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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025

or

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

For the transition period from _____ to_____

Commission File Number: 001-42270

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

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

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

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

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

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

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**

As of April 30 2025, there were 41,834,182 of the registrant's common stock, par value $0.0001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly 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;
- 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, tariffs and other trade measures, 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 Quarterly Report may prove incorrect. These forward-looking statements speak only as of the date of this Quarterly 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 Quarterly 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 Quarterly 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 II, Item 1A. "Risk Factors" in this Quarterly 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 Quarterly Report. Nevertheless, all rights to such trademarks are owned by Zenas BioPharma, Inc. Other trademarks referenced in this Quarterly Report are the property of their respective owners.

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

Zenas BioPharma, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 196,554	$ 319,742
Short-term investments	115,825	31,024
Restricted cash	—	90
Prepaid expenses and other current assets	5,428	5,067
Total current assets	317,807	355,923
Property and equipment, net	72	185
Operating lease right-of-use assets, net	1,204	1,004
Long-term investments	1,835	—
Other non-current assets	12,848	12,856
Total assets	$ 333,766	$ 369,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 20,018	$ 17,136
Accrued expenses	28,206	39,371
Operating lease liabilities, current	908	785
Total current liabilities	49,132	57,292
Operating lease liabilities, non-current	317	218
Total liabilities	49,449	57,510
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share; 25,000,000 shares authorized and no shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock, par value $0.0001 per share; 175,000,000 shares authorized; 41,821,887 and 41,793,412 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	4	4
Additional paid-in capital	705,136	699,651
Accumulated other comprehensive income	141	194
Accumulated deficit	(420,964)	(387,391)
Total stockholders' equity	284,317	312,458
Total liabilities and stockholders' equity	$ 333,766	$ 369,968

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

Zenas BioPharma, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2025	2024
Revenue:		
License and collaboration revenue	$ 10,000	$ —
Total revenue	10,000	—
Operating expenses:		
Research and development	34,915	22,645
General and administrative	12,415	4,933
Total operating expenses	47,330	27,578
Loss from operations	(37,330)	(27,578)
Other income (expense), net:		
Fair value adjustments to convertible notes	—	(694)
Other income, net	3,552	472
Total other income (expense), net	3,552	(222)
Loss before income taxes	(33,778)	(27,800)
Income tax benefit	205	—
Net loss to common stockholders	$ (33,573)	$ (27,800)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.80)	$ (17.89)
Weighted-average common stock outstanding - basic and diluted	41,800,802	1,554,087
Comprehensive loss:		
Net loss to common stockholders	$ (33,573)	$ (27,800)
Other comprehensive income (loss):		
Unrealized gain on investments	12	—
Foreign currency translation adjustment	(65)	37
Comprehensive loss	$ (33,626)	$ (27,763)

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

Zenas BioPharma, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share data)

	Three Months Ended March 31, 2025					
	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2024	41,793,412	$ 4	$ 699,651	$ 194	$ (387,391)	$ 312,458
Exercises of common stock options	28,475	—	99	—	—	99
Stock-based compensation expense	—	—	5,386	—	—	5,386
Unrealized gain on investments	—	—	—	12	—	12
Foreign currency translation adjustment	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	(33,573)	(33,573)
Balance as of March 31, 2025	41,821,887	$ 4	$ 705,136	$ 141	$ (420,964)	$ 284,317

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

Zenas BioPharma, Inc.
Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit
(Unaudited)
(in thousands, except share data)

	Three Months Ended March 31, 2024											
	Convertible Preferred Stock						Common Stock					
	Seed Series		Series A		Series B							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
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)	—	—	—	—	—
Exercises of common stock options	—	—	—	—	—	—	7,035	—	42	—	—	42
Stock-based compensation expense	—	—	—	—	—	—	—	—	947	—	—	947
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	37	—	37
Net loss	—	—	—	—	—	—	—	—	—	—	(27,800)	(27,800)
Balance as of March 31, 2024	1,785,714	$ 956	17,589,380	$ 55,840	81,242,587	$ 193,290	1,562,717	$ —	$ 5,634	$ 74	$ (258,203)	$ (252,495)

