023. There was no revenue recognized during the year ended December 31, 2022.

9. License and Option Agreements

Xencor, Inc.

2020 Xencor Agreement

In September 2020, the Company entered into a license agreement (the "2020 Xencor Agreement") with Xencor, Inc. ("Xencor"), to obtain (a) an exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (b) a non-exclusive payment bearing license under certain know-how controlled by Xencor to research, develop, manufacture, market and sell three antibody product candidates, including ZB002. The 2020 Xencor Agreement became effective in November 2020, upon the Company's issuance of 5,041,542 shares of its Series A Preferred Stock, which had a fair value of $16.1 million to Xencor as initial consideration. The Company concluded that as no processes or other activities that would constitute a business were acquired, and the acquired assets did not have an alternative future use, the upfront consideration was expensed to acquired IPR&D during the year ended December 31, 2020.

The Company is required to pay Xencor tiered royalties on annual net sales of successfully commercialized products utilizing the licensed assets. The royalty percentage rates vary by geographic areas as defined in the 2020 Xencor Agreement and range from the mid-single digits to the mid-teens.

The Company is also obligated to reimburse Xencor for third-party costs incurred by Xencor for certain patent filings, prosecution and maintenance as further specified in the 2020 Xencor Agreement. During the years ended December 31, 2023 and 2022, the Company incurred immaterial costs related to the 2020 Xencor Agreement.

2021 Xencor Agreement

In May 2021, the Company entered into a license agreement (the "2021 Xencor Agreement") with Xencor to obtain an (a) exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled

9. License and Option Agreements (Continued)

by Xencor and (b) a non-exclusive payment bearing license under certain know-how controlled by Xencor to research, develop, manufacture, market and sell obexelimab. The 2021 Xencor Agreement became effective in November 2021, upon the execution of an amendment to the 2021 Xencor Agreement and the Company's concurrent issuance of a warrant to Xencor as initial consideration. See Note 3, "Fair Value Measurement" for details regarding the Xencor Warrant. The Company concluded that as no processes or other activities that would constitute a business were acquired, and the acquired assets did not have an alternative future use, the upfront consideration of $20.7 million was expensed to acquired IPR&D during the year ended December 31, 2021.

The Company is obligated to make specified development, regulatory and commercial milestone payments of up to $10.0 million at Xencor's option either in cash or fully-paid newly issued shares. The Company is obligated to make regulatory milestone payments up to $75.0 million. The Company is also obligated to make one-time sales milestone payments up to $385.0 million upon achieving milestone events of net sales in a given calendar year in the territory equal to certain threshold amounts. In addition, the Company is required to pay Xencor tiered royalties on annual net sales of successfully commercialized products utilizing obexelimab, with the royalty rates varying based on regions and ranging from the mid-single digits to the mid-teens.

In April 2023, the Company incurred a $10.0 million development milestone pursuant to the 2021 Xencor Agreement, which Xencor elected to receive in the form of the Company's Series B Preferred Stock. See Note 10, "Convertible Preferred Stock," for details. The milestone was recorded as acquired in-process research and development expense in the Company's consolidated statements of operations and comprehensive loss.

Dianthus Therapeutics Inc.

In September 2020, the Company entered into an agreement (the "Dianthus Option Agreement") with Dianthus Therapeutics Inc. ("Dianthus"), a therapeutic antibody company. Under the terms of the Dianthus Option Agreement, the Company obtained an exclusive option to negotiate and enter into exclusive license agreements with Dianthus for the rights to research, develop, manufacture, market and sell products related to either or both of two antibody product candidates based on Dianthus' proprietary technology in China, Hong Kong, Macau and Taiwan (the "Zenas Territories"). Dianthus retains all rights to develop and commercialize the product candidate subjects of the two options outside of the Zenas Territories. Upon execution of the Dianthus Option Agreement, the Company issued 18,063 shares of its common stock to Dianthus as initial consideration, which was recorded to acquired IPR&D expense during the year ended December 31, 2020.

Under the Dianthus Option Agreement, Dianthus will notify the Company when it has identified each of two antibody product candidates, and the Company will then have sixty (60) days to notify Dianthus if the Company intends to exercise each of the options. In September 2021, Dianthus notified the Company that it had identified the first lead antibody product candidate pursuant to the Dianthus Option Agreement, ZB005 (also known as DNTH103). In October 2021, the Company notified Dianthus of its intention to exercise its option to ZB005 pursuant to the Dianthus Option Agreement. This notification resulted in a $1.0 million milestone obligation to Dianthus, which was expensed in 2021 upon exercise and subsequently paid during the year ended December 31, 2022. The Company and Dianthus executed a license agreement for ZB005 in June 2022 (the "Dianthus License Agreement"). As of December 31, 2023, Dianthus had not notified the Company of its identification of the second antibody product candidate.

The Company is also required to reimburse Dianthus for a specified percentage of certain third-party costs which Dianthus incurs in its initial discovery and development activities related to each of the two options. To date, the Company has only exercised its option with respect to the ZB005 program, and as a result, it has only reimbursed Dianthus with respect to costs associated with the ZB005 program. During the years ended December 31, 2023 and 2022, the Company incurred $3.0 million and $6.9 million of reimbursable expenses, respectively, which are recorded within research and development expenses in the consolidated statements of

9. License and Option Agreements (Continued)

operations and comprehensive loss. Of these amounts, less than $0.1 million and $1.6 million were recorded in accounts payable, and $0.4 million and $3.7 million in accrued expenses, on the Company's consolidated balance sheets as of December 31, 2023 and 2022, respectively.

The binding key terms included in the Dianthus License Agreement, and that would be included in a future license agreement if the Company exercises its option with respect to a second research program, also include the Company's obligation to make specified development milestone payments to Dianthus, one time only, regardless of the number of assets the Company in-licenses from Dianthus with respect to such research program. The milestone obligations for each research program would total up to $11.0 million, based on achievement of each of the specified milestone events. If the Company successfully commercializes a product(s) under a license agreement, the Company will be obligated to make tiered royalty payments, on a product-by-product basis, to Dianthus on annual net sales of such products. Royalties will be calculated as specified percentages of annual net sales, ranging from the mid-single digits to the low-double digits, with each specified tiered level of annual net sales having a specified percentage.

Viridian Therapeutics, Inc.

In October 2020, the Company entered into a license agreement (the "Viridian Agreement") with Viridian Therapeutics, Inc. ("Viridian"), to obtain an exclusive, royalty-bearing, sublicensable license to research, develop, manufacture, market and sell certain antibody product candidates based on Viridian's proprietary technology. The Company's license rights are limited to non-oncology indications and to the Zenas Territories. Viridian retains its rights to develop and commercialize such product candidates outside of the Zenas Territories. Upon execution of the Viridian Agreement, the Company issued 38,707 shares of its common stock to Viridian as initial consideration which was recorded as acquired in-process research and development expense in its consolidated statements of operations and comprehensive loss for the year ended December 31, 2020.

The Company is obligated to make development milestone payments to Viridian, totaling up to $12.0 million, based on achievement of each of the specified milestone events. The Company is also required to pay Viridian tiered royalties on annual net sales of successfully commercialized products utilizing the licensed technology. The royalty percentage rates range from the mid-single digits to the low-double digits. During the year ended December 31, 2023, the Company incurred and paid no milestones to Viridian. During the year ended December 31, 2022, the Company incurred and paid to Viridian a milestone of $1.0 million, which is recorded as acquired in-process research and development expense in the Company's consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2021, the Company and Viridian entered into two letter agreements to authorize initiation of certain manufacturing and development activities related to the licensed product candidate, ZB001 (also known as VRDN-001). In each of the letter agreements the Company requested, and Viridian agreed, to engage a third-party contract manufacturer (the "CMO") to initiate certain work with respect to activities pursuant to one or more statements of work under existing agreements between Viridian and the two CMOs. In May 2022, the Company entered into a manufacturing development and supply agreement with Viridian. The Company paid Viridian for all amounts the CMOs invoice to Viridian for the specified activities. The first letter agreement subsequently was amended three times to add further activities and costs to those detailed in the original letter agreement. During the years ended December 31, 2023 and 2022, the Company recognized an immaterial amount and $1.3 million of expenses, respectively, which were recorded in research and development expenses in the consolidated statements of operations. Of these amounts, less than $0.1 million was included in accrued expenses on the Company's consolidated balance sheet as of December 31, 2023. There were no research and development expenses included in accrued expenses as of December 31, 2022. As of December 31, 2023, Viridian had not notified the Company of any additional antibody product candidate.

10. Convertible Preferred Stock

In September 2020, the Company issued and sold 1,785,714 shares of Series Seed convertible preferred stock ("Series Seed") in a private financing transaction, at a purchase price of $0.56 per share, for total net cash proceeds of $1.0 million.

In November 2020, the Company issued 5,041,542 shares of Series A Preferred Stock to Xencor as initial consideration for the 2020 Xencor Agreement (which is more fully described in Note 9, "License and Option Agreements"). Also in November 2020, the Company issued and sold 12,547,838 shares of Series A Preferred Stock in a private financing transaction, at a purchase price of $3.1878 per share, for total net cash proceeds of $39.9 million.

