UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

or

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

For the transition period from _____ to_____

Commission File Number: 001-42270

Zenas BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware		93-2749244
(State or other jurisdiction of incorporation or organization)		**(I.R.S. Employer Identification Number)**

852 Winter Street, Suite 250
Waltham, MA 02451
(Address of Principal Executive Offices)

(857) 271-2954
(Registrant's telephone number)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common stock, par value $0.0001 per share	**ZBIO**	**Nasdaq Global Select Market**

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting equity held by non-affiliates as of such date. The number of shares of Registrant's Common Stock outstanding as of February 28, 2025 was 41,799,336.

Documents Incorporated by Reference

Portions of the Registrant's definitive proxy statement relating to the 2025 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	6
Item 1A. Risk Factors	60
Item 1B. Unresolved Staff Comments	118
Item 1C. Cyber Security	118
Item 2. Properties	119
Item 3. Legal Proceedings	119
Item 4. Mine Safety Disclosures	120
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	121
Item 6. Reserved	121
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	122
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	135
Item 8. Financial Statements and Supplementary Data	136
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	171
Item 9A. Controls and Procedures	171
Item 9B. Other Information	171
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	171
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	172
Item 11. Executive Compensation	172
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	172
Item 13. Certain Relationships and Related Transactions, and Director Independence	172
Item 14. Principal Accounting Fees and Services	172
PART IV	
Item 15. Exhibits and Financial Statement Schedules	172
Item 16. Form 10-K Summary	176
Signatures	177
Index to Consolidated Financial Statements	136

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, forward-looking statements can be identified 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 immunology and inflammation ("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 and drug product 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 existing cash and the sufficiency of our existing cash and proceeds from future capital-raising efforts, if any, 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 expected 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 Jumpstart Our Business Startups Act of 2012, as amended (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 Annual Report may prove incorrect. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report. 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 Annual Report 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 should not be unduly relied upon. 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, these forward-looking statements should not be relied upon 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.

SUMMARY RISK FACTORS

Our business is subject to a number of risks of which investors should be aware before making an investment decision. These risks are discussed more fully in Part I, Item 1A. "Risk Factors" in this Annual Report. 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;

- 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, 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 U.S. 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 U.S., 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 be sustained; and

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

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.

NOTE REGARDING TRADEMARKS

The Zenas BioPharma word mark, logo mark, and the "lightning bolt" design are trademarks of Zenas BioPharma, Inc. or its affiliated companies.

We have, in certain cases, omitted the ® and ™ designations for these trademarks used in this Annual Report. Nevertheless, all rights to such trademarks are owned by Zenas BioPharma, Inc. Other trademarks referenced in this Annual Report are the property of their respective owners.

PART I

Item 1. 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 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 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 believe obexelimab holds the potential to provide meaningful clinical benefit for patients in multiple I&I indications. 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 three indications we are pursuing include immunoglobulin G4-related disease ("IgG4-RD") through an ongoing registration-directed Phase 3 trial which completed enrollment in November 2024 and relapsing multiple sclerosis ("RMS") and systemic lupus erythematosus ("SLE") through ongoing Phase 2, double-blind, randomized, placebo-controlled trials, each of which are currently enrolling. We estimate that each of these potential indications represent a multi-billion-dollar commercial opportunity in the U.S. alone.

Beyond our lead product candidate, obexelimab, we have two other programs for the potential treatment of other I&I indications that we may continue to advance and ultimately develop and commercialize with partners. These consist of ZB002 (an anti-TNFα monoclonal antibody) and ZB004 (a CTLA-4-Ig fusion). We retain global rights for both assets. In addition, we hold the development and commercialization rights to one regional program, ZB001 (also known as VRDN-001, an insulin-like growth factor-1 receptor ("IGF-1R") monoclonal antibody and related programs, which were recently exclusively sublicensed to a partner in greater China.

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:

Program	Indication	Trial/Status
Obexelimab[1] CD19 x FcγRIIb Bifunctional mAb	IgG4-RD (Immunoglobulin G4-Related Disease)	Phase 3 INDIGO trial enrolled[2,3]
	RMS (Relapsing Multiple Sclerosis)	Phase 2 MoonStone trial enrolling[3]
	SLE (Systemic Lupus Erythematosus)	Phase 2 SunStone trial enrolling[3]

[1]Zenas acquired exclusive worldwide rights to obexelimab from Xencor, Inc.
[2]Bristol Myers Squibb & Co. holds exclusive development and commercialization rights in JPN, SK, TWN, HK, SGP, AUS
[3]Randomized versus placebo

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.

Other Programs

Beyond our lead product candidate, obexelimab, we have two other programs for the potential treatment of other I&I indications that we may continue to advance and ultimately develop and commercialize with partners.

Product Candidate	Territory	Plan of Development
ZB002 (anti-TNFα mAb)	Global	Phase 1b multiple ascending dose ("MAD") study in patients with RA ongoing
ZB004 (CTLA-4-Ig fusion)	Global	Phase 1 single ascending dose ("SAD") study in healthy volunteers completed

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*. 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.

We also own the global development and commercialization rights to 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. 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.

Partnered Regional Programs

We also have in-licensed the development and commercialization rights to ZB001 (also known as VRDN-001), an IGF-1R monoclonal antibody, and related programs from Viridian Therapeutics, Inc. ("Viridian") in China, Hong Kong, Macau and Taiwan (collectively, "greater China"). On January 24, 2025, we entered into a license agreement (the "Zai License Agreement") with Zai Lab (Hong Kong) Limited ("Zai"), under which we granted Zai an exclusive sublicense to develop and commercialize ZB001 and related programs in greater China. As partial consideration for the Zai License Agreement, we received an upfront fee of $10.0 million from Zai. In addition, we are eligible to receive up to $96.0 million upon the achievement of certain future development and commercial milestones and royalty percentage rates from the low to mid-single digits, net of pass-through obligations due to Viridian.

In addition, on October 21, 2024, we entered into a novation agreement with Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia"), under which we transferred to Tenacia our rights and obligations under our agreements with Dianthus Therapeutics Inc. ("Dianthus") for ZB005 (the "Tenacia Agreement"). As partial consideration for the Tenacia Agreement, we received an upfront fee of $5.0 million from Tenacia. In addition, we are eligible to receive up to $86.0 million upon the achievement of certain future regulatory and commercial milestones.

Our Management Team

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, Inc., GlaxoSmithKline plc., Amgen Inc., Nuvation Bio Inc., Mirati Therapeutics, Inc., Cubist Pharmaceuticals, Inc. 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.

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**. 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 three indications we are pursuing include IgG4-RD through an ongoing registration-directed Phase 3 trial; and RMS and SLE through ongoing Phase 2, double-blind, randomized, placebo-controlled trials.

- **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 that end, we have hired a Chief Commercial Officer and others within the commercial organization.

- **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. 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.

- **Leverage success with initial indications to expand into broader I&I opportunities.** 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 may in the future seek arrangements with other biopharmaceutical companies with strong and proven commercial capabilities for them to commercialize or co-commercialize our potential therapies in certain territories, if approved. In addition, for certain indications that may require larger clinical development programs, we may selectively seek to collaborate to help fund development.

Obexelimab (CD19 x FcγRIIb bifunctional monoclonal antibody) Program

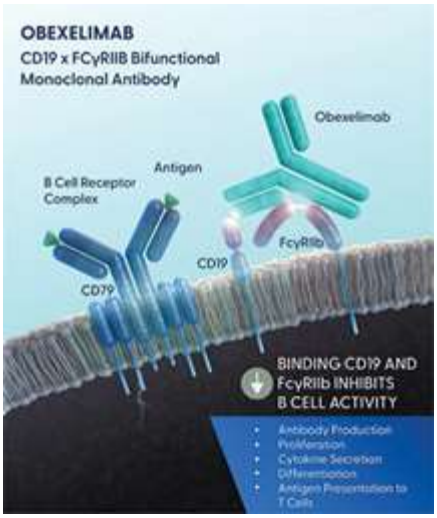
We believe that our lead product candidate, obexelimab, has the potential to address key unmet needs in multiple I&I indications due to its mechanism of action and chronic dosing regimen that may broadly and effectively address the pathogenic role of B cell lineage through reversible inhibition of B 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 rapidly achieved nearly 100% CD19 receptor occupancy, potently inhibiting 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 a reduction in disease relapse**
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 Responder Index ("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 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 U.S. 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 and ongoing Phase 2, double-blind, randomized, placebo-controlled clinical trials of obexelimab in patients with RMS and SLE. 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. While we believe that the preliminary results from the SApHiAre Trial in patients with warm autoimmune hemolytic anemia

("wAIHA") patients established proof of mechanism through an increase in Hgb and a positive effect on other clinical markers, we have determined not to progress to a registration-directed trial of obexelimab for the wAIHA indication based on several factors, including the expected length and expense of a potential Phase 3 trial.

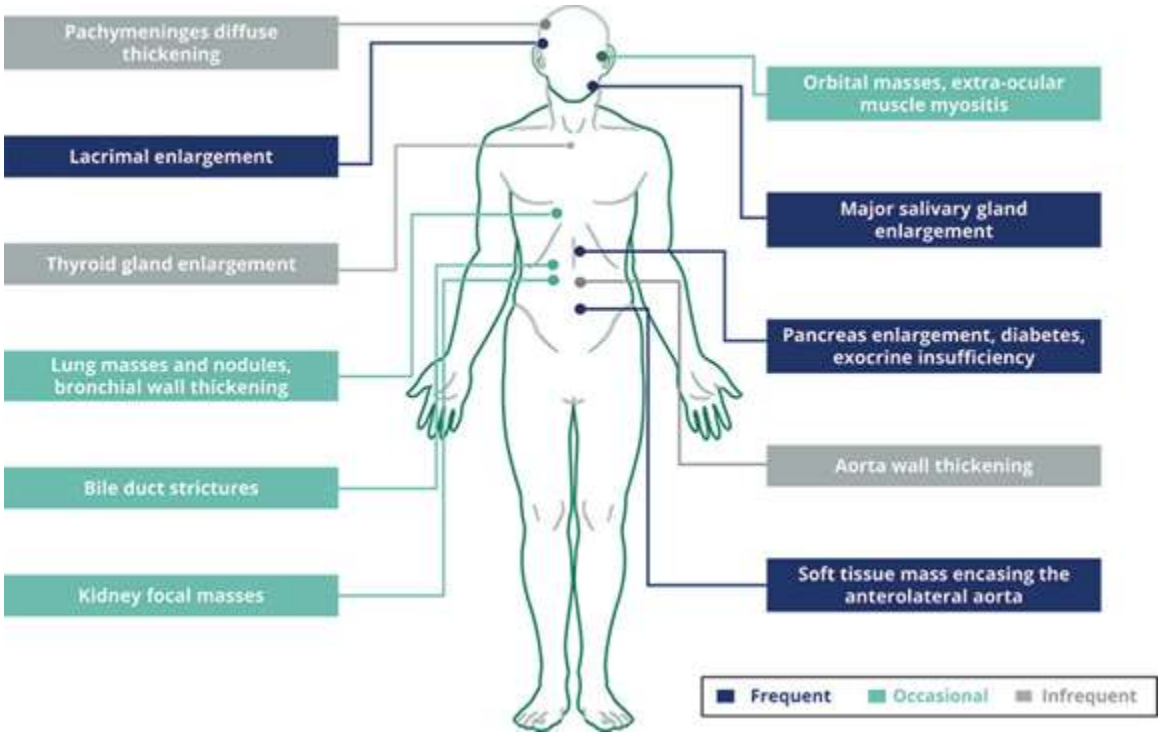
Obexelimab for the Treatment of IgG4-RD

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. In November 2024, we completed enrollment of 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 year end 2025 and, subject to the data, submit a biologics license application ("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 U.S. is approximately 20,000, with what we believe to be comparable prevalence rates globally. 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.

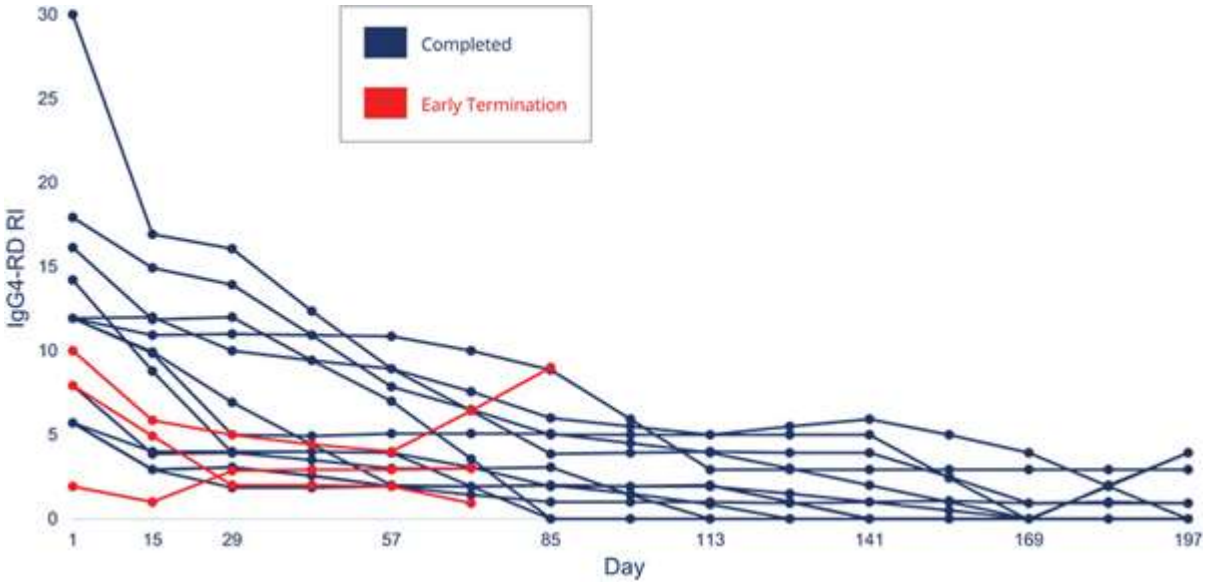
Summary of the Completed Phase 2 Trial of Obexelimab in IgG4-RD

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.