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

Zenas BioPharma, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (33,573)	$ (27,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	23	33
Loss on disposal of property and equipment	107	—
Net amortization of premiums and accretion of discounts on investments	(382)	—
Stock-based compensation expense	5,386	947
Change in fair value of convertible notes	—	694
Non-cash lease expense	246	159
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(353)	1,787
Accounts payable	2,882	3,407
Accrued expenses	(11,165)	335
Operating lease liabilities	(222)	(164)
Other current liabilities	—	1,500
Net cash used in operating activities	(37,051)	(19,102)
Cash flows from investing activities:		
Purchases of property and equipment	(18)	(22)
Purchases of investments	(99,114)	—
Proceeds from sales and maturities of investments	12,858	—
Net cash used in investing activities	(86,274)	(22)
Cash flows from financing activities:		
Payment of initial public offering costs	—	(656)
Proceeds from exercise of stock options	99	42
Net cash provided by (used in) financing activities	99	(614)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(52)	36
Net decrease in cash, cash equivalents and restricted cash	(123,278)	(19,702)
Cash, cash equivalents and restricted cash at beginning of period	319,832	56,942
Cash, cash equivalents and restricted cash at end of period	$ 196,554	$ 37,240
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained under operating lease arrangements	$ 445	$ —
Deferred offering costs in accounts payable and accrued expenses	$ —	$ 1,872
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 196,554	$ 37,154
Restricted cash	—	86
Total cash, cash equivalents and restricted cash	$ 196,554	$ 37,240

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

Zenas BioPharma, Inc.
Notes to Condensed Consolidated Financial Statements

1. Nature of Business

Organization

Zenas BioPharma, Inc. ("Zenas" or the "Company") was incorporated in November 2019 as Zenas BioPharma (Cayman) Limited, an exempted company incorporated in the Cayman Islands with limited liability and commenced operations in 2020. On August 2, 2023, the Company (then known as Zenas BioPharma (Cayman) Limited) de-registered from the Cayman Islands and registered by way of continuation in the State of Delaware. Zenas is a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies for patients in need. The Company's 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 condensed consolidated financial statements include the accounts of its wholly owned subsidiaries which include Zenas BioPharma (HK) Limited ("Zenas HK"), Zenas BioPharma (USA) LLC, Shanghai Zenas Biotechnology Co. Limited, 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"), novation agreement with Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia") and license agreement with Zai Lab (Hong Kong) Limited ("Zai") (please see *Note 7, License and Collaboration Revenue*, to these condensed consolidated financial statements). 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 condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split and the adjustment of the preferred stock conversion ratios.

The Company has incurred operating losses and negative cash flows, since its inception, including net losses of $33.6 million and $27.8 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, the

Company had an accumulated deficit of $421.0 million. 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 investments of $314.2 million as of March 31, 2025 will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date this Form 10-Q 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

The Company's significant accounting policies are disclosed in *Note 2, Summary of Significant Accounting Policies,* in the audited consolidated financial statements for the year ended December 31, 2024, and notes thereto, included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 11, 2025. Since the date of those financial statements, there have been no material changes to the Company's significant accounting policies.

Basis of Presentation and Consolidation

The accompanying condensed 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 condensed 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.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited financial statements and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2025, and the results of operations and its cash flows for the three months ended March 31, 2025 and 2024. The financial data and other information disclosed in these notes related to the three months ended March 31, 2025 and 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2025, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2024, and the notes thereto, which are included in the Company's Annual Report on Form 10-K as filed with the SEC, on March 11, 2025.

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 condensed 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.

Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgement. As of the date of the issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgements or revise the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's financial statements.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the "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 condensed consolidated statements or disclosures.

3. Fair Value Measurements

The following table presents 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 March 31, 2025			
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	$ 23,721	$ 23,721	$ —	$ —
Money market funds	172,833	172,833	—	—
Short-term investments:				
Commercial paper	6,387	—	6,387	—
Corporate debt securities	45,418	—	45,418	—
Government securities	64,020	64,020	—	—
Long-term investments:				
Corporate debt securities	1,835	—	1,835	—
Total assets	$ 314,214	$ 260,574	$ 53,640	$ —

	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	—	—
Short-term 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	$ —

There have been no material impairments of our assets measured and carried at fair value as of March 31, 2025 and December 31, 2024. In addition, there have been no changes in valuation techniques as of March 31, 2025 and 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. During the three months ended March 31, 2025 and year ended December 31, 2024, there were no transfers between levels.

The short and long-term investments are classified as available-for-sales securities. As of March 31, 2025, the remaining contractual maturities of the available-for-sales securities were 1 to 18 months, the balance in the Company's accumulated other comprehensive income was comprised 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 three months ended March 31, 2025 and 2024. As a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the same period. The Company had a limited number of available-for-sale securities in

insignificant loss positions as of March 31, 2025, which the Company does not intend to sell and has concluded will not be required to sell before recovery of amortized cost for the investment maturity.