In November 2022, the Company issued and sold 25,139,732 shares of Series B Preferred Stock in a private financing transaction, at a purchase price of $2.38666 per share, for total net cash proceeds of $59.4 million. Concurrent with the issuance and sale of the Series B Preferred Stock, which was deemed to be a qualified financing as defined in the convertible note agreement and resulted in the principal plus accrued interest being automatically converted into Series B Preferred Stock, the outstanding convertible notes were exchanged for 37,471,107 shares of Series B Preferred Stock. At the same time, the Xencor Warrant, which was issued as initial consideration for the 2021 Xencor Agreement, was deemed exercised for 14,441,793 shares of Series B Preferred Stock.

In April 2023, the Company incurred a $10.0 million development milestone pursuant to the 2021 Xencor Agreement. See Note 9, "License and Option Agreements," for details. Xencor elected to receive payment in the form of the Company's Series B Preferred Stock and the Company issued 4,189,955 shares of Series B Preferred Stock as payment for the development milestone in June 2023.

Upon the issuance of Series Seed, Series A and Series B Preferred Stock (collectively "Preferred Stock"), the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2023				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series Seed Preferred Stock	1,785,714	1,785,714	$ 956	$ 1,000	205,653
Series A Preferred Stock	17,589,380	17,589,380	55,840	56,071	2,025,699
Series B Preferred Stock	81,242,587	81,242,587	193,290	193,898	9,356,392
Total	100,617,681	100,617,681	$ 250,086	$ 250,969	11,587,744

	December 31, 2022				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series Seed Preferred Stock	1,785,714	1,785,714	$ 956	$ 1,000	205,653
Series A Preferred Stock	17,589,380	17,589,380	55,840	56,071	2,025,699
Series B Preferred Stock	77,052,632	77,052,632	183,290	183,898	8,873,851
Total	96,427,726	96,427,726	$ 240,086	$ 240,969	11,105,203

The holders of preferred stock have the following rights, preferences and privileges:

Voting

The holder of each share of Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters.

10. Convertible Preferred Stock (Continued)

Conversion

Each share of convertible preferred stock shall be automatically converted into a share of common stock, upon affirmative vote of majority of the holders of each series or upon the closing of an initial public offering of the Company's common stock which results in a specified minimum amount of gross cash proceeds. The conversion ratio is initially one share of common stock for each share of convertible preferred stock and shall be adjusted in the event of a split or reverse split of the Company's common stock, an issuance or declaration of dividends to holders of the Company's common stock, a reorganization or merger transaction, or certain issuances of shares of common stock which are dilutive to holders of the Company's preferred stock. Holders of preferred stock have the right to one vote for each share of the Company's common stock into which such holder's shares of preferred stock could then convert. See Note 18 for information on the reverse stock split that adjusted the preferred stock conversion ratio.

Dividends

Holders of Series B Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series B Preferred Stock issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). If any assets or funds remain after dividends have been distributed to holders of Series B Preferred Stock, holders of Series A Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series A issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). If any assets or funds remain after dividends have been distributed to holders of Series A Preferred Stock, holders of Series Seed Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series Seed issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). The right to receive dividends on shares of all series of preferred stock is not cumulative, and no such right accrues to holders of such shares. There have been no dividends declared or paid as of December 31, 2023.

Liquidation Preference

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, holders of Series B Preferred Stock prior and in preference to any distribution to holders of Series A Preferred Stock, Series Seed Preferred Stock and common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared but unpaid dividends. After full payment to holders of Series B Preferred Stock, holders of Series A Preferred Stock prior and in preference to any distribution to holders of Series Seed Preferred Stock and common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared and unpaid dividends. After full payment to holders of Series B Preferred Stock and Series A Preferred Stock, holders of Series Seed Preferred Stock prior and in preference to any distribution to holders of common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared and unpaid dividends. Any remaining amounts after payment to holders of preferred stock, would be paid to holders of common shares. A deemed liquidation event is defined (in the Company's Third Amended Articles of Association) as any consolidation, amalgamation, scheme of arrangement or merger of the Company (and any of its subsidiaries) or other reorganization resulting in loss of more than 50% voting power; the sale, transfer, lease or other disposition of all or substantially all of the Company's assets; or the exclusive licensing of all or substantially all of the Company's intellectual property.

Redemption

The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a Liquidation Event.

11. Common Stock

In August 2023, all outstanding shares of ordinary stock of Zenas Cayman were exchanged for shares of common stock upon the Redomicile and incorporation in the State of Delaware as Zenas BioPharma, Inc. The Company was authorized to issue 175,000,000 and 403,572,274 shares of $0.0001 par value common stock and ordinary stock as of December 31, 2023 and 2022, 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 preference of the holders of the preferred stock set forth above.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of convertible preferred stock.

The Company had reserved the following shares of common stock for the potential conversion of outstanding convertible preferred stock and exercise of stock options:

	December 31,	
	2023	2022
Conversion of outstanding shares of convertible preferred stock	11,587,744	11,105,203
Options to purchase common stock	2,382,933	2,046,998
Remaining shares reserved for future issuance	60,792	257,317
Total	14,031,469	13,409,518

12. Stock-Based Compensation

2020 Plan

On August 21, 2020, the Company's sole director and member approved the 2020 Plan. The 2020 Plan initially allowed the Company to grant awards for up to 36,162 shares of the Company's common stock. The 2020 Plan allows for grants of stock options, restricted stock awards, restricted stock units, and other stock-based awards to employees, officers, directors and consultants of the Company and its subsidiaries. The exercise price per share of stock options granted under the 2020 Plan must be no less than the fair value of a share of the Company's common stock on the grant date. If the Company's common stock is traded on a national securities exchange, then fair value is based on the stock's closing price as reported by that exchange. Otherwise, fair value is determined by the Board (or its Compensation Committee), consistent with the applicable rules of the U.S. Internal Revenue Code of 1986 (the "IRC"), or any successor statute.

Terms of stock award agreements, including vesting requirements, are determined by the Board, subject to the provisions of the 2020 Plan. The Company may grant stock awards to employees, non-employee consultants, and members of the Board, and all grantees must be providing services to the Company or its subsidiaries on the date of grant. Since inception of the 2020 Plan, the Company has granted RSAs and stock options. RSAs and stock options granted by the Company generally vest over four years, with 25% of the total shares granted vesting on the anniversary of the vesting commencement date and the remaining 75% vesting in equal monthly installments over the subsequent thirty-six (36) months.

The 2020 Plan was subsequently amended by the Board and provided for the issuance of 2,560,401 shares of common stock as of December 31, 2023, of which 60,792 shares of common stock remain available for future grant under the 2020 Plan.

12. Stock-Based Compensation (Continued)

Restricted Stock Awards

The following table presents a summary of the Company's RSA activity and related information:

	Number of Shares	Weighted-Average Grant-Date Fair Value
Unvested as of December 31, 2022	46,826	$ 2.36
Vested	(19,626)	1.88
Unvested as of December 31, 2023	27,200	$ 2.71

There were no RSAs granted during the year ended December 31, 2023. The total fair value of RSAs vested during the year ended December 31, 2023 was immaterial. As of December 31, 2023, unrecognized compensation cost related to unvested restricted stock awards was $0.1 million, which is expected to be recognized over a weighted average period of 1.2 years.

Stock Options

The Company has granted stock options with service-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

The table below presents the weighted-average assumptions used in estimating the fair values of stock options granted during the years ended December 31, 2023 and 2022:

	December 31,	
	2023	2022
Risk-free interest rate	4.13%	3.49%
Expected term (in years)	6.04	6.08
Expected volatility	87.86%	89.07%
Expected dividend yield	0.00%	0.00%

The following table presents a summary of the Company's stock option activity and related information:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Balance at December 31, 2022	2,046,998	$ 7.43		$ 3,772
Granted	1,054,346	10.23		
Exercised	(27,579)	4.21		163
Forfeited or cancelled	(690,832)	8.12		
Balance outstanding at December 31, 2023	2,382,933	$ 8.51	8.23	$ 8,084
Options vested and exercisable at December 31, 2023	675,584	$ 6.33	5.57	$ 3,762
Options vested and expected to vest at December 31, 2023	2,382,933	$ 8.51	8.23	$ 8,084

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those stock options that had an exercise price

12. Stock-Based Compensation (Continued)

lower than the fair value of the Company's common stock as of the measurement date of December 31, 2023. The aggregate intrinsic value of options exercised during the year ended December 31, 2023 was $0.2 million. There were no stock options exercised during the year ended December 31, 2022.

The weighted-average grant date fair value of the Company's stock options granted during the year ended December 31, 2023 and 2022 was $8.11 and $6.80 per option, respectively. As of December 31, 2023, unrecognized compensation cost related to unvested stock options was $11.6 million, which is expected to be recognized over a weighted average period of 3.2 years. The total fair value of options vested during the years ended December 31, 2023 and 2022 was $2.6 million and $0.7 million, respectively.