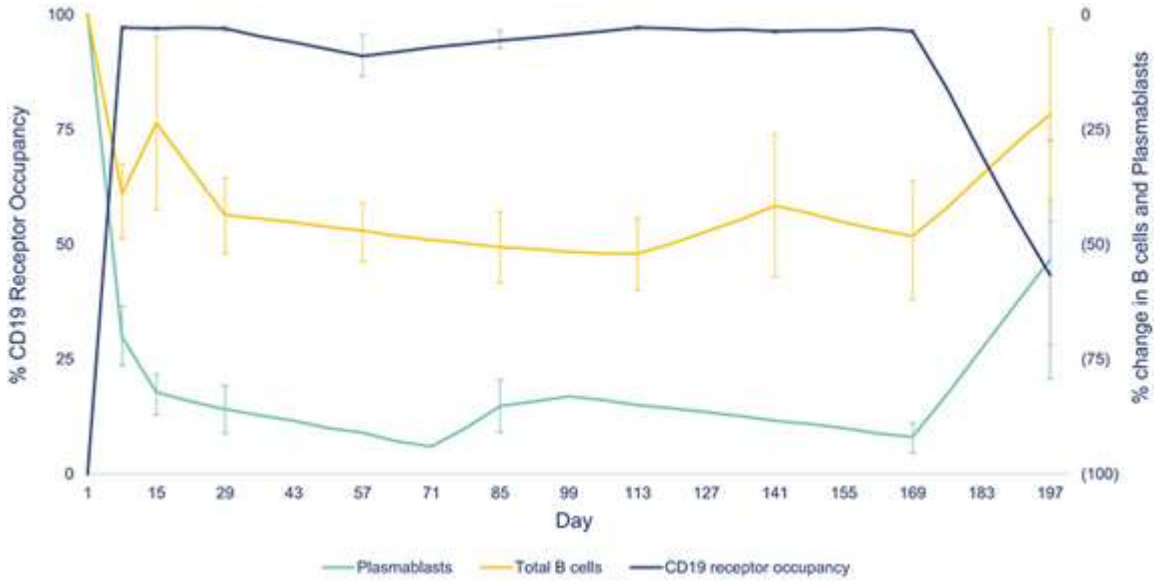
The pre-specified primary analysis of this study focused on the 15 patients enrolled at obexelimab 5 mg/kg. At baseline, the median IgG4-RD RI score was 12 (IQR 7-13). In the primary efficacy analysis, as shown in Figure 3 below, the median decrease in the IgG4-RD RI score was 11.5 points (IQR 7.5-14.5). 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 I&I 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.

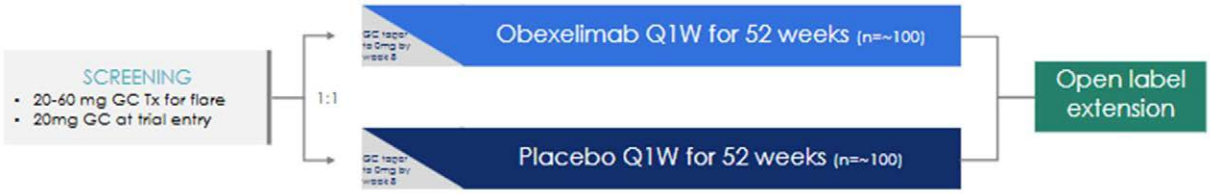
Safety Summary

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 Global Phase 3 Trial in IgG4-RD

In November 2024, we completed enrollment of 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. Approximately 190 patients were enrolled in the RCP and all patients from the RCP will be eligible for the OLE period. The trial is being 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 had a clinical diagnosis of IgG4-RD, met the 2019 ACR/EULAR classification criteria for IgG4-RD, as determined by an Adjudication Committee ("AC"), and had 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 were 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 could either have been 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 had no disease activity and been at a dose of 20 mg/day prednisone equivalent. Patients were randomized 1:1 to receive obexelimab or placebo. The primary efficacy assessment was time to first IgG4-RD flare, as determined by the investigator and the AC. If the investigator suspected an IgG4-RD flare, based on reappearance of previous signs/symptoms or appearance of new signs/symptoms of IgG4-RD, organ-specific diagnostic assessments were 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 then determined if an IgG4-RD flare occurred and whether the initiation of rescue therapy was required. The AC independently reviewed these diagnostic assessments to determine if, in their judgement, the signs/symptoms represent a flare. Patients who met the protocol-defined criteria for IgG4-RD flare, by both the investigator and the AC, were 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 would 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. Secondary endpoints include: 52-week flare rate, the proportion of patients achieving complete remission, use and quantity of rescue medication and the change in GC-associated toxicity as measured by the Glucocorticoid Toxicity Index ("GTI").

Patients who complete 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 116 weeks (104-week treatment period followed by a 12-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 the MoonStone Trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with RMS.

MS Histology and Disease Background

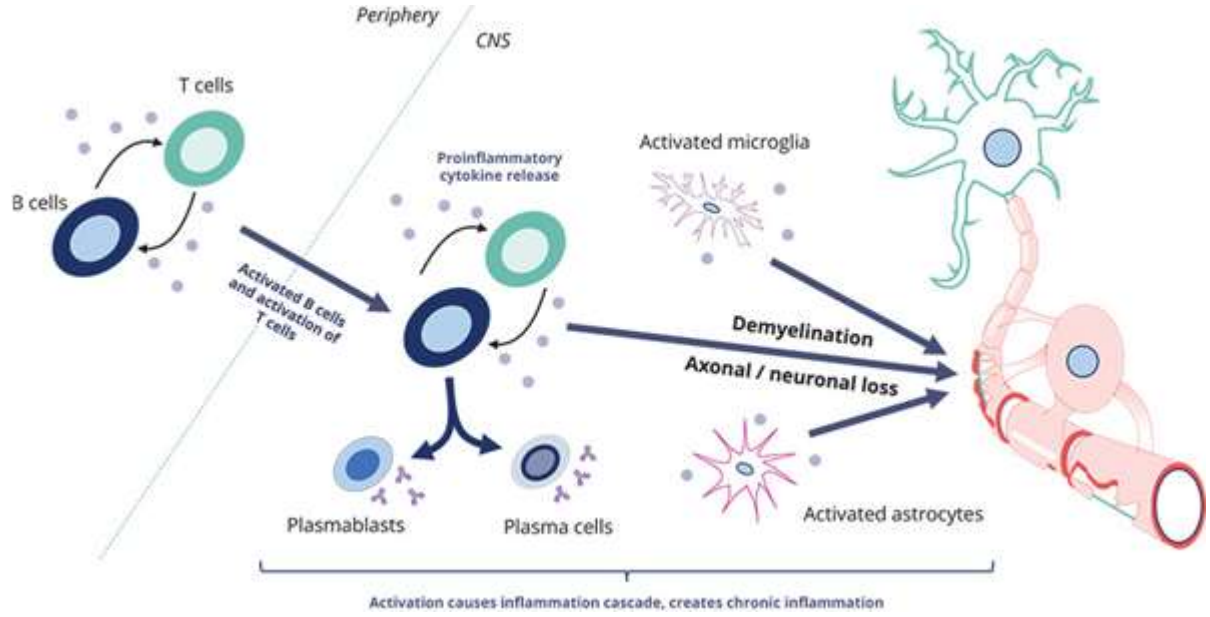
MS is the most common immune-mediated, chronic inflammatory demyelinating disease of the central nervous system ("CNS"), affecting over two million people worldwide including as many as 1,000,000 in the U.S., according to the National MS Society and the MS Foundation. We estimate a diagnosed prevalence of approximately 650,000 patients in the U.S. with MS.

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.

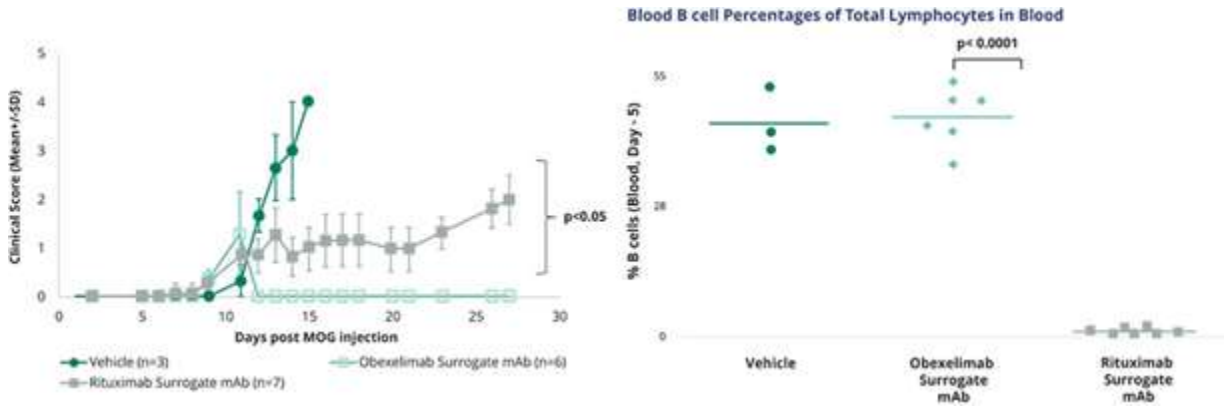
Currently, the cause of MS remains unknown; however, both B and T cells play an important role in the pathogenesis of the disease, including inflammation and demyelination process. In addition to producing autoantibodies and inflammatory cytokines, B cells have an important function as antigen-presenting 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 ("PIRA" or 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 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 Global Phase 2 Trial in RMS

Given the clinical activity observed with B cell depleting agents, we are currently enrolling patients in the MoonStone Trial, a global Phase 2 potential POC trial of obexelimab in RMS patients. We expect to enroll approximately 93 patients and to conduct the trial at multiple sites worldwide. 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 is 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 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 the third quarter of 2025.

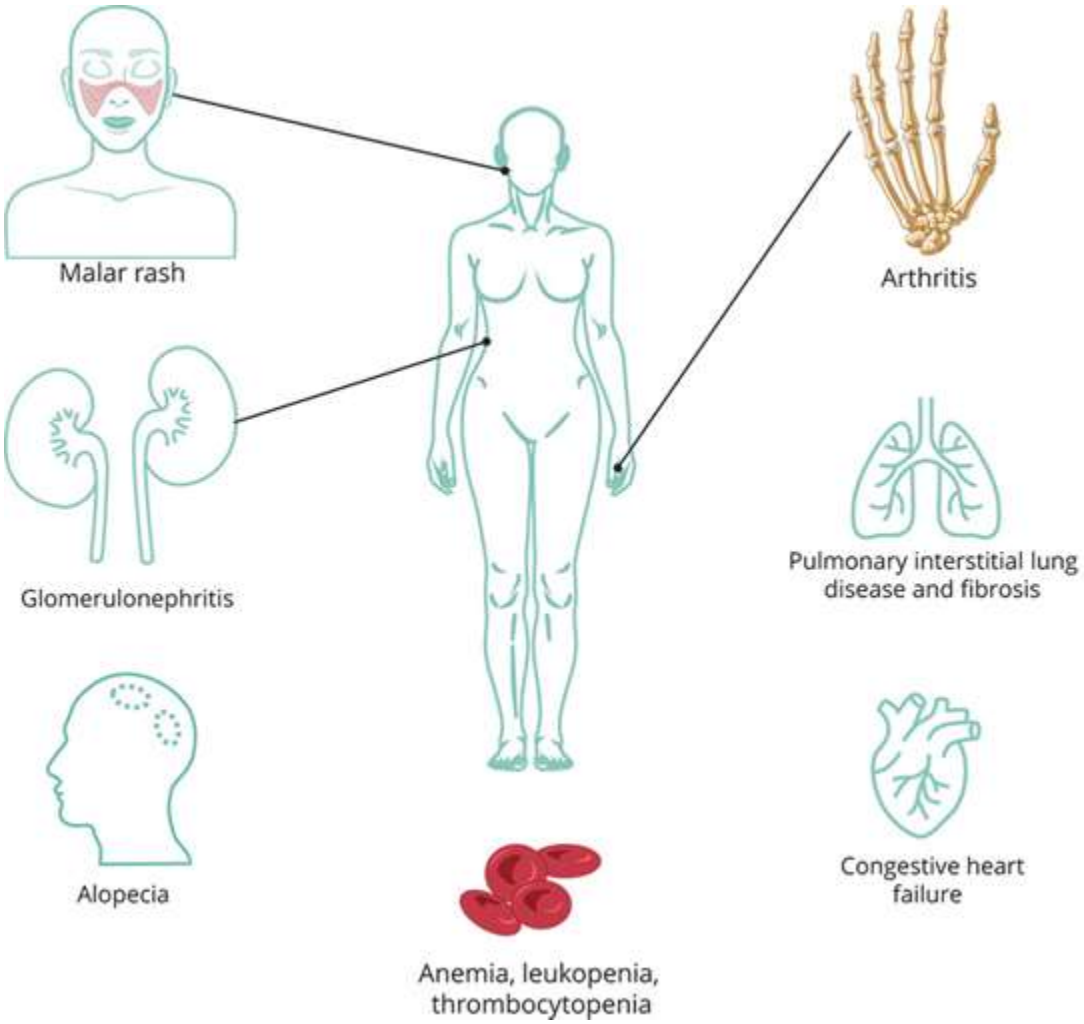
Obexelimab for the Treatment of SLE

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 approximately 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 U.S. having lupus, with approximately 150,000 having SLE.

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 FDA approved options are modestly effective with improvement in combination with standard therapy versus standard therapy alone in Phase 3 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 Ctrough 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 Global Phase 2 Trial in Patients with SLE

We are currently enrolling patients in the SunStone Trial, a global 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 is 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 – SApHiAre Trial

In December 2024, we announced preliminary results from patients in the open-label SRP of the Phase 2 portion of our SApHiAre Trial, a global study of obexelimab in patients with wAIHA. The primary objectives of the SRP are to provide preliminary safety, tolerability, PK/PD and efficacy data of obexelimab in patients with wAIHA. Patients were given 250 mg obexelimab weekly through subcutaneous administration for 24 weeks. 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 or after Week 8, with no use of blood transfusion or GC rescue therapy prior to attaining response.

As of the cut-off date, nine patients had been enrolled in the SRP over an approximately one-year period, including eight patients with primary wAIHA and one patient with secondary wAIHA due to autoimmune disease. One patient had not reached week four by the cut-off date and was not included in the analysis. Five of eight patients achieved an increase of >1 g/dL of Hgb from baseline during weeks 8-24 without influence of concomitant medications. Additionally, a Hgb increase of ≥ 2 g/dL measured from Hgb nadir to peak was observed in five of eight patients. LDH and total bilirubin levels decreased overall during weeks 8-24. No patients received transfusions. Obexelimab was well tolerated in patients with wAIHA with a safety profile similar to that observed in earlier studies.