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

	As of March 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2025				
Commercial paper	$ 6,378	$ 9	$ —	$ 6,387
Corporate debt securities	47,228	29	(4)	47,253
Government securities	64,011	13	(4)	64,020
Total	$ 117,617	$ 51	$ (8)	$ 117,660

	As of December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2024				
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 condensed consolidated balance sheets and are not included in the table above.

4. Other Assets

Other assets consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Clinical trial deposits	$ 12,639	$ 12,639
Other	209	217
Total other assets	$ 12,848	$ 12,856

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
External research, development and manufacturing expenses	$ 23,588	$ 29,338
Employee compensation and benefits	3,383	8,308
Professional and consultant fees	846	1,265
Income taxes payable	5	211
Other	384	249
Total accrued expenses	$ 28,206	$ 39,371

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 condensed consolidated statements of operations and comprehensive loss. Variable lease expense relates primarily to office lease common area maintenance, insurance, and property taxes, and it is expensed as incurred. Variable lease expense is also excluded from the calculation of lease liabilities and right-of-use-assets.

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

Fiscal Year		Amount
2025 (remaining nine months)	$	713
2026		453
2027		136
Thereafter		—
Total future minimum lease payments		1,302
Less: imputed interest		(77)
Total operating lease liabilities	$	1,225

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 (the "BMS Agreement") with BMS, 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, regulatory milestone payments from BMS of 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 will fund their pro rata share of the total global study costs up to a specified percentage of the patients enrolled in the study from the BMS Territory. Should the percentage of patients from the BMS Territory fall below the specified percentage, BMS's funding would proportionately decrease. The global development activities under the agreement do not represent a transaction with a customer and reimbursement payments received by the Company for global development activities are accounted for as a reduction of the related research and development expenses.

For the three months ended March 31, 2025 and 2024, the Company recorded $1.7 million and $1.0 million, respectively, as a receivable included in prepaid expenses and other current assets. The Company recorded $1.7 million and $1.0 million for the three months ended March 31, 2025 and 2024, respectively, as a reduction to research and development expense for global development costs to be reimbursed by BMS. The Company did not recognize revenue related to the BMS Agreement during the three months ended March 31, 2025 and 2024.

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 License Agreement (collectively the "Dianthus Agreements") to Tenacia, for the exclusive right to research, develop, manufacture and commercialize products within China, Hong Kong, Macau and Taiwan ("greater China"). As a result of the Tenacia Agreement, the Company has no further obligations to Dianthus pursuant to the Dianthus Agreements.

Pursuant to the Tenacia Agreement, Tenacia paid the Company a one-time non-refundable upfront cash payment of $5.0 million, which was recognized as revenue in the fourth quarter of 2024. 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 did not recognize revenue related to the Tenacia Agreement during the three months ended March 31, 2025 and 2024.

License Agreement with Zai Lab (Hong Kong) Limited

In January 2025, the Company entered into a license agreement (the "Zai License Agreement"), with Zai, under which the Company granted Zai an exclusive sublicense to develop, manufacture and commercialize ZB001 and related programs in greater China. Under the Zai Agreement, Zai will be responsible for conducting all research and development activities, manufacturing, regulatory and commercialization in greater China.

Pursuant to the Zai Agreement, Zai paid the Company a one-time non-refundable upfront cash payment of $10.0 million. The Company is entitled to receive further development, regulatory and sales milestones from Zai up to approximately $117.0 million if certain milestones are successfully achieved, with passthrough obligations of $21.0 million due to Viridian. The Company is also eligible to receive tiered royalties on net sales in greater China, ranging from the low to mid-single digits, net of passthrough obligations due to Viridian.

The Company evaluated the terms of the Zai Agreement and determined it is within the scope of ASC 606. The Company identified the following promises in the Zai Agreement that were evaluated under the scope of ASC 606: (i) transfer of the license for ZB001, (ii) licensed technology transfer (iii) licensed material transfer and (iv) continued licensed technology transfer. The Company also evaluated whether certain options outlined in the Zai Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options conveyed a material right to Zai or were immaterial and, therefore, are not considered separate performance obligations within the Zai Agreement.

The Company assessed the above promises and determined that the license for ZB001 and technology transfer are a combined distinct performance obligation within the scope of ASC 606. The licensed material transfer and the continued technology know-how transfer services are promises that are separately identifiable and considered to be distinct. The Company determined the transfer of the licensed materials and continued technology know-how transfer services were immaterial in the context of the contract based on the minimal resources required to fulfill the obligations and the estimated standalone selling price of the licensed materials. Therefore, the sublicense and technology transfer represent a single performance obligation at contract inception.