Stock-Based Compensation Expense

The following table presents stock-based compensation expense as reflected in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Research and development	$ 1,600	$ 357
General and administrative	1,895	380
Total stock-based compensation expense	$ 3,495	$ 737

13. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	December 31,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders	$ (37,124)	$ (119,282)
Denominator:		
Weighted-average common stock outstanding–basic and diluted	1,531,178	1,492,161
Net loss per share attributable to common stockholders–basic and diluted	$ (24.25)	$ (79.94)

The Company's potentially dilutive securities, which include convertible preferred stock, restricted stock 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 shares from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2023 and 2022 because including them would have had an anti-dilutive effect:

	December 31,	
	2023	2022
Convertible preferred stock	11,587,744	11,105,203
Unvested restricted stock	27,200	46,826
Options to purchase common stock	2,382,933	2,046,998

13. Net Loss Per Share (Continued)

The BMS Note was also outstanding as of December 31, 2023, which could obligate the Company to issue preferred shares or common shares upon the occurrence of various future events at prices and in amounts that are not determinable until the occurrence of those future events. Because the necessary conditions for the conversion of the BMS Note had not been satisfied as of December 31, 2023, the Company has excluded the BMS Note from the table above and the calculation of diluted net loss per share. See Note 7 for additional details.

14. Income Taxes

The following table presents the components of loss before the provision for (benefit from) income taxes during the years ended December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
U.S.	$ (10,845)	$ (52,210)
Non-U.S.	(25,978)	(67,072)
Loss before taxes on income	$ (36,823)	$ (119,282)

The components of the income tax provision for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	December 31,	
	2023	2022
Current income tax provision:		
Federal	$ 289	$ —
State	12	—
Foreign	—	—
Total current income tax provision	301	—
Deferred income tax provision:		
Federal, state and foreign	—	—
Total deferred income tax provision	—	—
Total income tax provision	$ 301	$ —

A reconciliation of the income tax expense computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	December 31,	
	2023	2022
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	3.4	2.9
Change in valuation allowance	(26.4)	(18.1)
Research and development tax credits	8.8	2.6
Foreign tax rate differential	(7.6)	(8.2)
Other adjustments	—	(0.2)
Effective income tax rate	(0.8)%	(0.0)%

14. Income Taxes (Continued)

The Company's change in effective tax rate for the year ended December 31, 2023 compared to the year ended December 31, 2022 increased primarily due to income earned in the U.S.

The following table presents the components of the Company's deferred tax assets and liabilities (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 9,960	$ 13,073
Capitalized research and development	19,573	10,795
Research and development tax credits	6,547	4,112
Accruals	1,424	1,068
Milestone payments	719	777
Lease liability	147	262
Stock-based compensation	1,188	258
Intangibles	320	—
Fair value adjustment–debt	81	—
Other	2	—
Total deferred tax assets	39,961	30,345
Deferred tax liabilities:		
ROU asset	(143)	(258)
Amortization and other	(57)	(5)
Valuation allowance	(39,761)	(30,082)
Net deferred tax assets	$ —	$ —

ASC Topic 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded full valuation allowances against its domestic and foreign deferred tax assets as of December 31, 2023, because management has determined that it is more likely than not that these assets will not be realized. The valuation allowance increased by $9.7 million from December 31, 2022 to December 31, 2023, primarily due to the capitalization of research and development expenses under Internal Revenue Code Section 174 ("Section 174") at the U.S. entity.

Beginning on or after January 1, 2022, Section 174 of the U.S. internal revenue code was amended as part of the Tax Cuts and Jobs Act of 2017 (the "TCJA") to no longer permit an immediate deduction for research and development expenditures in the tax year that such costs are incurred. Rather, the research and development expenses must be capitalized and amortized over five years for research performed in the U.S. and 15 years for research performed outside the U.S. As a result of this provision, the Company capitalized applicable costs resulting in a deferred tax asset of $19.6 million as of December 31, 2023.

As of December 31, 2023, the Company had approximately $2.3 million of U.S. federal net operating loss ("NOL") carryforwards. The Company had no state NOL carryforwards as of December 31, 2023. As of December 31, 2022, the Company had approximately $22.9 million and $22.2 million of U.S. federal and state NOL carryforwards, respectively. The Company utilized previous net operating loss carryforwards to offset the taxable income created from the mandatory capitalization of research and development expenses under

14. Income Taxes (Continued)

Section 174. The federal NOL carryforwards do not expire, but they may be limited in their usage to an annual deduction equal to 80% of annual taxable income. The Company anticipates the utilization of their state NOL carryforwards to occur in the period ending December 31, 2023. The federal and state NOL carryforwards are fully offset by valuation allowances.

As of December 31, 2023, the Company had $5.9 million and $0.8 million in federal and state general business or research and development tax credit carryforwards. As of December 31, 2022, the Company had $3.6 million and $0.6 million in federal and state general business or research and development tax credit carryforwards. These carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The federal and state research credit carryforwards expire in 20 years and 15 years, respectively, starting in 2036. The federal and state tax credit carryforwards are fully offset by valuation allowances.

As of December 31, 2023 and 2022, the Company had $53.7 million and $39.3 million of foreign NOL carryforwards, respectively. The foreign NOL carryforwards are fully offset by valuation allowances. The Zenas China net operating loss carryforwards expire at various dates beginning in 2026 through 2028 for tax purposes. The Zenas HK net operating losses may be carried forward indefinitely for tax purposes. The foreign NOL carryforwards are fully offset by valuation allowances.

The Company files income tax returns in the jurisdictions in which it operates. In the normal course of business, the Company may be subject to examinations by taxing authorities. The Company is not currently under any income tax examinations. Due to the Company's net operating losses, all tax years generally remain open in each jurisdiction.

There have been no unrecognized tax benefits since the Company's inception. The Company's policy is to record estimated interest and penalties related to the underpayment of income taxes as a component of its income tax provision. As of December 31, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions and since inception, no amounts have been recognized in the Company's consolidated statements of operations and comprehensive loss.

Under the provisions of Section 382 of the Internal Revenue Code of 1986, as amended, 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 and tax credits, which could be used annually to offset future taxable income.

15. Commitments and Contingencies

Operating Leases

The Company has entered into arrangements for leases of office space; see Note 6, "Leases," for details.

License and Option Agreements

The Company entered into licenses agreements under which it is obligated to make fixed and contingent payments; see Note 9 "License and Option Agreements," for details.

Other Contracts

The Company has entered into agreements with certain vendors for the provision of services that the Company is not contractually able to terminate for convenience and thereby avoid any and all future obligations to the vendors. Under such agreements, the Company is contractually obligated to make certain minimum payments to the vendors, with the exact amounts in the event of termination to be based on the timing of the termination and the exact terms of the agreement.

15. Commitments and Contingencies (Continued)

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its financial statements as of December 31, 2023.

Litigation and Other Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which the Company is focused.

16. Employee Benefit Plans

Effective June 2020, the Company adopted the Zenas BioPharma 401(k) Plan (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. Since inception of the 401(k) Plan and through the year ended December 31, 2023, the Company has not made any contributions to the 401(k) Plan.

17. Related Party Transactions

As further described above in Note 9, "License and Option Agreements," the Company has obtained exclusive, worldwide licenses from Xencor to research, develop, manufacture, market and sell four antibody product candidates pursuant to two license agreements. The Company has concluded that Xencor is a related party, because as initial consideration for the 2020 Xencor Agreement, the Company issued 5,041,542 shares of its Series A Preferred Stock to Xencor during the year ended December 31, 2020. In April 2023, Xencor elected to receive payment for a development milestone in the form of the Company's Series B Preferred Stock and the Company issued 4,189,955 shares of Series B Preferred Stock as payment for the development milestone in June 2023. As of that date, Xencor's equity interest in Zenas was approximately 24% of all outstanding shares of all classes of the Company's stock (common stock and convertible preferred stock). The Company recorded an immaterial amount to general and administrative expenses in the consolidated statements of operations and comprehensive loss during each of the years ended December 31, 2023 and 2022, relating to reimbursable patent-related costs owed to Xencor.

As further described above in Note 9, "License and Option Agreements," the Company has obtained a license from Viridian to research, develop, manufacture, market and sell an antibody product candidate in China. The Company has concluded that Viridian is a related party because Fairmount Funds Management LLC owns more than 5% of capital stock of the Company, has a seat on the Board and is also a 10% or greater stockholder of Viridian and has two seats on Viridian's board of directors. As initial consideration for this license, the Company issued 38,707 shares of its common stock to Viridian during the year ended December 31, 2020. As of that date, Viridian's equity interest in the Company was approximately 1% of all outstanding shares of all classes of the Company's stock (assuming conversion of all outstanding shares of convertible preferred stock).

17. Related Party Transactions (Continued)

As further described above in Note 9, "License and Option Agreements", the Company has obtained an exclusive option to negotiate and enter into exclusive license agreements with Dianthus for the rights (in the Zenas Territories only) to either or both of two antibody product candidates. The Company has concluded that Dianthus is a related party because the Company's Chair of the Board is a member of the board of directors of Dianthus. As initial consideration for this license, the Company issued 18,063 shares of its common stock to Dianthus during the year ended December 31, 2020. As of that date, Dianthus's equity interest in the Company was approximately 0.5% of all outstanding shares of all classes of the Company's stock (assuming conversion of all outstanding shares of convertible preferred stock).