While we believe that the preliminary results from the SApHiAre Trial established proof of mechanism through an increase in Hgb and a positive effect on other clinical markers, we have determined not to progress to a registration-directed trial of obexelimab for the wAIHA indication based on several factors, including the expected length and expense of potential Phase 3 trial.

Safety Profile of Obexelimab

In the completed studies, 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 observed in obexelimab treated subjects, 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 Ctrough 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 Cmax 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 ("EC50") of binding of obexelimab to a human CD19 expressing cell line is 0.3 nM, and the EC50 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 Programs

Beyond our lead product candidate, obexelimab, we have two other programs for the potential treatment of other I&I indications that we may continue to advance and ultimately commercialize with partners. These consist of ZB002 (an anti-TNFα monoclonal antibody) and ZB004 (a CTLA-4-Ig fusion). We retain global rights for both assets.

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 may 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 EC50 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 (KD = 6.54 $\times 10^{-8}$ M) compared to adalimumab (KD = 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 ("IC50") 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 IC50 values for interleukin 2 (IL-2) secretion driven by ZB004 or abatacept were < 0.003 µg/mL and 0.152 µg/mL, respectively. The IC50 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.

Partnered Regional Programs

We license ZB001, an anti-IGF-1R monoclonal antibody, and related programs, from Viridian. For these assets we hold the development and commercialization rights in greater China and recently sublicensed these rights to Zai.

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. With our sublicense to Zai, Zai will pay for the reimbursement obligations and provide us with specified milestones and royalties. 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 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 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.

On January 24, 2025, we entered into the Zai License Agreement with Zai, under which we granted Zai an exclusive sublicense to develop and commercialize ZB001 and related programs in greater China. As partial consideration for the Zai License Agreement, we received an upfront fee of $10.0 million from Zai. In addition, we are eligible to receive up to $96.0 million upon the achievement of certain future development and commercial milestones and royalty percentage rates from the low to mid-single digits, net of pass-through obligations due to Viridian.

In addition, on October 21, 2024, we entered into the Tenacia Agreement, under which we transferred to Tenacia our rights and obligations under our agreements with Dianthus for ZB005. As partial consideration for the Tenacia Agreement, we received an upfront fee of $5.0 million from Tenacia. In addition, we are eligible to receive up to $86.0 million upon the achievement of certain future regulatory and commercial milestones.

License Agreements

License Agreements with Xencor

2020 Xencor Agreement

In September 2020, we entered into a license agreement (the "2020 Xencor Agreement") with Xencor, to obtain (i) an exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (ii) 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 future preclinical, 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 (U.S., 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 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. 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 years ended December 31, 2024 and 2023, no costs and immaterial third-party costs were reimbursed, respectively.

Under the 2020 Xencor Agreement, (i) Xencor owns all know-how and patent rights invented solely by Xencor, (ii) we own all know-how and patent rights invented solely by us; and (iii) 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.

2021 Xencor Agreement

In May 2021, we entered into a license agreement (the "2021 Xencor Agreement") with Xencor to obtain (i) an exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (ii) 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 future preclinical, clinical, regulatory and other activities 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 (U.S., 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 (i) the last-to-expire licensed patent covering the product in the applicable region, (ii) 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. 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 or the 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 (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 (the "BMS Agreement") 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 years ended December 31, 2024 and 2023, we recorded $6.0 million and $4.1 million, respectively, 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 fiscal year ended December 31, 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 U.S. 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 U.S., 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 March 11, 2025, we own or exclusively in-license 14 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, nine pending U.S. applications, 123 issued foreign patents, four pending PCT applications and 41 pending foreign patent applications in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, Japan, Malaysia, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan and the United Arab Emirates. In addition, we own or exclusively in-license eight U.S. provisional patent applications, which belong to four different patent families, within the priority year. Any U.S. 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 U.S. 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 March 11, 2025, we own or exclusively in-license from Xencor ten 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 U.S., 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 U.S., five pending applications in Canada, Europe, Hong Kong and Japan, and 20 issued patents in Japan and European countries including Austria, Belgium, Denmark, France, Finland, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Spain, Switzerland, 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 U.S. 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 one pending U.S. Application, and 17 pending applications in Australia, Brazil, Canada, China, Eurasia, Europe, Isreal, Japan, Malaysia, Mexico, New Zealand, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan and the United Arab Emirates. 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 AIHA, including 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 and dosing regimen of obexelimab for treating forms of MS, including RMS, and currently including a pending PCT application and a pending U.S. application, and a pending Taiwanese application. 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 clinical use and dosing regimen of obexelimab for treating forms of MS, including RMS, and currently including a pending PCT application, a pending U.S. application, and a pending Taiwanese application. 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 SC administration of obexelimab for treating SLE currently including a pending PCT application, a pending U.S. application, and a pending Taiwanese application. 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.

A ninth 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 tenth patent family is related to the clinical use of obexelimab for treating wAIHA currently including two provisional applications within the priority year. 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 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 March 11, 2025, 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 four issued patents in the U.S., Brazil, Japan and Russia, and two pending applications in Europe and Hong Kong. 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 including one pending U.S. application, one pending PCT application and one pending application in Taiwan. 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 March 11, 2025, we own or exclusively in-licensed two patent families relating to the composition of matter of ZB004 and related methods of use. A first patent family specifically covers the composition of matter and related methods of use ZB004 including six issued patents and one pending application in the U.S., and 79 issued foreign patents in Australia, Canada, China, Hong Kong, 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 second patent family is related to the formulation and dosing regimen of ZB004 in treating autoimmune diseases currently including two provisional applications within the priority year. 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 September 2045. A PTE of up to five years may be available and can be applied in one of these families as appropriate.

Trademark Portfolio

The Company owns trademark applications and registrations for “Zenas BioPharma” and the Zenas BioPharma logo, and the “lightning bold” design in the U.S. and other foreign jurisdictions.

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. In addition, we have selected new CMOs in the U.S., which are not affiliated with Wuxi Biologics, to establish additional sources of supply for drug substance and drug product for both commercial and clinical use. However, should our CMO, Wuxi Biologics, become unavailable to us for any reason, we believe that we would incur delay and cost in order to complete the manufacturing validation and qualification process for 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.

We have a long-term commercial supply agreement with WuXi Biologics to fulfill and secure obexelimab drug substance and drug product for an anticipated commercial launch, if approved. In addition, we have selected new CMOs in the U.S., which are not affiliated with WuXi Biologics, to establish additional sources of supply for drug substance and drug product for both commercial and clinical use. For the medical device component of our product (i.e., prefilled syringe or autoinjector), we plan to utilize device assembly facilities in the U.S. 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 substance 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.

If our product candidates receive FDA or EMA approval, we intend to build our own commercialization infrastructure in the U.S. 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, and SLE. There are currently no approved products for IgG4-RD. 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, and SLE 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 filed a BLA and was granted Priority Review based on the results of its Phase 3 trial;
- a small molecule Bruton's tyrosine kinase ("BTK") inhibitor in a Phase 2 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 trial being developed by Sanofi S.A;

- several Phase 2 trial programs evaluating multiple targets / mechanisms of action including but not limited to CD19, BTK, M1R (muscarinic type 1 receptor), BLyS/APRIL, MOG (myelin oligodendrocyte glycoprotein), VLA-4 (very late antigen 4), Treg cells, 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 trials, being conducted by Biogen Inc.;

- a dual antagonist of BLyS and APRIL program in a Phase 3 (ex-China) trial, being developed by RemeGen Co., Ltd.;

- two anti-CD20 antibody programs in Phase 3 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 trials, being developed by Bristol Myers Squibb Company;

- a sphingosine-1-phosphate 1 receptor modulator in Phase 3 trials, being developed by Idorsia Pharmaceuticals Ltd.;

- a small molecule Janus kinase inhibitor in Phase 3 trials, being developed by AbbVie Inc.;

- an anti-BAFF-R antibody program in Phase 3 trials, being developed by Novartis AG;

- several Phase 2 trial programs evaluating multiple targets / mechanisms of action including but not limited to TLR7/8, CD28/ICOS, CD40/CD40L, BAFF/APRIL, IL2, IL21, CRL4-CRBN, IFNB1, BTLA, FcRn, TYK2, BTK, CD22, CD32B/CD79B, CD19, a CD19 CAR-γδT program, 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.

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 U.S. 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 U.S. 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 U.S.

We are currently developing product candidates that are biological products, or biologics. In the U.S., 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 U.S.

An applicant seeking approval to market and distribute a new biologic in the U.S. 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 Investigational New Drug Application ("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 U.S., 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 U.S. 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 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 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 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 acceptance 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 U.S., 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 acceptance 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 U.S. is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the U.S. or that affects 200,000 or more individuals in the U.S. 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 U.S.

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 U.S. 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 U.S., 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 U.S. 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 United States Patent and Trademark Office ("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 U.S., 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.

Regulation and Procedures Governing Approval of Medicinal Products in Europe

In order to market any medicinal product outside of the U.S., 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 U.S., 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 U.S. 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 European Medicines Agency ("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 U.S. 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 U.S., 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 U.S., 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 U.S. 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 U.S.

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 U.S. 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 U.S. 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.

Employees and Human Capital Resources

As of February 28, 2025, we had 130 full-time employees, consisting of clinical, scientific, development, medical affairs, 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 personnel outside of the U.S. are subject to employment contracts which contain customary notice periods. We consider our relationship with our employees to be good.

Of our 130 full-time employees as of February 28, 2025, 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 obexelimab in the Asia-Pacific region and technical operations, with all functions in China reporting to management in the U.S. We also have dedicated medical and commercial personnel located in Europe to advance our obexelimab strategy in that region. 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.

Corporate and Other Information

We 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) de-registered from the Cayman Islands and registered by way of continuation in the State of Delaware. Our principal executive offices are located at 852 Winter Street, Suite 250, Waltham MA 02451, and our telephone number at that address is (857) 271-2954.

On September 16, 2024, the Company completed its initial public offering ("IPO"), in which the Company issued and sold 15,220,588 shares of its common stock, including 1,985,294 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $258.7 million. The Company received approximately $234.3 million in net proceeds after deducting underwriting discounts, commissions and other offering expenses.

Available Information

Our Internet address is www.zenasbio.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") are available through the "Investor & Media Relations" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis and Retrieval system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors

Investors should carefully consider the risks described below, together with the other information contained in this Annual Report, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our audited consolidated financial statements and the related notes contained in this Annual Report. 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. These risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also affect our business. See "Special Note Regarding Forward-Looking Statements."

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 an 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. For the year ended December 31, 2024, we reported a net loss of $157.0 million. As of December 31, 2024, we had accumulated deficit of $387.4 million, which included non-cash charges for stock-based compensation and acquisition and development expenses. We expect to continue 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 may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate 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.

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 contract manufacturing organizations ("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 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.

As of December 31, 2024, we had $350.8 million in cash, cash equivalents and short-term investments. Based upon our current operating plan, we believe that our cash, cash equivalents and investments as of December 31, 2024, will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026. 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, we expect to incur costs associated with operating as a public company, including significant legal, accounting, investor relations, and other expenses that we did not incur prior to our IPO. 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 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, stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their 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. 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 or BLA, to the FDA or a comparable foreign regulatory authority. Even after the submission of an IND or BLA,

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 have 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 could 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, 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, and SLE. There are currently no approved therapies for IgG4-RD, 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, and SLE that may become available in the future, including UPLIZNA (inebilizumab-cdon), an anti-CD19 antibody being developed by Amgen Inc., for which Amgen filed a BLA based on the results of its Phase 3 trial in patients with IgG4-RD.

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 investors 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.

Our ongoing Phase 3 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 trials of the relevant biologic in the relevant patient population; however, in some cases the FDA may accept data from a single Phase 3 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 have partnered, and intend to further partner, with third parties with respect to the clinical development and commercialization, if approved, of certain of our programs in certain regions outside the U.S. 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;
- the grant of exclusive rights to our collaborators 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 U.S. 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, and SLE. 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 U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting clinical trials outside the U.S., 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 U.S. 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 U.S., the FDA will generally not approve the application unless the data are applicable to the U.S. population and U.S. 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 U.S. 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 U.S., we may never receive regulatory approval to market outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. In order to market any product outside of the U.S. 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 U.S. 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 U.S., 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 such coverage, reimbursement and pricing 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 U.S. Coverage and reimbursement for products can therefore 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 U.S. 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 drug product. A lack of coverage or adequate reimbursement for such a test could adversely affect access to a drug product.

Outside the U.S., 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 U.S., the reimbursement for our product candidates may be lower than in the U.S. and may be insufficient to generate meaningful revenue and profits. Factors outside the U.S. that may be relevant in pricing and reimbursement determinations by health authorities, including in European countries, may include, without limitation, perceived

cost-effectiveness perceived benefit to patient quality of life, and designation as an orphan drug indication, among others.

Moreover, increasing efforts by governmental and third-party payors in the U.S. 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 U.S. 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 U.S., or a patient population of greater than 200,000 individuals in the U.S. but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. The FDA and the EMA have each granted orphan drug designation to obexelimab for IgG4-RD. We may not be able to maintain orphan drug designation for obexelimab for IgG4-RD. Additionally, 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 any other indication or 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. The EMA is required to re-assess granted orphan designation at the time of marketing authorization to ensure that it continues to meet the criteria for the designation to be maintained. Otherwise, the orphan designation can be revoked. 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, and granted designations, if not maintained, will not provide the benefits of such designation.

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, the FDA could decide not 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 U.S. 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 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 U.S., 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.

Our estimates of commercial opportunities for product candidates and forecasts of market growth 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 are subject to significant uncertainty and are based on assumptions and estimates. Our 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 U.S. is approximately 20,000, with what we believe to be 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 U.S. 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 U.S. 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 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. can be less extensive than those in the U.S. 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 U.S., 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. can remain confidential until patents issue. In addition, patent applications in the U.S. 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 U.S. or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S., 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. Subsequent rulings could 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 precedential decisions in *In re Cellect* (No. 22-1293) and *Allergan v. MSN Laboratories* (No. 24-1061) that could shorten or eliminate an extended patent term awarded under Patent Term Adjustment ("PTA") in certain patent family members 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 U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional 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 U.S. over the lifetime of our owned or licensed patents and patent applications. Recently, the USPTO implemented new fee rules including Continuing Application Fee (CAF) which would increase our cost for obtaining and maintaining patent protection in the US and potentially limit our ability of seeking additional patents in our existing patent families, especially those early filed patent families that has been pending for close to our more than six years. 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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.