The Company concluded that the transaction price of $10.0 million was allocated to the combined performance obligation, which was recognized upon delivery prior to March 31, 2025. 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 and royalty 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 transaction price relates. The Company will recognize such milestone and

royalty 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 March 31, 2025, no milestones were achieved or deemed probable of achievement.

8. License Agreements

License Agreements with Xencor, Inc.

2020 Xencor Agreement

In September 2020, the Company entered into a license agreement (the "2020 Xencor Agreement") with Xencor, Inc. ("Xencor"), under which the Company is required to pay Xencor tiered royalties on annual net sales of successfully commercialized products, including ZB002 and ZB004. The royalty percentage rates vary by geographic areas as defined in the 2020 Xencor Agreement and range from the mid-single digits to mid-teens. The Company is also obligated to reimburse Xencor for third-party costs incurred for certain patent filings, prosecution and maintenance as further specified in the 2020 Xencor Agreement. During the three months ended March 31, 2025 and 2024, the Company incurred no such reimbursable costs.

2021 Xencor Agreement

In May 2021, the Company entered into a license agreement with Xencor (the "2021 Xencor Agreement"), under which the Company obtained an exclusive, royalty-bearing, sublicensable worldwide license to research, develop, manufacture, market and sell obexelimab. The Company is also obligated to make regulatory milestone payments up to $75.0 million and 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 percentages varying based on regions and ranging from the mid-single digits to the mid-teens.

For the three months ended March 31, 2025 and 2024, the Company recorded no reimbursable patent-related costs, respectively.

License Agreement with Viridian Therapeutics, Inc.

In October 2020, the Company entered into a license agreement with Viridian Therapeutics, Inc. (the "Viridian Agreement") to obtain an exclusive, royalty-bearing, sublicensable license to research, develop, manufacture, market and sell certain antibody product candidates based on Viridian's proprietary technology. The Company's license rights are limited to non-oncology indications and are limited to China, Hong Kong, Macau and Taiwan ("Zenas Territories"). Viridian retains its rights to develop and commercialize such product candidates outside of the Zenas Territories. In December 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. Under the terms of the letter agreements, Viridian engaged a third-party contract manufacturer to initiate certain work related to ZB001. In May 2022, the Company entered into a manufacturing development and supply agreement ("Viridian Supply Agreement"). In January 2025, the Company entered into a third amendment to the Viridian Agreement, under which the Company is obligated to make development and sales milestone payments to Viridian, totaling $21.0 million, based on achievement of certain specified development and sales milestones, and royalties on net sales.

In January 2025, the Company entered the Zai License Agreement under which the Company granted Zai an exclusive sublicense to develop, manufacture and commercialize ZB001 and related programs in greater China. In connection with the Zai License Agreement, the Company assigned the Viridian Supply Agreement to Zai. For additional information on the Zai Agreement, please *see License Agreement with Zai Lab (Hong Kong) Limited* in *Note 7 – License and Collaboration Revenue* to these condensed consolidated financial statements.

During the three months ended March 31, 2025 and 2024, the Company recognized no expense related to Viridian contract manufacturing organization ("CMO") costs. Viridian has agreed to reimburse the Company for certain services the Company performs on Viridian's behalf, with reimbursements being recorded as a reduction in research and development expenses. During the three months ended March 31, 2025, the Company recorded $0.1 million in reimbursable expenses. During the three months ended March 31, 2024, the Company had no reimbursable expenses. Additionally, during the three months ended March 31, 2025 and 2024, no milestones were achieved.

9. Common Stock

In September 2024, upon the completion of the IPO, the Company restated its certificate of incorporation, pursuant to which the Company is 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 no cumulative voting rights.

The Company had reserved the following shares of common stock for the potential conversion of outstanding stock options:

	March 31, 2025	December 31, 2024
Options to purchase common stock	8,670,569	8,706,197
Remaining shares reserved for future issuance	2,456,222	359,399
Employee stock purchase plan	815,890	397,956
Total	11,942,681	9,463,552

10. Stock-Based Compensation

2024 Plan

On September 3, 2024, the Board of Directors (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.

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 (i) five percent of the aggregate number of shares of common stock outstanding as of such date, and (ii) a number of shares as may be determined by the Board on or prior to such date. In January 2025, the number of shares of common stock available for issuance under the Company's 2024 Plan, was increased by 2,089,670 shares of common stock due to the automatic annual provision to increase shares of common stock available under the 2024 Plan. As of March 31, 2025, 2,456,222 shares of common stock were available for issuance under the 2024 Plan.