18. Subsequent Events

The Company assessed subsequent events through May 15, 2024, the date that these consolidated financial statements were issued, and through September 6, 2024, for the effects of the reverse stock split described below.

(A) 2020 Plan Amendment and Option Grants

On May 3, 2024, the Board approved an increase in the number of shares of common stock authorized for issuance under the 2020 Plan from 2,560,401 shares to 4,424,044 shares. This increase was approved by the Company's stockholders on May 3, 2024. In connection with the increase, the Company granted options to purchase 1,897,340 shares of the Company's common stock on May 9, 2024 at an exercise price of $9.99 per share.

(B) Series C Preferred Stock and BMS Note Conversion

On May 3, 2024, the Company entered into a Series C Preferred Stock purchase agreement ("Series C Agreement") whereby the Company issued 103,990,553 shares of Series C Preferred Stock at a price of $1.72131 per share for gross proceeds of $179.0 million. In connection with the issuance of the Series C Preferred Stock, which was considered a BMS Qualified Financing as further described above in Note 3, "Fair Value Measurement," the BMS Note converted into 12,284,686 shares of Series C Preferred Stock, thereby making the total Series C issuance equal to 116,275,239 shares. The Certificate of Incorporation was amended and restated in connection with the execution of the Series C Agreement. In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company, a deemed liquidation event, or a dividend distribution, holders of Series C Preferred Stock have preference above all other classes of outstanding stock. All other rights and preferences of the Series C Preferred Stock are substantially the same as the rights and preferences of the Company's existing classes of Preferred Stock, as further described in Note 10, "Convertible Preferred Stock".

(C) Reverse Stock Split

On September 5, 2024, the Company effected a 1-for-8.6831 reverse stock split of the Company's issued and outstanding common stock and adjusted the conversion ratio of the Company's outstanding convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split and the adjustment of the preferred stock conversion ratios.

(D) 2024 Equity Plans (unaudited)

2024 Equity Incentive Plan

On September 3, 2024, the Board adopted the 2024 Equity Incentive Plan (the "2024 Plan"), which will become effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The 2024

18. Subsequent Events (Continued)

Plan provides for the award of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, unrestricted stock, restricted stock units and other stock-based awards.

The number of shares initially reserved for issuance under the 2024 Plan will be the number of shares of common stock equal to 12% of the number of shares of common stock issued and outstanding as of immediately following the consummation of the Company's proposed IPO, not to exceed 5,657,830 shares, plus (i) the number of shares that remain available for issuance under the 2020 Plan at the time the 2024 Plan becomes effective and (ii) the number of shares of common stock underlying awards granted under the 2020 Plan that, after the effective date of the 2024 Plan, expire or become unexercisable without delivery of shares, are forfeited to, or repurchased for cash by, the Company, are settled in cash or otherwise become available again for grant under the 2020 Plan, in each case, in accordance with the terms of the 2024 Plan.

In addition, the number of shares reserved for issuance under the 2024 Plan will increase automatically on the first day of each fiscal year commencing on January 1, 2025 through January 1, 2034 by the number of shares equal to the lesser of (a) five percent of the aggregate number of shares of common stock outstanding as of such date, and (b) a number of shares as may be determined by the Board on or prior to such date.

2024 Employee Stock Purchase Plan

On September 3, 2024, the Board adopted the 2024 Employee Stock Purchase Plan (the "ESPP"), which will become effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The Company will initially reserve the number of shares equal to one percent of the number of shares of common stock issued and outstanding as of immediately following the consummation of the Company's proposed IPO. The number of shares reserved for sale under the ESPP will increase automatically on the first day of each fiscal year commencing on January 1, 2025 through January 1, 2034, by the number of shares equal to the lesser of (a) one percent of the aggregate number of shares of common stock outstanding as of such date, and (b) a number of shares as may be determined by the Board on or prior to such date, up to a maximum of 1,000,000 shares in the aggregate per year.

Zenas BioPharma, Inc.

Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 183,930	$ 56,857
Prepaid expenses and other current assets	4,670	2,947
Total current assets	188,600	59,804
Property and equipment, net	182	193
Operating lease right-of-use assets, net	524	821
Restricted cash	88	86
Other assets	10,558	7,276
Total assets	$ 199,952	$ 68,180
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable (includes $37 and $21 owed to related parties, respectively)	$ 8,358	$ 5,396
Accrued expenses (includes $1,751 and $404 owed to related parties, respectively)	29,726	17,306
Operating lease liabilities, current	494	556
Other current liabilities	530	—
Total current liabilities	39,108	23,258
Operating lease liabilities, non-current	14	257
Convertible notes, at fair value	—	20,300
Total liabilities	39,122	43,815
Commitments and contingencies (Note 13)		
Convertible preferred stock:		
Series Seed convertible preferred stock, par value $0.0001 per share; 1,785,714 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023; liquidation preference of $1,000 as of June 30, 2024	956	956
Series A convertible preferred stock, par value $0.0001 per share; 17,589,380 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023; liquidation preference of $56,071 as of June 30, 2024	55,840	55,840
Series B convertible preferred stock, par value $0.0001 per share; 81,242,587 shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023; liquidation preference of $193,898 as of June 30, 2024	193,290	193,290
Series C convertible preferred stock, par value $0.0001 per share; 116,275,239 and no shares authorized, issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; liquidation preference of $200,146 as of June 30, 2024	199,526	—
Stockholders' deficit:		
Common stock, par value $0.0001 per share; 294,784,925 and 175,000,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively; 1,578,372 and 1,576,854 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	7,294	4,645
Accumulated other comprehensive income	104	37
Accumulated deficit	(296,180)	(230,403)
Total stockholders' deficit	(288,782)	(225,721)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 199,952	$ 68,180

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

Zenas BioPharma, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Six Months Ended June 30,	
	2024	2023
Operating expenses:		
Research and development (includes $1,872 and $2,117 from related parties, respectively)	$ 56,452	$ 30,262
General and administrative (includes $0 and $5 from related parties, respectively)	10,828	7,729
Acquired in-process research and development	—	10,000
Total operating expenses	67,280	47,991
Loss from operations	(67,280)	(47,991)
Other income (expense), net:		
Fair value adjustments to convertible notes	(846)	—
Other income (expense), net	2,349	(153)
Total other income (expense), net	1,503	(153)
Net loss attributable to common stockholders	$ (65,777)	$ (48,144)
Net loss per share attributable to common stockholders–basic and diluted	$ (42.15)	$ (31.62)
Weighted-average common stock outstanding–basic and diluted	1,560,661	1,522,552
Comprehensive loss:		
Net loss attributable to common stockholders	(65,777)	(48,144)
Other comprehensive income:		
Foreign currency translation adjustment	67	156
Comprehensive loss	$ (65,710)	$ (47,988)

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

Zenas BioPharma, Inc.

Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit
(Unaudited)
(in thousands, except share data)

	Convertible Preferred Stock								Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Series Seed		Series A		Series B		Series C							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	1,785,714	$ 956	17,589,380	$ 55,840	81,242,587	$ 193,290	—	$ —	1,576,854	$ —	$ 4,645	$ 37	$ (230,403)	$ (225,721)
Repurchase of unvested restricted stock awards	—	—	—	—	—	—	—	—	(21,172)	—	—	—	—	—
Exercises of common stock options	—	—	—	—	—	—	—	—	22,690	—	166	—	—	166
Issuance of Series C convertible preferred stock, net of issuance costs of $619	—	—	—	—	—	—	116,275,239	199,526	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,483	—	—	2,483
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(65,777)	(65,777)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	67	—	67
Balance at June 30, 2024	1,785,714	$ 956	17,589,380	$ 55,840	81,242,587	$ 193,290	116,275,239	$199,526	1,578,372	$ —	$ 7,294	$ 104	$ (296,180)	$ (288,782)

	Convertible Preferred Stock						Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Series Seed		Series A		Series B							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	1,785,714	$ 956	17,589,380	$ 55,840	77,052,632	$ 183,290	1,549,275	$ —	$ 1,034	$ (41)	$ (193,279)	$ (192,286)
Exercises of common stock options	—	—	—	—	—	—	18,943	—	66	—	—	66
Issuance of Series B convertible preferred stock as payment of Xencor milestone	—	—	—	—	4,189,955	10,000	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,356	—	—	1,356
Net loss	—	—	—	—	—	—	—	—	—	—	(48,144)	(48,144)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	156	—	156
Balance at June 30, 2023	1,785,714	$ 956	17,589,380	$ 55,840	81,242,587	$ 193,290	1,568,218	$ —	$ 2,456	$ 115	$ (241,423)	$ (238,852)