We face uncertainty regarding the potential for changes in the regulatory environment following the change in presidential administration in January 2025. While many of the Trump administration's proposed policies appear to be focused on deregulation, the new administration and federal government could adopt legislation, regulation, or policy that adversely affects our business or creates a more challenging and costly environment to pursue the development and commercialization of our product candidates. For example, the federal government, including the FDA, may implement legislative, regulatory, or policy changes regarding the standards for approving biologic products that we may be unable to satisfy. It is difficult to predict how executive actions that may be taken under the current Trump administration may affect the FDA's ability to exercise its regulatory authority. If such executive actions impose constraints on the FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted.

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, the current Trump administration appears to be focused on decreasing spending in the federal government, including through significant staff reductions. Any significant staff reductions at FDA could impact the agency's ability to engage in routine regulatory and oversight activities and result in delays or limitations on our ability to proceed with clinical development programs and obtain regulatory approvals. Additionally, 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 U.S. 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 U.S., which substantially changed the way healthcare is financed by both governmental and private insurers in the U.S. 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 U.S. 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"), which became 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 U.S. 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 U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Governments outside the U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., 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 U.S., 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 U.S., 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.

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 may breach contractual obligations imposed by us, or they may 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. Our contractual measures and our own privacy and security-related safeguards may not 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 U.S., to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Significant political, trade, regulatory developments, including changes in relations between the U.S. and China, and other circumstances beyond our control, may adversely impact our business, financial condition, and results of operations.

Various political, trade, or regulatory developments have, and could further, adversely affect our business and the results of our operations and financial condition. For example, recent actions and statements by the governments of the U.S. and China, including those relating to the imposition or threatened imposition of tariffs, or increases to tariffs, affecting certain products manufactured in China, have impacted, and may continue to impact, companies like us who rely on suppliers and other commercial partners with significant operations in China. For example, while we have selected new CMOs in the U.S. to establish additional sources of supply, currently we import from China certain drug substance, drug product and other components, and such imports are subject to existing tariffs and may be impacted by additional tariffs. Currently, many of our suppliers primarily operate outside of the U.S., including our current sole CMO, WuXi Biologics, which provides its services to us from facilities located in China, and increases in tariffs could result in increased costs. As a result, we are subject to risks associated with political, trade, regulatory developments with respect to such countries, and between the U.S. and such countries. Any unfavorable legislation, regulations, executive orders, government policies on cross-border relations and/or international trade, including increased scrutiny on certain of our suppliers with significant China-based operations, capital controls, or tariffs, may have an adverse effect on our business, financial condition, and results of operations.

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. We have a long-term commercial supply agreement with WuXi Biologics to fulfill and secure obexelimab drug substance and drug product for an anticipated commercial launch, if approved. In addition, we have selected new CMOs in the U.S., which are not affiliated with WuXi Biologics, to establish additional sources of supply for drug substance and drug product for both commercial and clinical use. For the medical device component of our product (i.e., prefilled syringe or autoinjector), we plan to utilize device assembly facilities in the U.S. or EU for the global supply.

Any change in our relationship with our CMOs 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 new 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 U.S., 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 we could 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. If we change manufacturers after we receive regulatory approval for a product candidate, we will be required to conduct additional testing, including completion of validation batches, and obtain approval from regulatory authorities for the new manufacturer before we can begin using any drug substance or drug product they manufacture for commercial purposes. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products, if approved, 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 U.S., 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 U.S., 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, and as a result supply-related costs, from countries where our suppliers operate, including China, pursuant to our master services or commercial supply agreements with WuXi Biologics, as well as tariffs that impact the biopharmaceutical industry generally;
- 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 in 2024, 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, which passed 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 manufactured by 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 selected new CMOs in the U.S. to establish additional sources of 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, establishing new manufacturers requires significant effort and time and any delay in securing, or inability to secure, a commercial supplier of drug substance or drug product for a product candidate, if approved, including as a result of delays in contracting, technology transfer, production of validation batches or obtaining an inspection by the FDA or other applicable foreign regulatory authorities, 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 Ownership of Our Common Stock

An active and liquid trading market for our common stock may not be sustained.

Our common stock is listed on the Nasdaq Global Select Market under the symbol "ZBIO". If an active or liquid trading market for our common stock is not sustained, it may be difficult for investors to sell their shares of common stock at an attractive price or at all. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall. An inactive market may reduce the fair market value of our common stock, 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.

Since shares of our common stock were sold in our IPO in September 2024 at a price of $17.00 per share and through February 28, 2025, the closing price per share of our common stock on Nasdaq has ranged from $6.43 to $25.68. 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 U.S. 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 Annual Report, 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. The market price of our common stock may decline, and investors may lose some or all of their 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.

A significant portion of our total outstanding shares are, as of the date of filing this Annual Report, restricted from immediate resale but may be sold into the market upon expiration of the lock-up agreement entered into in connection with our IPO, 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 entered into by holders of substantially all of our common stock outstanding immediately prior to our IPO, 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. As of December 31, 2024, we had 41,793,412 shares of common stock outstanding. Of these shares, 15,220,588 shares sold in our IPO may be resold in the public market immediately, unless held by our affiliates. The remaining shares are currently restricted under securities laws or other agreements, subject in some cases to applicable volume limitations under Rule 144 beginning after the close of trading on March 11, 2025.

Additionally, holders of an aggregate of 26,557,087 shares of our common stock 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 registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares 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 entered into in connection with our IPO. 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 have substantial influence over us, which could limit other stockholders' ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers and greater than 5% stockholders and their affiliates, in the aggregate, beneficially own shares representing approximately 59% of our outstanding common stock as of December 31, 2024. 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 other stockholders 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 investors' 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 investors' sole source of gain on an investment in our common stock in the foreseeable future.

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. 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 Second Restated Certificate of Incorporation (our "Restated Charter"), our Amended and Restated Bylaws (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 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 investors might otherwise receive a premium for their shares. Our Restated Charter and Restated Bylaws 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 designates 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 provides 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 does not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our Restated Charter further provides 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 provides 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 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 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.

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 cease publishing 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 continue to cover 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 have incurred, and 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.

As a public company, we have incurred, 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. 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 required to comply with the SEC's rules implementing Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our annual 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 an annual basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our annual report on Form 10-K, for fiscal year ending December 31, 2025. 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 fiscal year ending December 31, 2025 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.

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.

We are 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.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cyber Security

Risk Management and Strategy

We have developed and maintain an information security program designed to assess, identify, and manage risks from cybersecurity threats. As part of this program, we conduct periodic assessments of our assets to evaluate the effectiveness of applicable security controls. These assessments are informed by industry standard frameworks and include a review of our information security controls to assess cybersecurity maturity compared to our peers and other security awareness trainings.

We engage security technology vendors to assist with detecting potential threats to our information assets. In addition, we have implemented a cybersecurity third party risk management process to assess mission and business critical third parties for cyber risks and to assist the business in making risk-informed technology product and services decisions. Our practice is to perform due diligence, including the completion of security questionnaires and risk assessments, as appropriate, on third parties who maintain material data or information to help us evaluate and verify third party information security capabilities.

Our process designed to detect and respond to cybersecurity incidents that may represent a threat to the confidentiality, integrity or availability of our information assets is based on industry standards and best practices of peer companies. Our technology, procedures and key vendors with security responsibilities are designed to help contain, eradicate and recover from cybersecurity incidents in a timely manner. Senior management is informed about incidents that may have a significant impact on the business. Incidents are reviewed once they are resolved, and policies and controls are updated to help mitigate gaps. We have not identified risks from known cybersecurity threats or past incidents that have materially affected or are reasonably likely to materially affect us.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. “Risk Factors” in this Annual Report.

Governance

Management is responsible for the day-to-day management of risks we face, while our Board of Directors, as a whole and through committees, has responsibility for the oversight of risk management, including risks from cybersecurity threats. Our Audit Committee has specific oversight of risk management, including risks from cybersecurity threats.

Our Executive Director of IT is responsible for developing, implementing, and maintaining our cybersecurity risk management policies and procedures. The individual currently serving in the role of Executive Director of IT has over thirty years of experience in cybersecurity, information security, data protection, privacy, regulatory compliance and risk management within complex and international business verticals such as pharmaceutical/biotech, technology, semiconductor and telecom. The Executive Director of IT reports to our Chief Human Resources Officer and provides periodic cybersecurity updates to the Audit Committee of our Board of Directors on at least an annual basis. Our incident response process contemplates that the executive team will notify the Audit Committee of our Board of Directors of any material cybersecurity incident.

Item 2. Properties

Our headquarters are located in Waltham, Massachusetts, and consists of 30,102 square feet of leased office space under a lease that expires on April 30, 2026. On June 28, 2022, we entered into a lease agreement for 5,127 square feet of office space in Shanghai, PRC. On January 13, 2025, we extended the Shanghai lease, which expires on September 9, 2027. To meet future needs of our business, we may lease additional or alternate space and we believe suitable additional or alternate space will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our

business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market and Stockholder Information

Our common stock began trading on the Nasdaq Global Select Market on September 13, 2024, under the symbol "ZBIO". Prior to that time, there was no public market for our common stock.

Holders of Record

As of February 28, 2025, we had approximately 53 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have not paid cash dividends on our common stock and do not have a current intention to pay cash dividends, we continually review our capital allocation strategies, including, amount other things, payment of cash dividends, share repurchase and acquisitions.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item will be included in our proxy statement with respect to our 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days after the end of our fiscal 2024 year ended and is incorporated herein by reference.

Use of Proceeds from our Initial Public Offering

On September 16, 2024, the Company completed its IPO, in which the Company issued and sold 15,220,588 shares of its common stock, including 1,985,294 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The offer and sale of common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-281713), which was declared effective by the SEC on September 12, 2024 and a registration statement on Form S-1MEF (File No. 333-282082), which was automatically effective upon filing with the SEC on September 12, 2024. Following the sale of all of the shares offered in connection with the closing of our IPO, the offering terminated. Morgan Stanley & Co. LLC, Jefferies LLC, Citigroup Global Markets Inc. and Guggenheim Securities, LLC acted as underwriters for the IPO.

We received aggregate gross proceeds from our IPO of $258.7 million, or aggregate net proceeds of $234.3 million after deducting underwriting discounts, commissions and other offering costs. None of the underwriting discounts and commissions or other offering costs were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

Item 6. Reserved

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

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

Investors should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contain forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future performance that involve risks, uncertainties, and assumptions, such as statements regarding our intentions, plans, objectives, and expectations for our business. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk Factors." See also the section titled "Special Note Regarding 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 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 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.

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 three indications we are pursuing include IgG4-RD through an ongoing registration-directed Phase 3 trial, RMS and SLE through ongoing Phase 2, double-blind, randomized, placebo-controlled trials, each of which are currently enrolling.

Beyond our lead product candidate, obexelimab, we have two other programs for the potential treatment of other I&I indications that we may continue to advance and ultimately commercialize with partners. These consist of ZB002 and ZB004. We retain global rights for both assets. In addition, we hold the development and commercialization rights to one regional program, ZB001, and related programs, which were recently exclusively sublicensed to a partner in greater China.

On September 16, 2024, we completed our IPO in which we issued and sold an aggregate of 15,220,588 shares of our common stock, including 1,985,294 shares of common stock sold pursuant to the full exercise of the underwriter's option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $258.7 million. We received $234.3 million in net proceeds after deducting underwriting discounts, commissions and other offering costs payable by us. In connection with the IPO, all outstanding shares of convertible preferred stock ("Preferred Stock") converted into an aggregate of 24,978,715 shares of common stock.

On October 21, 2024, we entered into the Novation Agreement with Tenacia, under which we transferred our rights and obligations under our agreements with Dianthus to Tenacia for ZB005. As partial consideration for the Tenacia Agreement, we received a non-creditable, non-refundable upfront fee of $5.0 million from Tenacia. In addition, we are eligible to receive up to $86.0 million upon the achievement of certain future regulatory and commercial milestones.

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 December 31, 2024, we have financed our operations primarily with the proceeds from the issuance of Preferred Stock and convertible notes, payments received from our license and collaboration agreement and from the sale of common stock in our IPO completed in September 2024.

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 years ended December 31, 2024 and 2023 were $157.0 million and $37.1 million, respectively. As of December 31, 2024, we had an accumulated deficit of $387.4 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 contract research organizations (“CROs”) and contract manufacturing organizations (“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 investors 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. We expect to continue to incur significant losses for the foreseeable future as we continue to advance the development of our product candidates and incur additional costs associated with being a public company. 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. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued research and development and other current liabilities.

We will need to continue to raise substantial additional capital 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, prospects, 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 December 31, 2024, we had $350.8 million in cash, cash equivalents and short-term investments. We believe that our cash, cash equivalents and short-term investments as of December 31, 2024 will be sufficient to fund our operations and capital expenditure requirements into the fourth quarter of 2026. 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.”

Significant Risks and Uncertainties

The current inflationary environment may materially affect our business and operating results by increasing the costs of our clinical trial materials and supplies, driving the U.S. Federal Reserve system to increase interest rates, which in turn increase our overhead costs. Rising interest rates could make it more difficult to obtain traditional financing on acceptable terms, if at all. Additionally, the ongoing recession risk together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term and, as a result could negatively affect our operations. Furthermore, such economic conditions have produced downward pressure on share prices. Although we do not believe that inflation has had a material impact on our financial positions or results of operations to date, additional high inflation could increase our operating costs, including our labor costs and research and development costs. These costs may also be negatively impacted due to supply chain constraints, global geopolitical tensions, worsening macroeconomic conditions and employee availability and wage increases, which may result in additional stress on our working capital. We import from China drug product and other components for use in our clinical studies, and such products are subject to tariffs. Increases in tariffs could result in increased costs.

Additionally, we are subject to other challenges and risk specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the clinical stage biopharmaceutical industry.

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.

License and Collaboration Revenue

License and collaboration revenue is generated from our Bristol-Myers Squibb ("BMS") Agreement and our Tenacia Agreement.

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.

Pursuant to the Tenacia Agreement, we transferred our rights, title, interest, liabilities, duties and obligations under the Option and License Agreements with Dianthus to Tenacia for ZB005. The revenue recognized to date pursuant to this arrangement relates to the novation of the ZB005 license, asset transfer and technology transfer, which was recognized upon delivery of the license, related assets and technology transfer. We will recognize development and regulatory milestones as defined in the Tenacia 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 *Note 7, License and Collaboration Revenue*, to our consolidated financial statements included elsewhere in this Annual Report.

Operating Expenses

Our operating expenses consist 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 U.S. Food and Drug Administration ("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 and maintain 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 Investigational New Drug Application ("IND"), 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, Net

Other Income, Net

Other income, net primarily consists of interest income generated from cash equivalents and investments, and realized and unrealized gains and losses on foreign currency transactions.

Change in Fair Value of Convertible Notes

In August 2023, we issued a convertible note to BMS (the "BMS Note") in connection with the BMS Agreement, (see *Note 7, License and Collaboration Revenue* to our audited consolidated financial statements). We elected to record the BMS Note at fair value upon issuance and to subsequently remeasure the note at fair value at the end of each reporting period with the change in fair value being recorded as a component of other expense in our consolidated statement of operations and comprehensive loss. In May 2024, in connection with our Series C convertible preferred stock ("Series C Preferred Stock") financing, the BMS Note plus accrued interest was automatically converted into 12,284,686 shares of Series C Preferred Stock. 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 consolidated statement of operations and comprehensive loss during the years ended December 31, 2024 and 2023.

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.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Years Ended December 31,		Increase (Decrease)
	2024	2023	$
Revenue:			
License and collaboration revenue	$ 5,000	$ 50,000	$ (45,000)
Total revenue	5,000	50,000	(45,000)
Operating expenses:			
Research and development	$ 139,139	$ 60,033	$ 79,106
General and administrative	29,749	17,114	12,635
Acquired in-process research and development	—	10,000	(10,000)
Total operating expenses	168,888	87,147	81,741
Loss from operations	(163,888)	(37,147)	(126,741)
Other income, net:			
Fair value adjustments to convertible notes	(846)	(300)	(546)
Other income (expense), net	8,175	624	7,551
Total other income (expense), net	7,329	324	7,005
Loss before income taxes	(156,559)	(36,823)	(119,736)
Income tax provision	(429)	(301)	(128)
Net loss	$ (156,988)	$ (37,124)	$ (119,864)

Revenue

For the year ended December 31, 2024, we recognized revenue of $5.0 million, related to the upfront payment under the Tenacia Agreement. For the year ended December 31, 2023, we recognized revenue of $50.0 million, related to the upfront payment under the BMS Agreement.

Research and Development Expenses

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

	Years Ended December 31,		Increase (Decrease)
	2024	2023	$
Direct research and development expenses by program:			
Obexelimab	$ 94,563	$ 25,446	$ 69,117
Other programs (ZB002 & ZB004)	2,115	6,242	(4,127)
Partnered regional programs (ZB001 & ZB005)	6,737	6,738	(1)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	34,364	20,458	13,906
Other expenses	1,360	1,149	211
Total research and development expenses	$ 139,139	$ 60,033	$ 79,106

Research and development expenses were $139.1 million for the year ended December 31, 2024, compared to $60.0 million for the year ended December 31, 2023. The increase of $79.1 million was primarily attributable to the following:

- a $69.1 million increase in costs related to the development of obexelimab, our lead product candidate, driven by a $36.6 million increase in manufacturing costs for clinical trial materials and also a $32.0 million increase clinical trial costs;
- a $4.1 million decrease in costs related to our other programs, including a $2.3 million decrease related to ZB002 and a $1.8 million decrease related to ZB004; and
- a $13.9 million increase in personnel costs, including a $9.5 million increase in salary and benefit related expense, primarily due to an increase in headcount, a $2.5 million increase in stock-based compensation expense, and a $1.9 million increase in external contractor expense and other personnel costs.

General and Administrative Expense

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

	Years Ended December 31,		Increase
	2024	2023	$
Personnel related expenses (including stock-based compensation)	$ 18,613	$ 9,859	$ 8,754
Legal and professional fees	6,318	4,626	1,692
Facilities and supplies	2,375	1,825	550
Other expenses	2,443	804	1,639
Total general and administrative expenses	$ 29,749	$ 17,114	$ 12,635

General and administrative expenses were $29.7 million for the year ended December 31, 2024, compared to $17.1 million for the year ended December 31, 2023. The increase of $12.6 million was primarily attributable to the following:

- a $8.8 million increase in personnel costs, including a $4.9 million increase in stock-based compensation expense, a $3.8 million increase in salary and benefit related expense, primarily due to an increase in headcount, and a $0.1 million increase in recruiting expense, partially offset by a $0.1 million decrease in external contractor expense;
- a $1.7 million increase in professional fees, including legal, audit and tax expenses, primarily attributable to operating as a public company; and
- a $1.6 million increase in other expenses, including insurance and other variable costs related to operating as a public company.

Acquired In-Process Research and Development Expenses

There was no acquired IPR&D expense recorded for the year ended December 31, 2024. Acquired IPR&D for the year ended December 31, 2023 was comprised of a $10.0 million development milestone expense related to obexelimab.

Total Other Income (Expense), Net

For the year ended December 31, 2024, total other income (expense), net increased from the comparable period in the prior year primarily due to interest earnings as a result of higher cash, cash equivalents and short-term investments due to proceeds from the Series C Preferred Stock and IPO.

Liquidity and Capital Resources

Overview

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 December 31, 2024, we had $350.8 million in cash, cash equivalents and short-term investments and we had an accumulated deficit of $387.4 million. Through December 31, 2024, we have funded our operations primarily with gross proceeds of $358.0 million through the sale and issuance of our Preferred Stock, our convertible notes, as well as $55.0 million through our BMS Agreement and Tenacia Agreement, and most recently, from the sale of common stock in our IPO.

Future Funding Requirements

We believe that our available cash, cash equivalents and short-term investments, as of December 31, 2024, are sufficient to fund existing and planned cash requirements for at least the next 12 months, from the filing of this Form 10-K. Our primary uses of capital are, and we expect to continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses and general overhead costs. We have based our estimates on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect.

Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. 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, 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.

We have no products approved for commercial sale and have not generated any product revenues from product sales to date. 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 financing and additional funding from license, strategic alliances and collaboration arrangements. Except for any obligations of our collaborators to reimburse us for research and development expenses or make milestone or royalty payments under our agreements with them, we will not have any committed external source of liquidity.

We have incurred losses and cumulative negative cash flows from operations since our inception. We anticipate that we will continue to incur significant losses for at least the next several years. We expect our research and development, general and administrative expenses will continue to increase. As a result, we will need additional capital to fund our operations, which we may raise through a combination of the sale of our equity, debt financings, or other sources, including potential collaborations. To the extent that we raise capital through the future sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we enter into debt financing arrangements, if available, they may involve 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 license, strategic alliances or collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise 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 drug candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

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

	Years Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (119,674)	$ (30,529)
Net cash used in investing activities	(30,552)	(17)
Net cash provided by financing activities	412,958	20,116
Effect of exchange rate changes on cash and restricted cash	157	78
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 262,889	$ (10,352)

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $119.7 million, and was primarily due to our net loss of $157.0 million adjusted for non-cash items including stock-based compensation of $10.8 million, an investment accretion of $0.6 million and non-cash operating lease of $0.7 million, and an increase in assets and liabilities of $25.3 million. The significant items of the increase in operating assets and liabilities include an increase in accrued expenses and accounts payable of $33.8 million and prepaid expenses and other assets of $7.7 million.

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, adjusted for non-cash items including acquired in-process research and development expense related to a milestone payment of $10.0 million, stock-based compensation of $3.5 million and non-cash operating lease of $0.7 million, offset by a decrease in assets and liabilities of $8.0 million. The significant items of the decrease in operating assets and liabilities include a $4.0 million decrease in accrued expense and accounts payable and an increase of $3.3 million decrease in prepaid expenses and other assets.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2024 was $30.6 million and was due to the purchase of $36.4 million of investments, partially offset by $6.0 million in proceeds from the maturities of investments.

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was $413.0 million, resulting from $178.4 million in net proceeds received from the issuance and sale of shares of our Series C Preferred Stock, proceeds of $240.6 million from our IPO, net of underwriting discounts and commissions, and $0.3 million of proceeds received from the exercise of stock options, partially offset by a $6.3 million payment of offering costs related to our IPO.

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.

Contractual obligations and commitments

Leases

We have entered into lease arrangements for facilities, which are comprised of office space, through April 30, 2026. As of December 31, 2024, our total fixed lease payment obligations outstanding are $1.1 million of which $0.9 million is payable within 12 months.

For additional information on our lease obligations, please see *Note 6, Leases*, to these consolidated financial statements.

License and Option Agreements

We have 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 December 31, 2024 and 2023, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

For additional information on our license and option agreements, please see *Note 8, License and Option Agreements*, to these consolidated financial statements.

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. As of December 31, 2024, our total clinical manufacturing contract payment obligations are $15.3 million of which the full obligation is payable within 12 months.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"), requires us to make judgments, assumptions and estimates that may affect the reported amounts of assets and liabilities, equity and 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. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experiences. 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. 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. Other significant accounting policies are outlined in *Note 2, Summary of Significant Accounting Policies*, to our consolidated financial statements.

We have listed below our critical accounting estimates that we believe to have the greatest potential impact on our consolidated financial statements. Our assumptions, judgements and estimates relative to our critical accounting estimates have not differed materially from actual results.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and vendor agreements, communicating with our applicable personnel 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 actual cost. We make estimates of our accrued and prepaid clinical expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to CROs, and investigative sites in connection with clinical studies and to vendors related to product manufacturing and development of clinical supplies.

We base our expenses related to clinical study and trial costs on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies 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 and expense recognition. Payments under some of these contracts depend on factors out of our control, as such as the successful enrollment of patients and the completion of clinical trial milestones. 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

accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period.

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, Summary of Significant Accounting Policies,* in our consolidated financial statements included elsewhere in this Annual Report.

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 nonbinding 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 December 31, 2029 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 nonconvertible 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.

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 following the IPO is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide the information required by this item in this report.

Item 8. Financial Statements and Supplementary Data

ZENAS BIOPHARMA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements for the Years Ended December 31, 2024 and 2023:

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	137
Consolidated Balance Sheets	138
Consolidated Statements of Operations and Comprehensive Loss	139
Consolidated Statements of Stockholders' Equity	140
Consolidated Statements of Cash Flows	141
Notes to Consolidated Financial Statements	142

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Zenas BioPharma, Inc.

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

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.
Boston, Massachusetts
March 11, 2025

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

Zenas BioPharma, Inc.

Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 319,742	$ 56,857
Short-term investments	31,024	—
Restricted cash	90	—
Prepaid expenses and other current assets	5,067	2,947
Total current assets	355,923	59,804
Property and equipment, net	185	193
Operating lease right-of-use assets, net	1,004	821
Restricted cash	—	86
Other non-current assets	12,856	7,276
Total assets	$ 369,968	$ 68,180
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable (includes $560 and $21 owed to related parties, respectively)	$ 17,136	$ 5,396
Accrued expenses (includes $260 and $404 owed to related parties, respectively)	39,371	17,306
Operating lease liabilities, current	785	556
Total current liabilities	57,292	23,258
Operating lease liabilities, non-current	218	257
Convertible notes, at fair value	—	20,300
Total liabilities	57,510	43,815
Commitments and contingencies (Note 14)		
Convertible preferred stock:		
Series Seed convertible preferred stock, par value $0.0001 per share; 0 and 1,785,714 shares authorized, issued and outstanding as of December 31, 2024 and 2023, respectively.	—	956
Series A convertible preferred stock, par value $0.0001 per share; 0 and 17,589,380 shares authorized, issued and outstanding as of December 31, 2024 and 2023, respectively.	—	55,840
Series B convertible preferred stock, par value $0.0001 per share; 0 and 81,242,587 shares authorized, issued and outstanding as of December 31, 2024 and 2023, respectively.	—	193,290
Stockholders' equity (deficit):		
Preferred stock, par value $0.0001 per share; 25,000,000 and no shares authorized as of December 31, 2024 and 2023, respectively; no shares issued and outstanding as of December 31, 2024 and 2023.	—	—
Common stock, par value $0.0001 per share; 175,000,000 shares authorized as of December 31, 2024 and 2023; 41,793,412 and 1,576,854 shares issued and outstanding as of December 31, 2024 and 2023, respectively.	4	—
Additional paid-in capital	699,651	4,645
Accumulated other comprehensive income	194	37
Accumulated deficit	(387,391)	(230,403)
Total stockholders' equity (deficit)	312,458	(225,721)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 369,968	$ 68,180

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)

	Years Ended December 31,	
	2024	2023
Revenue:		
License and collaboration revenue	$ 5,000	$ 50,000
Total revenue	5,000	50,000
Operating expenses:		
Research and development (includes $3,524 and $3,041 from related parties, respectively)	139,139	60,033
General and administrative (includes $0 and $8 from related parties, respectively)	29,749	17,114
Acquired in-process research and development	—	10,000
Total operating expenses	168,888	87,147
Loss from operations	(163,888)	(37,147)
Other income, net:		
Fair value adjustments to convertible notes	(846)	(300)
Other income, net	8,175	624
Total other income (expense), net	7,329	324
Loss before income taxes	(156,559)	(36,823)
Income tax provision	(429)	(301)
Net loss to common stockholders	$ (156,988)	$ (37,124)
Net loss per share attributable to common stockholders - basic and diluted	$ (11.89)	$ (24.25)
Weighted-average common stock outstanding - basic and diluted	13,198,960	1,531,178
Comprehensive loss:		
Net loss to common stockholders	$ (156,988)	$ (37,124)
Other comprehensive income:		
Unrealized gain on marketable securities, net tax	31	—
Foreign currency translation adjustment	126	78
Comprehensive loss	$ (156,831)	$ (37,046)

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' Equity (Deficit)
(in thousands, except share data)

	Convertible Preferred Stock													
	Series Seed		Series A		Series B		Series C		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of 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
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	78	—	78
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(37,124)	(37,124)
Balance as of 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)	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of $619	—	—	—	—	—	—	116,275,239	199,526	—	—	—	—	—	—
Conversion of convertible preferred stock to common stock upon closing of initial public offering	(1,785,714)	(956)	(17,589,380)	(55,840)	(81,242,587)	(193,290)	(116,275,239)	(199,526)	24,978,715	2	449,610	—	—	449,612
Issuance of common stock from initial public offering, net of underwriting discounts, commissions and other issuance costs	—	—	—	—	—	—	—	—	15,220,588	2	234,300	—	—	234,302
Exercises of common stock options									38,427	—	275	—	—	275
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	10,821	—	—	10,821
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	—	—	31	—	31
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	126	—	126
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(156,988)	(156,988)
Balance as of December 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	41,793,412	$ 4	$ 699,651	$ 194	$ (387,391)	$ 312,458