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

Zenas BioPharma, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (65,777)	$ (48,144)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	10,000
Depreciation expense	68	57
Stock-based compensation expense	2,483	1,356
Change in fair value of convertible notes	846	—
Non-cash lease expense	298	398
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,315)	(1,697)
Accounts payable	2,927	(2,198)
Accrued expenses	10,184	(6,357)
Operating lease liabilities	(305)	(390)
Other current liabilities	530	—
Net cash used in operating activities	(50,061)	(46,975)
Cash flows from investing activities:		
Purchases of property and equipment	(57)	—
Net cash used in investing activities	(57)	—
Cash flows from financing activities:		
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	178,381	—
Payment of initial public offering costs	(1,422)	—
Proceeds from exercise of stock options	166	66
Net cash provided by financing activities	177,125	66
Effect of exchange rate changes on cash and restricted cash	68	161
Net increase (decrease) in cash and restricted cash	127,075	(46,748)
Cash and restricted cash at beginning of period	56,943	67,295
Cash and restricted cash at end of period	$ 184,018	$ 20,547
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of BMS Note into Series C convertible preferred stock	$ 21,146	$ —
Deferred offering costs in accounts payable and accrued expenses	$ 2,268	$ —
Reconciliation of cash and restricted cash:		
Cash	$ 183,930	$ 20,461
Restricted cash	88	86
Total cash and restricted cash	$ 184,018	$ 20,547

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

Zenas BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements

1. Nature of Business

Organization

Zenas BioPharma, Inc. ("Zenas" or the "Company") was incorporated in November 2019 as Zenas BioPharma (Cayman) Limited, an exempted company incorporated in the Cayman Islands with limited liability, and commenced operations in 2020. On August 2, 2023, the Company (then known as Zenas BioPharma (Cayman) Limited ("Zenas Cayman")) de-registered from the Cayman Islands and registered by way of continuation in the State of Delaware. Zenas is a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies for patients in need. The Company's primary focus is to transform the lives of patients with unmet medical needs by developing and commercializing immune-based therapies. The Company has in-licensed and is developing several product candidates for the treatment of various auto-immune and rare diseases. The Company is headquartered in Waltham, Massachusetts and operates in one segment, which is the business of acquiring and developing immune-based therapies for potential commercialization.

The Company's consolidated financial statements include the accounts of its wholly owned subsidiaries which include Zenas BioPharma (HK) Limited ("Zenas HK"), a Zenas BioPharma (USA) LLC ("Zenas US"), Shanghai Zenas Biotechnology Co. Limited ("Zenas China"), Zenas Securities Corporation, and Zenas BioPharma GmbH.

Since its inception, the Company has devoted its efforts principally to research and development and raising capital. The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, completing preclinical studies and clinical trials, obtaining regulatory approval for product candidates, market acceptance of products, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, and the ability to raise additional capital to fund operations. The Company's revenues to date have been generated from payments received under the Company's license agreement with Bristol-Myers Squibb Company ("BMS") (see Note 7). The Company has not generated any revenue from product sales since inception, and its product candidates currently under development will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization.

Redomicile

On August 2, 2023, Zenas Cayman de-registered from the Cayman Islands and registered by way of continuation in the State of Delaware, whereby the Company filed a Certificate of Domestication to incorporate in the State of Delaware (the "Redomicile") under the name of Zenas BioPharma, Inc. In connection with the Redomicile, (i) the existing shares of convertible preferred stock and ordinary stock holders of Zenas Cayman were automatically converted into shares of Zenas Cayman for the same number and classes of common stock and convertible preferred stock, as applicable, of the Company on a one-to-one basis, with rights substantially similar to the exchanged shares of Zenas Cayman; and (ii) all outstanding stock awards of Zenas Cayman under the Zenas BioPharma (Cayman) Limited 2020 Equity Incentive Plan (the "2020 Plan") exercisable for ordinary stock, were automatically converted into outstanding awards of the Company, exercisable for common stock, with no other changes to the underlying terms of the awards.

Upon completion of the Redomicile and name change, the historical consolidated financial statements of Zenas Cayman became the historical consolidated financial statements of Zenas BioPharma, Inc. For the period ended June 30, 2023, the ordinary stock is referred to as common stock throughout the condensed consolidated financial statements and related footnotes for consistency with the presentation as of June 30, 2024 and December 31, 2023. There was no impact on the condensed consolidated financial statements as a result of the Redomicile and name change.

Zenas BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements

1. Nature of Business (Continued)

Going Concern

The Company has incurred operating losses and negative cash flows since its inception, including net losses of $65.8 million and $48.1 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, the Company had an accumulated deficit of $296.2 million. The Company has not generated any product revenue since inception and has relied on its ability to fund its operations through collaboration arrangements, private equity and convertible debt financings. Management expects operating losses and negative operating cash flows to continue for the foreseeable future as it continues its research and development efforts, advances its product candidates through preclinical and clinical development, enhances its platforms and programs, expands its product pipeline, seeks regulatory approval, prepares for commercialization, hires additional personnel, protects its intellectual property and grows its business. As the Company continues to incur losses, transitioning to profitability is dependent upon the successful development, approval, and commercialization of its product candidates and the generation of sufficient revenues to support its cost structure.

The Company expects that its existing cash of $183.9 million as of June 30, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2025, which is at least twelve months from the date these condensed consolidated financial statements were issued. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company will need additional financing to support its continuing operations and to pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of private equity financings, debt financings or other capital sources, including collaborations with other companies or other strategic transactions and licensing agreements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed could have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the completion of an IPO, the Company's outstanding convertible preferred stock will convert into shares of common stock (see Note 9).

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in Note 2, "Summary of Significant Accounting Policies," in the audited consolidated financial statements for the years ended December 31, 2023 and 2022 included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies, except as noted below.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2024, and the condensed consolidated statements of operations and comprehensive loss, statements of changes in convertible preferred stock and stockholders' deficit and statements of cash flows for the six months ended June 30, 2024 and 2023 are unaudited. The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial position as of June 30, 2024 and the results of its operations and its cash flows for the six months ended June 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the

2. Summary of Significant Accounting Policies (Continued)

six months ended June 30, 2024 and 2023 are also unaudited. The results for the six months ended June 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, or for any other subsequent period.

Deferred Offering Costs

The Company capitalizes legal, professional accounting and other third-party fees that are directly associated with the planned IPO and other in-process equity financings as other non-current assets until such financings are consummated. After consummation of the IPO or equity financing, these costs will be recorded in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. If the Company terminates its plan for an IPO or equity financing, any costs deferred will be expensed immediately. As of June 30, 2024 and December 31, 2023, the Company had $3.7 million and $1.4 million in deferred offering costs, respectively, which were included in other assets.

3. Fair Value Measurement

The Company had no assets or liabilities utilizing fair value measurements as of June 30, 2024. The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

		December 31, 2023			
Description	**Balance Sheet Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Liabilities:					
BMS Note	Non-current liability	$ —	$ —	$ 20,300	$ 20,300
		$ —	$ —	$ 20,300	$ 20,300

During the six months ended June 30, 2024 and year ended December 31, 2023, there were no transfers between levels. The Company uses the carrying amounts of its prepaid expenses and other current assets, accounts payable and accrued expenses to approximate their fair value due to the short-term nature of these amounts.

Convertible Notes

BMS Note

In August 2023, the Company entered into a $20.0 million convertible promissory note agreement with BMS (the "BMS Note") in connection with its strategic license and collaboration agreement with BMS (the "BMS Agreement") (see Note 7). The BMS Note has a stated interest rate of 8.5% per annum and a maturity date of August 30, 2026, and contains various conversion features including mandatory conversion upon the occurrence of a qualified financing event, IPO, reverse merger, or special purpose acquisition company transaction and conversion at the option of BMS upon the occurrence of a non-qualified financing event. If the Company issues and sells its convertible preferred stock to accredited investors with total gross proceeds equal to at least $70.0 million (a "BMS Qualified Financing"), the outstanding principal and accrued interest of the BMS Note shall automatically convert into equity securities sold in the BMS Qualified Financing at a conversion price equal (i) to the outstanding principal and accrued interest under the BMS Note divided by (ii) the lowest cash price paid per equity security. Similarly, automatic conversion of the BMS Note upon an IPO would result in a conversion price equal to (i) the outstanding principal and accrued interest under the BMS Note divided by (ii) the price per share listed in the registration statement to be paid by the investors for the Company's common stock. The Company elected the fair value option to account for the BMS Note. Changes in fair value at every reporting date are recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

3. Fair Value Measurement (Continued)

The BMS Note is classified as a liability on the Company's condensed consolidated balance sheet as of December 31, 2023 and was initially recorded at fair value. The fair value of the BMS Note was estimated based on significant inputs not observable in the market, representing a Level 3 measurement within the fair value hierarchy. The Company used a scenario-based analysis to incorporate estimates and assumptions concerning the Company's prospects and market indications into a model to estimate the fair value of the BMS Note. The most significant estimates and assumptions used as inputs were those concerning the timing and probability of possible scenarios for conversion or settlement of the BMS Note and the discount rate.

On May 3, 2024, the Company issued and sold Series C convertible preferred stock ("Series C Preferred Stock"), which was deemed to be a BMS Qualified Financing, as described above, and resulted in the outstanding BMS Note plus accrued interest being automatically converted into 12,284,686 shares of Series C Preferred Stock (see Note 9). Immediately prior to settlement, the BMS Note was remeasured to fair value utilizing the fair value of the shares of Series C Preferred Stock for which the BMS Note converted into. The conversion of the BMS Note into shares of Series C Preferred Stock was accounted for as an extinguishment. Upon extinguishment, no gain or loss was recognized. The Company recorded a $0.9 million change in fair value of the BMS Note as a component of other income (expense), net in the Company's condensed consolidated statements of operations and comprehensive loss for the six months ended June 30, 2024. There were no liabilities with significant unobservable inputs outstanding as of June 30, 2023.

The table below presents changes in the Company's liabilities with significant unobservable inputs (Level 3 liabilities) during the six months ended June 30, 2024 (in thousands):

	Convertible notes
Balance as of December 31, 2023	$ 20,300
Change in fair value of BMS Note	846
Issuance of Series C Preferred Stock in exchange for BMS Note	(21,146)
Balance as of June 30, 2024	$ —

4. Other Assets

Other assets consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid clinical expenses	$ 6,771	$ 5,788
Deferred offering costs	3,690	1,388
Other	97	100
Total other assets	$ 10,558	$ 7,276

Zenas BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Employee compensation and benefits	$ 3,842	$ 5,122
External research, development and manufacturing expenses	22,458	9,398
Professional and consultant fees	3,017	2,379
Income taxes payable	—	301
Other	409	106
Total accrued expenses	$ 29,726	$ 17,306

6. Leases

On September 8, 2021, Zenas US entered into a lease agreement for office space in Waltham, Massachusetts (the "Waltham Lease"), commencing on March 1, 2022. The Waltham Lease was classified as an operating lease, and has a lease term of 3.3 years with total fixed payments of approximately $1.8 million over that period. Zenas US has an irrevocable letter of credit agreement for the benefit of its landlord for the Waltham Lease in the amount of $0.1 million.

On June 28, 2022, Zenas China entered into a lease agreement for office space in Shanghai, China (the "Shanghai Lease"), commencing on September 10, 2022. The Shanghai Lease has a lease term of 3.0 years with total fixed payments of $0.8 million over that period, and an option to extend the lease term for an additional three years.

For the six months ended June, 2024 and 2023, the total lease cost for operating leases (recorded in general and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive loss) was $0.4 million and $0.5 million, respectively.

Maturities of the operating lease liabilities as of June 30, 2024 are as follows (in thousands):

Fiscal Year	Amount
2024 (remaining six months)	$ 401
2025	434
Total future minimum lease payments	835
Less: imputed interest	(327)
Total operating lease liabilities	$ 508

7. Collaboration Revenue

In August 2023, the Company entered into a license agreement with Bristol-Myers Squibb (the "BMS Agreement"), under which the Company granted BMS an exclusive license to (i) develop, manufacture (subject to the Company's rights to be the exclusive manufacturer for BMS for a certain period of time), commercialize or otherwise exploit obexelimab and any biological product (irrespective of presentations, formulations or dosages) containing obexelimab but not any of the Company's other proprietary active ingredient (the "BMS Product") into Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia (collectively, the "BMS Territory") and (ii) develop and manufacture obexelimab and the BMS Product outside the BMS Territory provided that obexelimab and the BMS Product are solely used in the BMS Territory. The details of the BMS Agreement are further described in Note 8, "Collaboration Revenue," in the audited consolidated financial statements for the years ended December 31, 2023 and 2022, included elsewhere in this prospectus. Since the

7. Collaboration Revenue (Continued)

date of the audited consolidated financial statements for the years ended December 31, 2023 and 2022, there have been no changes to the BMS Agreement.

Pursuant to the BMS Agreement, BMS paid the Company a one-time non-refundable upfront cash payment of $50.0 million, which was determined to be the transaction price. The Company is entitled to receive further separate development, regulatory, and sales milestone payments from BMS of up to approximately $149.5 million if certain milestones are successfully achieved. The Company is also eligible to receive tiered high single-digit to low double-digit royalties on net sales in the BMS Territory, subject to specified reductions. As of June 30, 2024, no milestones were achieved or deemed probable of achievement, and as such, all remaining milestones remained fully constrained and excluded from the transaction price.

The Company and BMS collaborate on the performance of the ongoing Phase 3 clinical study of obexelimab in the IgG4-RD indication. BMS will fund their pro rata share of the total global study costs up to a specified percentage of the patients enrolled in the study from the BMS Territory. Should the percentage of patients from the BMS Territory fall below the specified percentage, BMS's funding would proportionately decrease. The global development activities under the agreement do not represent a transaction with a customer and reimbursement payments received by the Company for global development activities are accounted for as a reduction of the related research and development expenses. The Company recorded $2.2 million as a reduction to research and development expense during the six months ended June 30, 2024, with a $1.2 million receivable included in prepaid expenses and other current assets, on the Company's condensed consolidated balance sheet as of June 30, 2024.

The Company satisfied the performance obligation through delivery of the license and initial technology transfer prior to December 31, 2023 and recognized the upfront payment of $50.0 million as revenue during the year ended December 31, 2023. The Company recognized no revenue during each of the six months ended June 30, 2024 and 2023.

8. License and Option Agreements

Prior to 2024, the Company entered into license and option agreements with various companies in the biotechnology and life sciences industry to in-license certain technologies for the Company's use. The Company's agreements are disclosed in Note 9, "License and Option Agreements," in the audited consolidated financial statements for the years ended December 31, 2023 and 2022, included elsewhere in this prospectus. Since the date of the audited consolidated financial statements for the years ended December 31, 2023 and 2022, there have been no changes to these agreements.

Xencor, Inc.

2020 Xencor Agreement

In September 2020, the Company entered into the 2020 Xencor Agreement, under which the Company is obligated to reimburse Xencor for third-party costs incurred for certain patent filings, prosecution and maintenance as further specified in the 2020 Xencor Agreement. During the six months ended June 30, 2024, the Company incurred no such reimbursable costs. During the six months ended June 30, 2023, the Company incurred less than $0.1 million of such reimbursable costs, which are included in general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

2021 Xencor Agreement

In May 2021, the Company entered into the 2021 Xencor Agreement, through which they obtained an exclusive, royalty-bearing, sublicensable worldwide license to research, develop, manufacture, market and sell obexelimab. In April 2023, the Company incurred a $10.0 million development milestone pursuant to the 2021 Xencor Agreement, which Xencor elected to receive in the form of the Company's Series B convertible

8. License and Option Agreements (Continued)

preferred stock ("Series B Preferred Stock). See Note 9, "Convertible Preferred Stock," for details. The milestone was recorded as acquired in-process research and development expense in the Company's condensed consolidated statements of operations and comprehensive loss during the six months ended June 30, 2023.

Dianthus Therapeutics Inc.

In September 2020, the Company entered into the Dianthus Option Agreement, under which Dianthus will notify the Company when it has identified each of two antibody product candidates, and the Company will then have sixty (60) days to notify Dianthus if the Company intends to exercise each of the options. In October 2021, the Company notified Dianthus of its intention to exercise its option to ZB005 (also known as DNTH103). As of June 30, 2024, Dianthus had not notified the Company of its identification of the second antibody product candidate.

During the six months ended June 30, 2024 and 2023, the Company incurred $2.8 million and $2.0 million of reimbursable expenses, respectively, which are recorded within research and development expenses in the condensed consolidated statements of operations and comprehensive loss. Of these amounts, less than $0.1 million and $1.7 million were recorded in accounts payable and accrued expenses, respectively, on the Company's condensed consolidated balance sheet as of June 30, 2024. As of December 31, 2023, less than $0.1 million and $0.4 million were recorded in accounts payable and accrued expenses, respectively, on the Company's consolidated balance sheet.

Viridian Therapeutics, Inc.

In October 2020, the Company entered into the Viridian Agreement to obtain an exclusive, royalty-bearing, sublicensable license to research, develop, manufacture, market and sell certain antibody product candidates based on Viridian's proprietary technology. The Company's license rights are limited to non-oncology indications and are limited to China, Hong Kong, Macau and Taiwan (the "Zenas Territories"). Viridian retains its rights to develop and commercialize such product candidates outside of the Zenas Territories. The Company is obligated to make development milestone payments to Viridian, totaling up to $12.0 million, based on achievement of each of the specified milestone events. During each of the six months ended June 30, 2024 and 2023, the Company incurred and paid no milestones to Viridian. As of June 30, 2024, Viridian had not notified the Company of any additional antibody product candidate.

During each of the six months ended June 30, 2024 and 2023, the Company recognized $0.1 million of expense related to amounts reimbursed to Viridian for manufacturing activities, which were recorded in research and development expenses in the condensed consolidated statement of operations. Of these amounts, $0.1 million was recorded in accrued expenses and no related amount was recorded in accounts payable on the Company's condensed consolidated balance sheet as of June 30, 2024. As of December 31, 2023, less than $0.1 million was included in accrued expenses and no amount was included in accounts payable on the Company's consolidated balance sheet. In addition, Viridian has agreed to reimburse the Company for certain services it performs on Viridian's behalf, with reimbursements being recorded as a reduction of research and development expense. Such amounts have been and are expected to be immaterial.