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

Zenas BioPharma, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (156,988)	$ (37,124)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	10,000
Depreciation expense	137	113
Net amortization of premiums and accretion of discounts on short-term investments	(602)	—
Stock-based compensation expense	10,821	3,495
Change in fair value of convertible notes	846	300
Non-cash lease expense	681	726
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(7,701)	(3,349)
Accounts payable	11,740	(418)
Accrued expenses	22,065	(3,558)
Operating lease liabilities	(673)	(714)
Net cash used in operating activities	(119,674)	(30,529)
Cash flows from investing activities:		
Purchase of property and equipment	(131)	(17)
Purchase of short-term investments	(36,421)	—
Proceeds from sale and maturities of short-term investments	6,000	—
Net cash used in investing activities	(30,552)	(17)
Cash flows from financing activities:		
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	178,381	—
Proceeds from initial public offering, net of underwriting discount and commissions	240,636	—
Payment of initial public offering costs	(6,334)	—
Proceeds from sale of convertible notes	—	20,000
Proceeds from exercise of stock options	275	116
Net cash provided by financing activities	412,958	20,116
Effect of exchange rate changes on cash, cash equivalents and restricted cash	157	78
Net increase (decrease) in cash, cash equivalents and restricted cash	262,889	(10,352)
Cash, cash equivalents and restricted cash at beginning of period	56,943	67,295
Cash, cash equivalents and restricted cash at end of period	$ 319,832	$ 56,943
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of BMS Note recognized as Series C Convertible preferred stock upon conversion	$ 21,146	$ —
Conversion of convertible preferred stock to common stock upon closing of initial public offering	$ 449,612	$ —
Right-of-use assets obtained under operating lease arrangements	$ 1,100	$ —
Deferred offering costs in accrued expenses	$ —	$ 1,388
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 319,742	$ 56,857
Restricted cash	90	86
Total cash, cash equivalents and restricted cash	$ 319,832	$ 56,943

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 (the "Redomicile"). 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 goal is to build an immunology and inflammation ("I&I") focused biopharmaceutical company. 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"), Zenas BioPharma (USA) LLC ("Zenas US"), Shanghai Zenas Biotechnology Co. Limited ("Zenas China"), Zenas BioPharma Securities Corp., and Zenas BioPharma GmbH.

Liquidity and Capital Resources

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 clinical 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 and collaboration agreement with Bristol-Myers Squibb Company ("BMS") and novation agreement with Tenacia Biotechnology ("Tenacia") (see *Note 7, License and Collaboration Revenue*). 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.

On September 16, 2024, the Company completed its initial public offering ("IPO"), in which the Company issued and sold 15,220,588 shares of its common stock, including 1,985,294 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $258.7 million. The Company received $234.3 million in net proceeds after deducting underwriting discounts, commissions and other offering expenses. In connection with the IPO, all outstanding shares of convertible preferred stock converted into 24,978,715 shares of the Company's common stock.

In connection with, and prior to, the Company's IPO, 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 all 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.

The Company has incurred operating losses and negative cash flows since its inception, including net losses of $157.0 million and $37.1 million in the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, the Company had an accumulated deficit of $387.4 million and $230.4 million, respectively. Management expects operating losses and negative operating cash flows to continue for the foreseeable future.

The Company expects that its existing cash, cash equivalents and short-term investments of $350.8 million as of December 31, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date this Form 10-K is filed. 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 or public 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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the operations of the Company and its wholly-owned subsidiaries. All intercompany accounts, transactions, and balances have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been or omitted pursuant to such rules and regulations.

Use of Estimates

The preparation of financial statements in conformity with 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 assumptions. Significant estimates in these consolidated financial statements include estimates made in connection with accrued research and development expenses, stock-based compensation and pre-initial public offering ("IPO") valuations of common stock, and convertible debt.

Cash, 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 equivalents may include money market funds, corporate debt securities, U.S government agency notes and overnight deposits.

Short-Term Investments

The Company classifies all investments with a remaining maturity when purchased of greater than three months as "available-for-sale". Available-for-sale securities with a remaining maturity of greater than one year are classified as non-current assets. Available-for-sale securities are carried at fair value based upon market prices at period end, with the unrealized gains and losses included in accumulated other comprehensive loss as a component of stockholders' equity (deficit) until realized. The amortized cost of investments in this category is adjusted for amortization of premiums and accretions of discounts over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense). The Company reviews its portfolio of investments, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss. If the decline in fair value is due to credit-related factors, a loss is recognized in other income (expense).

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, which terminated in January 2025. Amounts are reported as non-current unless restrictions are expected to be released in the next 12 months.

Deferred Offering Costs

The Company capitalizes legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as other non-current assets until such financings are consummated. After consummation of the equity financing, these costs will be recorded in stockholders' equity (deficit) as a reduction of additional paid-in-capital generated as a result of the offering. If the Company terminates its plan for an equity financing, any costs deferred will be expensed immediately. Upon closing the IPO in September 2024, the related deferred offering costs were recorded against the IPO proceeds. No deferred offering costs were recorded as of December 31, 2024. As of December 31, 2023, the Company had $1.4 million in deferred offering costs which were included in other assets.

Segment Reporting

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 reportable segment focused on the research and development of precision immunology-based therapies. The Company's chief operating decision-maker (the "CODM"), its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of making operating decisions, assessing financial performance, and allocating resources. As of December 31, 2024 and 2023, the Company's long-lived assets held outside of the U.S. were immaterial.

For additional information on our segment reporting, see *Note 17, Segment Information* to these consolidated financial statements.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents and short-term investments. The Company attempts to minimize the risks related to cash, cash equivalents and short-investments by investing in a broad range of financial instruments, as defined by the Company's investment policy. The Company has established guidelines related to the quality of the institutions, financial instruments and allowable investments. The Company minimizes credit risk by choosing only highly rated financial institutions as counterparties.

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.

Translation of Foreign Currency

The functional currency for most of our foreign subsidiaries is their local currency. For our non-U.S subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments resulting from the translation of the financial statements of our foreign subsidiaries into U.S. dollars are excluded from our determination of net loss and are recorded in accumulated other comprehensive income (loss), as a separate component of equity. For foreign subsidiaries where the functional currency of assets and liabilities differs from their local currency, non-monetary assets and liabilities are translated at the rate of the exchange in effect on the date assets were acquired while monetary assets and liabilities are translated at current rates of exchange as of the balance sheet date.

Income and expense items are translated at the average foreign currency rates for the period. Translation adjustments of these subsidiaries are included in other (income) expense, net in our consolidated statements of income. Realized and unrealized foreign currency transaction losses were $0.2 million and $0.1 million for each of the years ended December 31, 2024 and 2023, respectively.

Fair Value Measurements

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.

The majority of our financial assets have been classified as Level 1. Our financial assets (which typically include cash equivalents and marketable equity securities) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or option pricing valuation models. The pricing services utilize industry standard valuation models, including both income and market- based approaches and observable market inputs to determine value. These observation market inputs included reportable tables, benchmark yields, broker quotes, bids, offers, current spot rates and other industry and economic events.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amount of the assets to their undiscounted expected future cash flows. If this comparison indicates there is an impairment, the amount of the impairment is calculated as the difference between the carrying value and fair value. To date, no such impairments have been recognized.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets (three to seven years). Assets under capital leases are amortized over the shorter of their useful

lives or lease terms using the straight-line method. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred.

License and 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 may perform 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.

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.

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 license and 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 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 acquired IPR&D expense as of the acquisition date. The Company will recognize additional acquired 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, 2024, the Company did not recognize any acquired IPR&D expense. 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.

For additional information on our asset acquisitions and acquired in-process research and development, please see *Note 8, License and Option Agreements,* to these consolidated financial statements.

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, 2024 and 2023, 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 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.

For additional information on our leases, please see *Note 6, Leases*, to these consolidated financial statements.

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, 2024 and 2023. 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 on the date of grant. The Company's share-based payments include stock options and grants of restricted 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.

The Company estimates the fair value of each restricted stock award ("RSA's") 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 estimates the fair value of stock option awards on the grant date using a Black-Scholes option pricing model. The Company estimates the expected option lives using the simplified method, volatility using historical stock prices of peer companies, the risk-free rates using the U.S Treasury yield curve in effect with a remaining term equal to the expected term and dividend yield based on the Company's history of paying no dividends and the expectations of paying no cash dividends in the foreseeable future. Prior to the Company's IPO, the fair value of the Company's common stock on the date of grant was determined by the Board, taking into consideration its most recently available third-party valuations of common stock as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the grant date.

For additional information on our share-based compensation, please see *Note 11, Stock-Based Compensation*, to these consolidated financial statements.

Convertible Preferred Stock

The Company classified its convertible preferred stock as temporary equity (between liabilities and stockholders' equity (deficit)) in the accompanying consolidated balance sheet because it could have become redeemable due to certain change in control clauses that were outside of the Company's control. The convertible preferred stock was not redeemable, except in the event of a deemed liquidation event. As the occurrence of a deemed liquidation event was not currently probable at December 31, 2023, the carrying values of the convertible preferred stock were not being accreted to their redemption values. Upon the completion of the Company's IPO on September 16, 2024, all outstanding shares of the Company's convertible preferred stock converted into shares of the Company's common stock.

For additional information on our convertible preferred stock, please see *Note 9, Convertible Preferred Stock*, to these consolidated financial statements.

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 contained 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 their effect is antidilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2024 and 2023.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standard Board ("FASB") or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed, we do not believe that the adoption of recently issued standards have or may have a material impact on our consolidated statements or disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures ("ASU 2023-07")*, which requires public entities to disclose information about their reportable segments' significant expenses on an interim and annual basis. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for annual periods beginning after December 15, 2023 and for interim periods within fiscal years beginning after December 15, 2024. This standard became effective for the Company for the annual reporting period ended December 31, 2024, using the retrospective method. The adoption of this standard resulted in additional disclosure of the significant expenses reviewed by the Company's CODM. The adoption did not have a material impact on the consolidated financial position or results of operations. See *Note 17, Segment Information*, for our updated segment presentation.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures ("ASU 2023-09")*, which requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for the Company beginning in fiscal year 2025, with early adoption permitted. ASU 2023-09 may be applied retrospectively or prospectively to the financial statements. The Company is currently evaluating the impact of ASU 2023-09 on the consolidated financial statements and related disclosures.

In November 2024, the FASB issued 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03")*, which requires entities to disclose additional information about specific expense categories in the notes to the financial statements. ASU 2024-03 is effective annual periods beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. ASU 2024-03 may be applied retrospectively or

prospectively to the financial statements. The Company is currently evaluating the impact of ASU 2024-03 on the consolidated financial statements and related disclosures.

3. Fair Value Measurements

The following tables present information about the Company's assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value (in thousands):

	As of December 31, 2024			
Description	**Total Carrying Value**	**Quoted Prices in Active Market (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Other Observable Inputs (Level 3)**
Assets:				
Cash	$ 19,070	$ 19,070	$ —	$ —
Money market funds	300,672	300,672	—	—
Investments:				
Commercial paper	3,315	—	3,315	—
Corporate debt securities	8,601	—	8,601	—
Government securities	19,108	19,108	—	—
Total assets	$ 350,766	$ 338,850	$ 11,916	$ —

	As of December 31, 2023			
Description	**Total Carrying Value**	**Quoted Prices in Active Market (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Other Observable Inputs (Level 3)**
Liabilities:				
BMS note	$ 20,300	$ —	$ —	$ 20,300
Total liabilities	$ 20,300	$ —	$ —	$ 20,300

There have been no material impairments of our assets measured and carried at fair value during the year ended December 31, 2024. The fair value of Level 1 instruments classified as money market funds and government securities are valued using quoted market prices in active markets. The fair value of Level 2 instruments classified as short-term investments was determined using other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date and fair value is determined using models or other valuation methodologies. There were no transfers between levels during the years ended December 31, 2024 and 2023.

The short-term investments are classified as available-for-sales securities. As of December 31, 2024, the remaining contractual maturities of the available-for-sales securities were within one year, the balance in the Company's accumulated other comprehensive income was comprised solely of activity related to the Company's available-for-sale securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during the year ended December 31, 2024. As a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the same period. The Company has a limited number of available-for-sale securities in insignificant loss

positions as of December 31, 2024, which the Company does not intend to sell and has concluded will not be required to sell before recovery of the amortized cost for the investment maturity.

The following table summarizes the available-for-sale securities (in thousands):

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Commercial paper	$ 3,311	$ 4	$ —	$ 3,315
Corporate debt securities	8,589	12	—	8,601
Government securities	19,093	17	(2)	19,108
Total	$ 30,993	$ 33	$ (2)	$ 31,024

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the table above. The Company did not hold any investments as of December 31, 2023.

Convertible Notes

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, License and Collaboration Revenue*). In the event that the Company issued and sold 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 were automatically convertible into equity securities sold in the BMS Qualified Financing at the 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. 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 the other income (expense), net. The BMS Note was classified as a liability on the Company's consolidated balance sheet as of December 31, 2023 and was initially recorded at fair value. The Company subsequently remeasured the fair value of the BMS Note at each applicable reporting period.

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, Convertible Preferred Stock*). Immediately prior to settlement, the BMS Note was remeasured to fair value utilizing fair value of the shares of Series C Preferred Stock for which the BMS Note converted into. The BMS Note settling in shares of Series C Preferred Stock represents the redemption of stock-settled debt and was therefore accounted for as an extinguishment. Upon extinguishment, no gain or loss was recognized. The Company recorded a $0.8 million change in fair value of the BMS Note as component of other income (expense), net for the year ended December 31, 2024.

The following tables presents changes to the Company's liabilities with significant unobservable inputs (Level 3 liabilities) during the years ended December 31, 2024 and 2023 (in thousands):

		Convertible notes
Convertible Note:		
Balance as of December 31, 2022	$	—
Issuance of BMS Note		20,000
Change in fair value of BMS Note		300
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 December 31, 2024	$	—

4. Other Assets

Other assets consisted of the following (in thousands):

	December 31,	
	2024	2023
Clinical trial deposits	$ 12,639	$ 5,788
Deferred offering costs	—	1,388
Other	217	100
Total other assets	$ 12,856	$ 7,276

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2024	2023
External research, development and manufacturing expenses	$ 29,338	$ 9,398
Employee compensation and benefits	8,308	5,122
Professional and consultant fees	1,265	2,379
Income taxes payable	211	301
Other	249	106
Total accrued expenses	$ 39,371	$ 17,306

6. Leases

The Company has various leases for office space, which are accounted for as operating leases and generally have terms of less than two years in length, some of which have the option to renew. 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. For each of the years ended December 31, 2024 and 2023, the Company incurred variable lease expense of $0.1 million, respectively.

Supplemental balance sheet information related to operating lease assets and liabilities was as follows (in thousands):

	December 31,	
	2024	2023
Operating lease assets	$ 1,004	$ 821
Operating lease liabilities	$ 1,003	$ 813
Weighted average remaining term in years	1.3	1.6
Weighted average discount rate used to measure lease liabilities	10.99%	18.39%

For each of the years ended December 31, 2024 and 2023, 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, respectively.

The minimum lease payments under the Company's operating leases are expected to be as follows:

Fiscal Year	Amount
2025	$ 896
2026	241
Thereafter	—
Total future minimum lease payments	1,137
Less: imputed interest	(134)
Total operating lease liabilities	$ 1,003

During the year ended December 31, 2024, the amount of right-of-use assets obtained under new operating lease arrangements was $1.1 million. There were no right-of-use assets obtained under new operating lease arrangements during the year ended December 31, 2023. Cash paid for lease liabilities was $0.9 million for the years ended December 31, 2024 and 2023, respectively.

7. License and Collaboration Revenue

License and Collaboration Agreement with Bristol-Myers Squibb

In August 2023, the Company entered into a license and collaboration 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.

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 trial 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 terms of 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 trial for IgG4-RD. The Company used 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 $6.0 million and $4.1 million as a reduction to research and development expenses during the years ended December 31, 2024 and 2023, respectively, with $2.0 million and $1.3 million of outstanding receivable, included in prepaid expenses and other current assets on the Company's consolidated balance sheet as of December 31, 2024 and 2023, respectively.

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 (i) the exclusive license, (ii) the initial technology transfer, (iii) clinical manufacturing supply related to development in the BMS Territory and (iv) 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.

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, Fair Value Measurements*). 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 the 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 and therefore recognized the upfront payment of $50.0 million as revenue during year ended December 31, 2023. The Company did not recognize revenue under this arrangement in the year ended December 31, 2024, as no milestones were achieved or deemed probable of achievement, and as such, all remaining milestones remained fully constrained and excluded from the transaction price.

Tenacia Biotechnology Co. Novation Agreement

In October 2024, the Company entered into a novation agreement with Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia"), under which the Company transferred its rights and obligations under the agreements with Dianthus to Tenacia (the "Tenacia Agreement"). Pursuant to the Tenacia Agreement, the Company, transferred all the ZB005 inventory, analytical methods and manufacturing records generated, under the Dianthus Option Agreement and the License Agreement (collectively the "Dianthus Agreements"), see *Note 8, License and Options Agreements,* for additional information, to Tenacia, for the exclusive right to research, develop, manufacture and commercialize products within greater China.

Pursuant to the Tenacia Agreement, Tenacia paid the Company a one-time non-refundable upfront cash payment of $5.0 million. The Company is entitled to receive further development, regulatory and sales milestones from Tenacia of up to approximately $86.0 million if certain milestones are successfully achieved.

The Company evaluated the terms of the Tenacia Agreement and determined it is within the scope of *ASC 606*. The Company identified the following promises in the Tenacia Agreement that were evaluated under the scope of *ASC 606:* (i) transfer of the license, (ii) assignment of all rights, title and interests in ZB005 inventory, manufacturing records, analytical methods and draft IND component, (iii) services to be performed in accordance with manufacturing technology transfer and (iv) transfer, up to one year after the effective date, of any tangible embodiments of know-how that was not previously provided. The Company also evaluated whether certain options outlined in the Tenacia Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options conveyed a material right to Tenacia and, therefore, are not considered separate performance obligations within the Tenacia Agreement.

The Company assessed the above promises and determined that the license for ZB005, asset transfer and technology transfer are a combined distinct performance obligation within the scope of *ASC 606*. The future technology know-how transfer services, for one year after the effective date, is a promise that is separately identifiable. The Company determined the likelihood of Tenacia requesting additional know-how transfer to be remote and any requests to require minimal resource allocation, as the Company has concluded all work on ZB005 within greater China. As such, the Company considered the continued know-how transfer to be immaterial in the context of the promises. Therefore, the license, asset transfer and technology transfer represent a single performance obligation within the scope of *ASC 606* at contract inception.

The Company concluded that the transaction price of $5.0 million was allocated to the combined performance obligation, which was recognized upon delivery prior to December 31, 2024.

The Company used the most likely amount method to estimate variable consideration and estimated that the most likely amount for each potential developmental and regulatory variable consideration milestone payment under the agreement is zero, as achievement of those milestones is uncertain and susceptible to factors outside the Company's control. Accordingly, all such milestone payments were excluded from the transaction price. Management will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, will adjust the transaction price as necessary. Sales based milestones structured on the level of sales, were also excluded from the transaction price, as the license is deemed to be the predominant item to which the sales relate. The Company will recognize such 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).

As of December 31, 2024, no milestones were achieved or deemed probable of achievement.

8. 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 (i) an exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (ii) 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 year ended December 31, 2024 no costs were incurred related to the 2020 Xencor Agreement. During the year ended December 31, 2023, 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 (i) exclusive, royalty-bearing, sublicensable worldwide license under certain patent rights controlled by Xencor and (ii) 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 (the "Xencor Warrant") as initial consideration, which entitled Xencor to receive a number of the Company's convertible preferred stock in the Company's next "qualified financing". 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 9, Convertible Preferred Stock,* for details. The milestone was recorded as acquired IPR&D expense in the Company's consolidated statements of operations and comprehensive loss. The Company did not record any expenses related to reimbursable patent-related costs during the year ended December 31, 2024. The Company recorded an immaterial amount to general and administrative expenses in the consolidated statements of operations and comprehensive loss

during each of the year ended December 31, 2023, relating to reimbursable patent-related costs owed to Xencor. During the year ended December 31, 2024 no milestone expense was incurred.

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").

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, 2024 and 2023, the Company incurred $5.1 million and $3.0 million of reimbursable expenses, respectively, which are recorded within research and development expenses in the consolidated statements of operations and comprehensive loss. Of these amounts, $0.5 million and an immaterial amount were recorded in accounts payable, and $0.3 million and $0.4 million were recorded in accrued expenses on the Company's consolidated balance sheets as of December 31, 2024 and 2023, 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.

In October 2024, the Company entered into the Tenacia Agreement. Pursuant to the Tenacia Agreement, the Company transferred its rights, and obligations under the Dianthus Option Agreement and the Dianthus License Agreement to Tenacia. As a result, Zenas has no further obligations to Dianthus under the Dianthus Option Agreement and the Dianthus License Agreement.

For additional information on our Tenacia Agreement, please see *Note 7, License and Collaboration Revenue*, to these consolidated financial statements.

Viridian Therapeutics, Inc.

In October 2020, the Company entered into a license 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 "Viridian Agreement"). 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, 2024 and 2023, the Company did not incur or pay any milestones to Viridian.

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 pays 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, 2024 and 2023, the Company recognized an immaterial amount of expenses, respectively, which were recorded in research and development expenses in the consolidated statements of operations. As of December 31, 2024, and 2023, immaterial amounts were recorded in accounts payable and accrued expenses. Viridian has agreed to reimburse the Company for certain services it performs on Viridian's behalf, with reimbursements being recorded as a reduction in research and development expenses. During the year ended December 31, 2024, the Company recorded $1.7 million in reimbursable expenses. During the year ended December 31, 2023, the Company had no reimbursable expenses. As of December 31, 2024, Viridian had not notified the Company of any additional antibody product candidate.

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.

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 from notes issued to several investors in 2021, and resulted in the principal plus accrued interest being automatically converted into Series B Preferred Stock, the outstanding convertible notes from 2021 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 (see *Note 8, License and Option Agreement* to these consolidated financial statements).

In May 2024, the Company issued and sold 103,990,553 shares of Series C convertible preferred stock ("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 the Series Seed, Series A, Series B, and Series C 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.

In September 2024, the Company completed its IPO, in which the Company issued and sold 15,220,588 shares of its common stock, including 1,985,294 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $17.00 per share, for aggregate gross proceeds of $258.7 million. The Company received approximately $234.3 million in net proceeds, after deducting underwriting discounts and commissions and other offering costs. In connection with the IPO, all outstanding shares of Preferred Stock converted into an aggregate of 24,978,715 shares of common stock and no convertible preferred stock was outstanding as of December 31, 2024.

Preferred Stock consisted of the following as of December 31, 2023 (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

The holders of preferred stock had the following rights, preferences and privileges prior to conversion into common stock upon the closing of the IPO:

Voting

The holder of each share of Preferred Stock was 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.

Conversion

Each share of convertible preferred stock was 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 resulted in a specified minimum amount of gross cash proceeds. The conversion ratio was initially one share of common stock for each share of convertible preferred stock and was adjustable 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 were dilutive to holders of the Company's preferred stock. Holders of preferred stock had the right to one vote for each share of the Company's common stock which were dilutive to holders of the Company's preferred stock. Holders of preferred stock had 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.

Dividends

Holders of Series C Preferred Stock were 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 had been distributed to holders of Series C Preferred Stock, holders of Series B Preferred Stock would have been entitled to receive dividends, only when, as and if declared by the Board, at the annual rate of 6% of the Series B 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 had been distributed to holders of Series B Preferred Stock, holders of Series A Preferred Stock would had been 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 had been distributed to holders of Series A Preferred Stock, holders of Series Seed Preferred Stock would have been 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 was not cumulative, and no such right accrued to holders of such shares. There were no dividends declared or paid as of December 31, 2024 and 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 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 have been 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 have been 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 have been 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, Series A Preferred Stock, holders of Series Seed Preferred Stock prior and in preference to any distribution to holders of common shares, would have been 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 have been paid to holders of common shares. A deemed liquidation event was defined 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 did 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 automatically converted into shares of common stock of the Company upon the Redomicile and incorporation of the Company in the State of Delaware as Zenas BioPharma, Inc. In May 2024, the Company amended and restated its certificate of incorporation, whereby the Company increased the shares of common stock it was authorized to issue to 294,784,925 shares. Upon consummation of the IPO,

the Company restated its certificate of incorporation, and as of December 31, 2024, the Company was authorized to issue 175,000,000 shares of $0.0001 par value common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock were subject to and qualified by the rights, powers and preference of the holders of any preferred stock then issued and outstanding.

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,	
	2024	2023
Conversion of outstanding shares of convertible preferred stock	—	11,587,744
Options to purchase common stock	8,706,197	2,382,933
Remaining shares reserved for future issuance	359,399	60,792
Total	9,065,596	14,031,469

11. Stock-Based Compensation

2020 Plan

On August 21, 2020, the Company's sole director and member approved the Zenas BioPharma (Cayman) Limited 2020 Equity Incentive Plan (the "2020 Plan"). Upon effectiveness of the 2024 Plan (as defined below), the Company ceased granting additional awards under the 2020 Plan. The 2020 Plan allowed the Company to grant 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.

Since inception of the 2020 Plan, the Company has granted RSAs and stock options which 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 remained available for future grant under the 2020 Plan. Upon effectiveness of the 2024 Plan (as defined below), the remaining available shares for future grant were transferred to the 2024 Plan.

2024 Plan

On September 3, 2024, the Board adopted the 2024 Equity Incentive Plan (the "2024 Plan"), which became 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.

Upon the effectiveness of the 2024 Plan, the number of shares of common stock initially reserved for issuance was 4,775,477 shares of common stock which is equal to 12% of the number of shares of common stock issued and outstanding immediately following the consummation of the Company's IPO. The number of shares reserved and available for issuance under the 2024 Plan will automatically increase each January 1, beginning 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.

As of December 31, 2024, there were 359,399 shares available for issuance under the 2024 Plan. On January 1, 2025, the shares available for issuance under the 2024 Plan was increased to 2,449,069.

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	27,200	$ 2.71
Vested	(6,028)	0.01
Repurchased	(21,172)	3.48
Unvested as of December 31, 2024	—	$ —

There were no RSAs granted during the year ended December 31, 2024. As of December 31, 2024, there was no compensation cost related to unvested RSAs as all were fully vested.

Stock Options

The Company has granted stock-based awards with either service or performance based vesting conditions. Compensation expense related to awards to employees and directors with service based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to employees with performance based vesting conditions is recognized based on the grant date fair value once the achievement of the performance condition is probable.

The table below presents the weighted-average assumptions used in estimating the fair values of stock options granted during the years ended December 31, 2024 and 2023:

	December 31,	
	2024	2023
Risk-free interest rate	3.80 %	4.13 %
Expected term (in years)	6.07	6.04
Expected volatility	94.31 %	87.86 %
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 (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding - December 31, 2023	2,382,933	$ 8.51		$ 8,084
Granted	6,736,822	14.67		
Exercised	(38,427)	7.11		231
Forfeited or cancelled	(375,131)	10.29		
Outstanding - December 31, 2024	8,706,197	$ 13.21	8.76	$ 2,104
Options vested and exercisable as of December 31, 2024	1,294,162	$ 7.64	5.51	$ 1,901
Options vested and expected to vest as of December 31, 2024	8,706,197	$ 13.21	8.76	$ 2,104

The aggregate intrinsic value of the 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 December 31, 2024. There were 38,427 options exercised for the year ended December 31, 2024, resulting in total proceeds of $0.3 million and 27,579 options exercised for the year ended December 31, 2023, resulting in total proceeds of $0.1 million.

The weighted-average grant date fair value of options granted during the years ended December 31, 2024 and 2023, was $11.38 and $8.11 per share, respectively. The fair value is being expensed over the associated service period of the award on a straight-line basis based on the grant date fair value or once the achievement of the performance condition is probable.

As of December 31, 2024, unrecognized compensation was $74.4 million, which is expected to be recognized over a weighted average period of 3.6 years. The total fair value of options vested during the years ended December 31, 2024 and 2023 was $4.6 million and $2.6 million, respectively.

The Company recognized stock-based compensation expense related to the issuance of equity awards to employees in the consolidated statement of operations as follows (in thousands):

	December 31,	
	2024	2023
Research and development	$ 4,066	$ 1,600
General and administrative	6,755	1,895
Total stock-based compensation expense	$ 10,821	$ 3,495

Employee Stock Purchase Plan

On September 3, 2024, the Board adopted the 2024 Employee Stock Purchase Plan (the "ESPP"), which became effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The Company initially reserved 397,956 shares for issuance under the ESPP. The number of shares of common stock available under the ESPP will automatically increase on January 1st of each year, beginning on January 1, 2025 through January 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. On January 1, 2025, the shares of common stock reserved for issuance under the ESPP was increased to 815,890.