9. Convertible Preferred Stock

In September 2020, the Company issued and sold 1,785,714 shares of Series Seed convertible preferred stock ("Series Seed Preferred Stock") in a private financing transaction, at a purchase price of $0.56 per share, for total net cash proceeds of $1.0 million.

In November 2020, the Company issued 5,041,542 shares of Series A convertible preferred stock ("Series A Preferred Stock") to Xencor as initial consideration for the 2020 Xencor Agreement. Also in November 2020, the Company issued and sold 12,547,838 shares of Series A Preferred Stock in a private financing transaction, at a purchase price of $3.1878 per share, for total net cash proceeds of $39.9 million.

Zenas BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements

9. Convertible Preferred Stock (Continued)

In November 2022, the Company issued and sold 25,139,732 shares of Series B Preferred Stock in a private financing transaction, at a purchase price of $2.38666 per share, for total net cash proceeds of $59.4 million. Concurrent with the issuance and sale of the Series B Preferred Stock, which was deemed to be a qualified financing as defined in the convertible note agreement and resulted in the principal plus accrued interest being automatically converted into Series B Preferred Stock, the outstanding convertible notes were exchanged for 37,471,107 shares of Series B Preferred Stock. At the same time, the Xencor Warrant, which was issued as initial consideration for the 2021 Xencor Agreement, was deemed exercised for 14,441,793 shares of Series B Preferred Stock.

In April 2023, the Company incurred a $10.0 million development milestone pursuant to the 2021 Xencor Agreement. Xencor elected to receive payment in the form of the Company's Series B Preferred Stock and the Company issued 4,189,955 shares of Series B Preferred Stock as payment for the development milestone in June 2023.

In May 2024, the Company issued and sold 103,990,553 shares of Series C Preferred Stock in a private financing transaction, at a purchase price of $1.72131 per share, for total net cash proceeds of $178.4 million. Concurrent with the issuance and sale of the Series C Preferred Stock, which was deemed to be a BMS Qualified Financing as defined above in Note 3, "Fair Value Measurements," the principal plus accrued interest of the BMS Note was automatically converted into 12,284,686 shares of Series C Preferred Stock, thereby making the total Series C issuance equal to 116,275,239 shares.

Upon the issuance of Series Seed, Series A, Series B, and Series C Preferred Stock (collectively "Preferred Stock"), the Company assessed the embedded conversion and liquidation features of the shares and determined that such features did not require the Company to separately account for these features.

Preferred Stock consisted of the following (in thousands, except share amounts):

	June 30, 2024				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series Seed Preferred Stock	1,785,714	1,785,714	$ 956	$ 1,000	205,653
Series A Preferred Stock	17,589,380	17,589,380	55,840	56,071	2,025,699
Series B Preferred Stock	81,242,587	81,242,587	193,290	193,898	9,356,392
Series C Preferred Stock	116,275,239	116,275,239	199,526	200,146	13,390,971
Total	216,892,920	216,892,920	$ 449,612	$ 451,115	24,978,715

	December 31, 2023				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series Seed Preferred Stock	1,785,714	1,785,714	$ 956	$ 1,000	205,653
Series A Preferred Stock	17,589,380	17,589,380	55,840	56,071	2,025,699
Series B Preferred Stock	81,242,587	81,242,587	193,290	193,898	9,356,392
Total	100,617,681	100,617,681	$ 250,086	$ 250,969	11,587,744

The holders of preferred stock have the following rights, preferences and privileges:

Voting

The holder of each share of Preferred Stock is entitled to one vote for each share of common stock into which it would convert and to vote with the common stock on all matters.

9. Convertible Preferred Stock (Continued)

Conversion

Each share of convertible preferred stock shall be automatically converted into a share of common stock, upon affirmative vote of majority of the holders of each series or upon the closing of an initial public offering of the Company's common stock which results in a specified minimum amount of gross cash proceeds. The conversion ratio is initially one share of common stock for each share of convertible preferred stock and shall be adjusted in the event of a split or reverse split of the Company's common stock, an issuance or declaration of dividends to holders of the Company's common stock, a reorganization or merger transaction, or certain issuances of shares of common stock which are dilutive to holders of the Company's preferred stock. Holders of preferred stock have the right to one vote for each share of the Company's common stock into which such holder's shares of preferred stock could then convert. See Note 16 for information on the reverse stock split that adjusted the preferred stock conversion ratio.

Dividends

Holders of Series C Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series C Preferred Stock issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). If any assets or funds remain after dividends have been distributed to holders of Series C Preferred Stock, holders of Series B Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series B Preferred Stock issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). If any assets or funds remain after dividends have been distributed to holders of Series B Preferred Stock, holders of Series A Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series A issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). If any assets or funds remain after dividends have been distributed to holders of Series A Preferred Stock, holders of Series Seed Preferred Stock will be entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series Seed issue price, payable in preference to and satisfied before any dividend or distribution on any other class or series of the Company's shares (except for certain exempted distributions). The right to receive dividends on shares of all series of preferred stock is not cumulative, and no such right accrues to holders of such shares. There have been no dividends declared or paid as of June 30, 2024.

Liquidation Preference

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, holders of Series C Preferred Stock prior and in preference to any distribution to holders of Series B Preferred Stock, Series A Preferred Stock, Series Seed Preferred Stock and common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared but unpaid dividends. After full payment to holders of Series C Preferred Stock, holders of Series B Preferred Stock prior and in preference to any distribution to holders of Series A Preferred Stock, Series Seed Preferred Stock and common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared and unpaid dividends. After full payment to holders of Series B Preferred Stock, holders of Series A Preferred Stock prior and in preference to any distribution to holders of Series Seed Preferred Stock and common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared and unpaid dividends. After full payment to holders of Series C Preferred Stock, Series B Preferred Stock, and Series A Preferred Stock, holders of Series Seed Preferred Stock prior and in preference to any distribution to holders of common shares, would be entitled to be paid the issue price they originally paid to acquire their shares, plus any declared and unpaid dividends. Any remaining amounts after payment to holders of preferred stock, would be paid to holders of common shares. A deemed liquidation event is defined as any merger or consolidation of the Company (and any of its subsidiaries) or other reorganization

9. Convertible Preferred Stock (Continued)

resulting in loss of more than 50% voting power; the sale, transfer, lease or other disposition of all or substantially all of the Company's assets; or the exclusive licensing of all or substantially all of the Company's intellectual property.

Redemption

The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a Liquidation Event.

10. Common Stock

In August 2023, all outstanding shares of ordinary stock of Zenas Cayman were automatically converted into shares of common stock upon the Redomicile and incorporation in the State of Delaware as Zenas BioPharma, Inc. In May 2024, the Company executed the fourth amended and restated certificate of incorporation ("A&R COI"), whereby the Company increased the shares of common stock it was authorized to issue. The Company was authorized to issue 294,784,925 shares and 175,000,000 shares of $0.0001 par value common stock as of June 30, 2024 and December 31, 2023, 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 preference of the holders of the preferred stock set forth above.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of convertible preferred stock.

The Company had reserved the following shares of common stock for the potential conversion of outstanding convertible preferred stock and exercise of stock options:

	June 30, 2024	December 31, 2023
Conversion of outstanding shares of convertible preferred stock	24,978,715	11,587,744
Options to purchase common stock	4,270,097	2,382,933
Remaining shares reserved for future issuance	35,745	60,792
Total	29,284,557	14,031,469

11. Stock-Based Compensation

2020 Plan

On August 21, 2020, the Company's sole director and member approved the 2020 Plan. The 2020 Plan initially allowed the Company to grant awards for up to 36,162 shares of the Company's common stock. The 2020 Plan allows for grants of stock options, restricted stock awards ("RSAs"), restricted stock units, and other stock-based awards to employees, officers, directors and consultants of the Company and its subsidiaries. The exercise price per share of stock options granted under the 2020 Plan must be no less than the fair value of a share of the Company's common stock on the grant date. If the Company's common stock is traded on a national securities exchange, then fair value is based on the stock's closing price as reported by that exchange. Otherwise, fair value is determined by the Board (or its Compensation Committee), consistent with the applicable rules of the U.S. Internal Revenue Code of 1986 (the "IRC"), or any successor statute.

11. Stock-Based Compensation (Continued)

Terms of stock award agreements, including vesting requirements, are determined by the Board, subject to the provisions of the 2020 Plan. The Company may grant stock awards to employees, non-employee consultants, and members of the Board, and all grantees must be providing services to the Company or its subsidiaries on the date of grant. Since inception of the 2020 Plan, the Company has granted RSAs and stock options. RSAs and stock options granted by the Company generally vest over four years, with 25% of the total shares granted vesting on the anniversary of the vesting commencement date and the remaining 75% vesting in equal monthly installments over the subsequent thirty-six (36) months.

In August 2023, as part of the Redomicile, the 2020 Plan was transferred from Zenas Biopharma Cayman Limited to Zenas Biopharma, Inc and was renamed the Zenas BioPharma, Inc. 2020 Equity Incentive Plan. Upon the transfer, there was no legal modification to the outstanding RSAs and stock options, and no changes to any existing terms of the outstanding awards (exercise price, term, vesting, etc.).

The 2020 Plan was subsequently amended by the Board numerous times, most recently in May 2024, whereby the Board approved an increase in the number of shares of common stock authorized for issuance from 2,560,401 shares to 4,424,044 shares. Of the 4,424,044 shares, 35,745 shares of common stock remain available for future grant under the 2020 Plan as of June 30, 2024.

Restricted Stock Awards

The following table presents a summary of the Company's RSA activity and related information:

	Number of Shares	Weighted-Average Grant-Date Fair Value
Unvested as of December 31, 2023	27,199	$ 2.71
Vested	(4,520)	0.01
Repurchased	(21,172)	3.48
Unvested as of June 30, 2024	1,507	$ 0.01

There were no RSAs granted during the six months ended June 30, 2024. As of June 30, 2024, unrecognized compensation cost related to unvested restricted stock awards was immaterial and is expected to be recognized over a weighted average period of 0.1 years.

Stock Options

The Company has granted stock options with service-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

11. Stock-Based Compensation (Continued)

The following table presents a summary of the Company's stock option activity and related information:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	2,382,933	$ 8.51		
Granted	1,954,946	10.04		
Exercised	(22,690)	7.31		$ 76
Forfeited or cancelled	(45,092)	8.67		
Balance outstanding at June 30, 2024	4,270,097	$ 9.21	8.70	$4,064
Options vested and exercisable at June 30, 2024	894,713	$ 6.82	5.98	$2,838
Options vested and expected to vest at June 30, 2024	4,270,097	$ 9.21	8.70	$4,064

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those stock options that had an exercise price lower than the fair value of the Company's common stock as of the measurement date of June 30, 2024.

As of June 30, 2024, unrecognized compensation cost related to unvested stock options was $25.0 million, which is expected to be recognized over a weighted average period of 3.4 years.

Stock-Based Compensation Expense

The following table presents stock-based compensation expense as reflected in the Company's condensed consolidated statements of operations and comprehensive loss for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,	
	2024	2023
Research and development	$ 1,121	$ 529
General and administrative	1,362	827
Total stock-based compensation expense	$ 2,483	$ 1,356

12. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Six Months Ended June 30,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (65,777)	$ (48,144)
Denominator:		
Weighted-average common stock outstanding–basic and diluted	1,560,661	1,522,552
Net loss per share attributable to common stockholders–basic and diluted	$ (42.15)	$ (31.62)

Zenas BioPharma, Inc.

Notes to Condensed Consolidated Financial Statements

12. Net Loss Per Share (Continued)

The Company's potentially dilutive securities, which include convertible preferred stock, restricted stock 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 shares from the computation of diluted net loss per share attributable to common stockholders as of June 30, 2024 and 2023 because including them would have had an anti-dilutive effect:

	June 30,	
	2024	2023
Convertible preferred stock	24,978,715	11,587,744
Unvested restricted stock	1,507	31,719
Options to purchase common stock	4,270,097	2,027,157

13. Commitments and Contingencies

Operating Leases

The Company has entered into arrangements for leases of office space; see Note 6, "Leases," for details.

License and Option Agreements

The Company entered into licenses agreements under which it is obligated to make fixed and contingent payments; see Note 8 "License and Option Agreements," for details.

Other Contracts

The Company has entered into agreements with certain vendors for the provision of services that the Company is not contractually able to terminate for convenience and thereby avoid any and all future obligations to the vendors. Under such agreements, the Company is contractually obligated to make certain minimum payments to the vendors, with the exact amounts in the event of termination to be based on the timing of the termination and the exact terms of the agreement.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2024.

Litigation and Other Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which the Company is focused. As of June 30, 2024, the Company was not

13. Commitments and Contingencies (Continued)

subject to any material legal proceedings which would reasonably be expected to have a material adverse effect on the Company's financial results.

14. Employee Benefit Plans

Effective June 2020, the Company adopted the Zenas BioPharma 401(k) Plan (the "401(k) Plan") for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. Since inception of the 401(k) Plan and through June 30, 2024, the Company has not made any contributions to the 401(k) Plan.

15. Related Party Transactions

As further described above in Note 8, "License and Option Agreements," the Company has obtained exclusive, worldwide licenses from Xencor to research, develop, manufacture, market and sell four antibody product candidates pursuant to two license agreements. The Company has concluded that Xencor is a related party, because as initial consideration for the 2020 Xencor Agreement, the Company issued 5,041,542 shares of its Series A Preferred Stock to Xencor during the year ended December 31, 2020. In April 2023, Xencor elected to receive payment for a development milestone in the form of the Company's Series B Preferred Stock and the Company issued 4,189,955 shares of Series B Preferred Stock as payment for the development milestone in June 2023. Immediately following the Series C Preferred Stock financing in May 2024, Xencor's equity interest in Zenas was approximately 12% of all outstanding shares of all classes of the Company's stock (common stock and convertible preferred stock). The Company recorded no reimbursable costs and less than $0.1 million in reimbursable patent-related costs to general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss during the six months ended June 30, 2024 and 2023, respectively.

As further described above in Note 8, "License and Option Agreements," the Company has obtained a license from Viridian to research, develop, manufacture, market and sell an antibody product candidate in China. The Company has concluded that Viridian is a related party because Fairmount Funds Management LLC owns more than 5% of capital stock of the Company, has a seat on the Board and is also a 10% or greater stockholder of Viridian and has two seats on Viridian's board of directors. As initial consideration for this license, the Company issued 38,707 shares of its common stock to Viridian during the year ended December 31, 2020. As of that date, Viridian's equity interest in the Company was approximately 1% of all outstanding shares of all classes of the Company's stock (assuming conversion of all outstanding shares of convertible preferred stock).

As further described above in Note 8, "License and Option Agreements", the Company has obtained an exclusive option to negotiate and enter into exclusive license agreements with Dianthus for the rights (in the Zenas Territories only) to either or both of two antibody product candidates. The Company has concluded that Dianthus is a related party because the Company's Chair of the Board is a member of the board of directors of Dianthus. As initial consideration for this license, the Company issued 18,063 shares of its common stock to Dianthus during the year ended December 31, 2020. As of that date, Dianthus's equity interest in the Company was approximately 0.5% of all outstanding shares of all classes of the Company's stock (assuming conversion of all outstanding shares of convertible preferred stock).

16. Subsequent Events

The Company assessed subsequent events through August 22, 2024, the date that these condensed consolidated financial statements were issued, and through September 6, 2024, for the effects of the reverse stock split described below.

16. Subsequent Events (Continued)

(A) Reverse Stock Split

On September 5, 2024, the Company effected a 1-for-8.6831 reverse stock split of the Company's issued and outstanding common stock and adjusted the conversion ratio of the Company's outstanding convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split and the adjustment of the preferred stock conversion ratios.

(B) 2024 Equity Plans

2024 Equity Incentive Plan

On September 3, 2024, the Board adopted the 2024 Equity Incentive Plan (the "2024 Plan"), which will become effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The 2024 Plan provides for the award of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, unrestricted stock, restricted stock units and other stock-based awards.

The number of shares initially reserved for issuance under the 2024 Plan will be the number of shares of common stock equal to 12% of the number of shares of common stock issued and outstanding as of immediately following the consummation of the Company's proposed IPO, not to exceed 5,657,830 shares, plus (i) the number of shares that remain available for issuance under the 2020 Plan at the time the 2024 Plan becomes effective and (ii) the number of shares of common stock underlying awards granted under the 2020 Plan that, after the effective date of the 2024 Plan, expire or become unexercisable without delivery of shares, are forfeited to, or repurchased for cash by, the Company, are settled in cash or otherwise become available again for grant under the 2020 Plan, in each case, in accordance with the terms of the 2024 Plan.

In addition, the number of shares reserved for issuance under the 2024 Plan will increase automatically on the first day of each fiscal year commencing on January 1, 2025 through January 1, 2034 by the number of shares equal to the lesser of (a) five percent of the aggregate number of shares of common stock outstanding as of such date, and (b) a number of shares as may be determined by the Board on or prior to such date.

2024 Employee Stock Purchase Plan

On September 3, 2024, the Board adopted the 2024 Employee Stock Purchase Plan (the "ESPP"), which will become effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The Company will initially reserve the number of shares equal to one percent of the number of shares of common stock issued and outstanding as of immediately following the consummation of the Company's proposed IPO. The number of shares reserved for sale under the ESPP will increase automatically on the first day of each fiscal year commencing on January 1, 2025 through January 1, 2034, by the number of shares equal to the lesser of (a) one percent of the aggregate number of shares of common stock outstanding as of such date, and (b) a number of shares as may be determined by the Board on or prior to such date, up to a maximum of 1,000,000 shares in the aggregate per year.

13,235,294 Shares

Common Stock

PROSPECTUS

MORGAN STANLEY ***JEFFERIES*** ***CITIGROUP*** ***GUGGENHEIM SECURITIES***

Through and including October 7, 2024 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

September 12, 2024