As of December 31, 2024, no shares of common stock have been issued and no stock-based compensation has been recognized related to the ESPP.

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):

	December 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (156,988)	$ (37,124)
Denominator:		
Weighted-average common stock outstanding - basic and diluted	13,198,960	1,531,178
Net loss per share attributable to common stockholders - basic and diluted	$ (11.89)	$ (24.25)

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, 2024 and 2023 because including them would have had an anti-dilutive effect:

	December 31,	
	2024	2023
Convertible preferred stock	—	11,587,744
Unvested restricted stock	—	27,200
Options to purchase common stock	8,706,197	2,382,933

The BMS Note was also outstanding as of December 31, 2023, which could have obligated 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 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. As of December 31, 2024 the BMS Note is no longer outstanding.

13. Income Taxes

The following table presents the components of loss before the provision for (benefit from) income taxes during the years ended December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
U.S.	$ (160,918)	$ (10,845)
Non-U.S.	4,359	(25,978)
Loss before taxes on income	$ (156,559)	$ (36,823)

The components of the income tax provision for the years ended December 31, 2024 and 2023 are as follows (in thousands):

	December 31,	
	2024	2023
Current income tax provision:		
Federal	$ 123	$ 289
State	306	12
Foreign	—	—
Total current income tax provision	429	301
Deferred income tax provision:		
Federal, state and foreign	—	—
Total deferred income tax provision	—	—
Total income tax provision	$ 429	$ 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,	
	2024	2023
Federal statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	6.4	3.4
Change in valuation allowance	(32.3)	(26.4)
IP transfer	(0.3)	—
Research and development tax credits	4.9	8.8
Foreign tax rate differential	0.2	(7.6)
Other adjustments	(0.2)	—
Effective income tax rate	(0.3)%	(0.8)%

The Company's change in effective tax rate for the year ended December 31, 2024 compared to the year ended December 31, 2023 decreased primarily due to a change in 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,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 29,605	$ 9,960
Capitalized research and development	39,716	19,573
Research and development tax credits	14,292	6,547
Accruals	1,886	1,424
Milestone payments	442	719
Stock-based compensation	4,016	1,188
Other	901	550
Total deferred tax assets	90,858	39,961
Deferred tax liabilities:		
Amortization and other	(563)	(200)
Total deferred tax liabilities	(563)	(200)
Net deferred tax asset before valuation allowance	90,295	39,761
Valuation allowance	(90,295)	(39,761)
Net deferred tax asset	$ —	$ —

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, 2024, because management has determined that it is more likely than not that these assets will not be realized. The valuation allowance increased by $50.5 million from December 31, 2023 to December 31, 2024, primarily due to additional net operating losses related to the U.S. and non-U.S. entities as well as 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 fifteen 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 $39.7 million as of December 31, 2024.

As of December 31, 2024, the Company had approximately $75.5 million and $65.0 million of U.S. federal and state net operating loss ("NOL") carryforwards, respectively. As of December 31, 2023, the Company had approximately $2.3 million of U.S. federal NOL carryforwards. The Company had no state NOL carryforwards as of December 31, 2023. The Company utilized previous net operating loss carryforwards to offset the taxable income in prior years. 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 state NOL carryforwards expire in 20 years, starting in 2042. The federal and state NOL carryforwards are fully offset by valuation allowances.

As of December 31, 2024, the Company had $13.3 million and $1.2 million in federal and state general business or research and development tax credit carryforwards. 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. 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, 2024 and 2023, the Company had $54.2 million and $53.7 million of foreign NOL carryforwards, respectively. Foreign NOL carryforwards of $47.8 million will carryforward indefinitely, with the remaining expiring between 2026 and 2028. The foreign NOL carryforwards are fully offset by valuation allowances. The Company files income tax returns in the U.S., as well as various state and foreign jurisdictions. The Company is not currently under any income tax examinations. 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, 2024 and 2023, 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, utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382, as well as similar state provisions. These ownership changes may limit the amount of NOLs and research and development tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. If a change in control as defined by Section 382 has occurred at any time since the Company's formation, utilization of its NOLs or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, which could then be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOLs or research and development tax carryforwards before their utilization.

14. 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 agreement 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 and certain officers 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 consolidated financial statements as of December 31, 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 December 31, 2024, the Company was not subject to any material legal proceedings which would reasonably be expected to have a material adverse effect on the Company's financial results.

15. 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, 2024, the Company has made a one-time contribution of $0.1 million to the 401(k) Plan.

16. Related Party Transactions

Xencor, Inc.

The Company has obtained exclusive, worldwide licenses from Xencor to research, develop, manufacture, market and sell three 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 December 31, 2024, Xencor held 7.4% of shares of the Company's outstanding common stock. The Company did not incur any costs related to reimbursable patent-related costs as of December 31, 2024.

Viridian Therapeutics, Inc.

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 although Fairmount Funds Management LLC owns less than 5% of shares of the Company's outstanding common stock, they have a seat on the Board and are also a 10% or greater stockholder of Viridian and have 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 December 31, 2024, Viridian held less than 0.1% of shares of the Company's outstanding common stock.

Dianthus Therapeutics, Inc

The Company 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. In June 2022, the Company and Dianthus entered into the Dianthus License Agreement. 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. In October 2024, the Dianthus Option Agreement and Dianthus License Agreement and all of their related rights and obligations were transferred to Tenacia. As of December 31, 2024, Dianthus held less than 0.1% of shares of the Company's outstanding common stock.

For additional information on our license arrangements, please see *Note 8, License and Option Agreements*, to these consolidated financial statements.

17. Segment Information

The Company manages its operations on a consolidated basis as a single reportable segment focused on the research and development of precision immunology-based therapies. The accounting policies of the single reportable segment are

identical to those described in *Note 2, Summary of Significant Accounting Policies*. When evaluating the Company's financial performance, the CODM regularly reviews consolidated net loss, total expense and direct expenses by program and compared to budget. The CODM allocates resources based on the Company's available cash resources, forecasted expenditures on a consolidated basis, as well as an assessment of the probability of success of its research and development activities on a program basis. Segment asset information regularly provided to the CODM is consistent with that reported on the consolidated balance sheets with particular emphasis on the Company's available liquidity, including its cash, cash equivalents and marketable securities balances. Revenue is primarily attributed to individual countries based on the location of the license, as of December 31, 2024 and 2023, revenue was attributed to our China and U.S. entity, respectively.

The following table presents certain financial data for the Company's reportable segments for the years ended December 31, 2024 and 2023 (in thousands):

	December 31	
	2024	**2023**
Revenue	$ 5,000	$ 50,000
Less:		
Direct research and development expenses:[1]		
Obexelimab	94,563	25,446
Other programs (ZB002 & ZB004)	2,115	6,242
Partnered regional programs (ZB001 & ZB005)	6,737	6,738
Unallocated research and development[2]	31,658	20,008
General and administrative[3]	22,995	15,218
Stock-based compensation	10,821	3,495
Other segment items[4]	(6,901)	9,977
Segment Net Loss	$ (156,988)	$ (37,124)

[1] Direct research and development expenses primarily consist of direct costs incurred to specific programs research and development activities, including costs to conduct clinical trials and to manufacture clinical drug supply.

[2] Unallocated research and development expenses primarily consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, such as personnel costs for employees involved in research and development activities, excluding stock-based compensation, as well as contract services not allocated to specific programs.

[3] General and administrative expenses primarily consist of all other personnel costs, excluding stock-based compensation, professional fees, depreciation expense, as well as facilities expenses.

[4] Other segment items consist of acquired in-process research and development, fair value adjustments to convertible notes, other income, net and income tax provision. Other income, net consists of interest income and realized and unrealized gains and losses on foreign currency transactions.

18. Subsequent Events

Zai License Agreement

On January 24, 2025, the Company entered into a license agreement (the "Zai License Agreement") with Zai Lab (Hong Kong) Limited ("Zai"), under which the Company granted Zai an exclusive sublicense to develop and commercialize ZB001 and related programs in greater China. As partial consideration for the Zai License Agreement, the Company received an upfront fee of $10.0 million from Zai. In addition, the Company is eligible to receive up to $96.0 million upon the achievement of certain future development and commercial milestones and royalty percentage rates from the low to mid-single digits, net of pass-through obligations due to Viridian.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During our fiscal quarter ended December 31, 2024, no "Rule 10b5-1 plans" or "non-Rule 10b5-1 trading arrangements", as each term is defined in Item 408(a) of Regulation S-K, were adopted, modified, or terminated by officers or directors of the Company.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

Not applicable

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this item will be included in our proxy statement with respect to our 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days after the end of our 2024 fiscal year and is incorporated herein by reference.

Insider Trading Policies and Procedures

We have adopted an insider trading policy that governs the purchase, sale, and other dispositions of our securities by our directors, officers and employees, and other covered persons. The insider trading policy also applies to transactions by the Company in its securities. We believe that the insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations and the listing standards of Nasdaq. A copy of our Insider Trading Policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

Item 11. Executive Compensation

The information required by this item will be included in our proxy statement with respect to our 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days after the end of our 2024 fiscal year and is incorporated herein by reference.

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

The information required by this item will be included in our proxy statement with respect to our 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days after the end of our 2024 fiscal year and is incorporated herein by reference.

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

The information required by this item will be included in our proxy statement with respect to our 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days after the end of our 2024 fiscal year and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be included in our proxy statement with respect to our 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days after the end of our 2024 fiscal year and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statements.

(1) For a list of the financial statements included herein, see the Index to the Consolidated Financial Statements on page 136 of this Annual Report on Form 10-K, incorporated into this item by reference.

(2) Financial statement schedules have been omitted because they are either not required, not appliable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit No.	Description
3.1	Second Restated Certificate of Incorporation of Zenas BioPharma, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on September 16, 2024, File No. 001-42270)
3.2	Amended and Restated Bylaws of Zenas BioPharma, Inc. (incorporated by reference to Exhibit 3.2 to the Form 8-K filed on September 16, 2024, File No. 001-42270)
4.1	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
4.2	Fourth Amended and Restated Shareholders Agreement, among the Registrant and certain of its stockholders, dated May 3, 2024 (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
4.3†	Description of Securities
10.1+	License Agreement by and between Zenas BioPharma (Cayman) Limited and Xencor, Inc., dated September 23, 2020 (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.2	First Amendment to License Agreement by and between Zenas BioPharma, Inc. and Xencor, Inc., dated June 24, 2024 (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.3+	License Agreement by and between Zenas BioPharma (Cayman) Limited and Xencor, Inc., dated May 27, 2021(incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 filed on August 22,2024, File No. 333-281713).
10.4+	First Amendment to License Agreement by and between Zenas BioPharma (Cayman) Limited and Xencor, Inc., dated May 27, 2021 (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.5+	Second Amendment to License Agreement by and between Zenas BioPharma, Inc. and Xencor, Inc., dated May 27, 2021 (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.6+	License Agreement by and between the Registrant and Bristol-Myers Squibb Company, dated as of August 30, 2023 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.7#	Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.8#	Amendment to Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.9#	Amendment to Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).

10.10#	Form of Restricted Share Agreement under the Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.11#	Form of Non-Qualified Stock Option Agreement (Non-Employee Directors) under the Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.12#	Form of Non-Qualified Stock Option Agreement (Employees) under the Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.13#	Form of Incentive Stock Option Agreement under the Zenas BioPharma, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.14#	Zenas BioPharma, Inc. Short-Term Incentive Plan (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.15#	Zenas BioPharma, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 4.6 the Form S-8 filed on September 16, 2024, File No. 333-282151)
10.16#	Form of U.S. Non-Qualified Stock Option Agreement under the Zenas BioPharma, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.17#	Form of Global Non-Qualified Stock Option Agreement under the Zenas BioPharma, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.18#†	Zenas BioPharma, Inc. 2024 Employee Stock Purchase Plan (amended and restated).
10.19#†	Zenas BioPharma, Inc. Non-Employee Director Compensation Policy (as amended).
10.20#	Amended and Restated Employment Agreement between the Registrant and Leon O. Moulder, Jr., dated September 4, 2024 (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.21#	Amended and Restated Employment Agreement between the Registrant and Joseph Farmer, dated September 4, 2024 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.22#	Amended and Restated Employment Agreement between the Registrant and Jennifer Fox, dated September 4, 2024 (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.23#	Amended and Restated Employment Agreement between the Registrant and Orlando Oliveira, dated September 4, 2024 (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.24#	Employment Agreement between the Registrant and Tanya Fischer, dated September 22, 2023 (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).

10.25#	Transition and Separation Agreement between the Registrant and Hua Mu, dated June 29, 2023 (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form S-1 filed on August 22, 2024, File No. 333-281713).
10.26#	Transition and Separation Agreement between the Registrant and Tanya Fischer, dated August 29, 2024 (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
10.27	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.27 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
19.1†	Insider Trading Policy
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form S-1 filed on September 6, 2024, File No. 333-281713).
23.1†	Consent of Ernst & Young LLP, independent registered public accounting firm.
31.1†	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1†	Policy for Recoupment of Incentive Compensation (Clawback) Policy
101.INS†	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH†	XBRL Taxonomy Extension Schema Document
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

† Filed herewith.

# Indicates management contract or compensatory plan.

+ Portions of this exhibit (indicated by asterisks) have been redacted pursuant to Item 601 S-K because they are both not material and the registrant customarily and actually treats such information as private of confidential.

* This certification will not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under

the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

Date: March 11, 2025

ZENAS BIOPHARMA, INC.

By: /s/ Leon O. Moulder, Jr.
Name: Leon O. Moulder, Jr.
Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Jennifer Fox
Name: Jennifer Fox
Title: Chief Business Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Leon O. Moulder, Jr. Leon O. Moulder, Jr.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 11, 2025
/s/ Jennifer Fox Jennifer Fox	Chief Business Officer and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 11, 2025
/s/ Patricia Allen Patricia Allen	Director	March 11, 2025
/s/ James Boylan James Boylan	Director	March 11, 2025
/s/ Patrick Enright Patrick Enright	Director	March 11, 2025
/s/ Tomas Kiselak Tomas Kiselak	Director	March 11, 2025
/s/ Hongbo Lu, Ph.D. Hongbo Lu, Ph.D.	Director	March 11, 2025
/s/ Jake Num Jake Nunn	Director	March 11, 2025

/s/ John Orloff, M.D. John Orloff, M.D.	Director	March 11, 2025
/s/ Ting Xiao Ting Xiao	Director	March 11, 2025