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 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, 2024	8,706,197	$ 13.21		$ 2,104
Granted	108,000	$ 7.28		
Exercised	(28,475)	$ 3.48		$ 136
Forfeited or cancelled	(115,153)	$ 13.94		
Outstanding - March 31, 2025	8,670,569	$ 13.16	8.53	$ 1,877
Options vested and exercisable as of March 31, 2025	1,434,494	$ 7.93	5.62	$ 1,708
Options vested and expected to vest as of March 31, 2025	8,670,569	$ 13.16	8.53	$ 1,877

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 March 31, 2025.

As of March 31, 2025, there was $68.4 million of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted-average period of 3.15 years.

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

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 1,581	$ 411
General and administrative	3,805	536
Total stock-based compensation expense	$ 5,386	$ 947

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 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 1, 2034, by the number of shares equal to the lesser of (i) one percent of the aggregate number of shares of common stock outstanding as of such date, and (ii) 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 number of shares of common stock authorized for issuance under the ESPP increased automatically by 417,934 shares and as of March 31, 2025, a total of 815,890 shares were available for future issuance under the ESPP. There were no shares issued under the ESPP during the three months ended March 31, 2025.

11. 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):

	Three Months Ended March 31,	
	2025	2024
Numerator:		
Net loss attributable to common stockholders	$ (33,573)	$ (27,800)
Denominator:		
Weighted-average common stock outstanding - basic and diluted	41,800,802	1,554,087
Net loss per share attributable to common stockholders - basic and diluted	$ (0.80)	$ (17.89)

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 March 31, 2025 and 2024 because including them would have had an anti-dilutive effect:

	March 31,	
	2025	2024
Convertible preferred stock	—	100,617,681
Unvested restricted stock	—	3,767
Options to purchase common stock	8,670,569	2,403,183

12. Commitments and Contingencies

Operating Leases

The Company has entered into arrangements for leases of office space; see *Note 6, Leases*, for details.

License Agreements

The Company entered into license agreements under which it is obligated to make fixed and contingent payments; see *Note 8, License 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. As of March 31, 2025, our total non-cancellable clinical manufacturing contract payment obligations are $18.4 million of which the full obligation is payable within 12 months.

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 condensed consolidated financial statements as of March 31, 2025.

Litigation and Other Proceedings

The Company may periodically become subject to legal proceedings and claims arising in the ordinary course of business. As of March 31, 2025, 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.

13. 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, due to the issuance of convertible preferred stock in December 2020 and April 2023. In connection with the completion of the IPO, in September 2024, all outstanding shares of preferred stock converted into shares of common stock. As of March 31, 2025, Xencor held less than 10% of shares of the Company's outstanding common stock.

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 10% 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 March 31, 2025, Viridian held 0.1% of shares of the Company's outstanding common stock.

Zai Lab (Hong Kong) Limited

The Company has granted a sublicense to Zai to develop, manufacture and commercialize ZB001 and related programs in greater China. The Company has concluded that Zai is a related party, as the Company's CEO and Chairman is a member of Zai's board of directors.

For additional information on these arrangements, please see *Note 7, License and Collaboration Revenue* and *Note 8, License Agreements,* to these condensed consolidated financial statements.

14. 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 Company's chief operating decision-maker (the "CODM"), its Chief Executive Officer 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 entity owning the license, During the three months ended March 31, 2025, revenue was attributed to Zenas HK. The Company did not recognize revenue during the three months ended March 31, 2024.

The following table presents certain financial data for the Company's reportable segments for the three months ended March 31, 2025 and 2024 (in thousands):

	March 31,	
	2025	**2024**
Revenue	$ 10,000	$ -
Less:		
Direct research and development expenses:[1]		
Obexelimab	23,491	12,295
Other programs (ZB002 & ZB004)	203	894
Partnered regional programs (ZB001 & ZB005)	99	1,588
Unallocated research and development[2]	9,541	7,457
General and administrative[3]	8,610	4,397
Stock-based compensation	5,386	947
Other segment items[4]	(3,757)	222
Segment net loss	$ (33,573)	$ (27,800)

[1] Direct research and development expenses primarily consist of direct costs incurred to specific program 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 professional fees, depreciation expense, facilities expenses as well as all other personnel costs, excluding stock-based compensation.

[4] Other segment items consist of other income (expense), net and income tax benefit (provision). Other income (expense), net consists of interest income and realized and unrealized gains and losses on foreign currency transactions.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report and the audited financial information and the notes thereto included in our Annual Report on Form 10-K that was filed with the Securities and Exchange Commission, or SEC, on March 11, 2025. This discussion and analysis contains forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future performance that involves 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" in this Quarterly Report on Form 10-Q. 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, 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.

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 exclusively sublicensed to a partner in China, as discussed below.

On September 16, 2024, we completed our initial public offering ("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 expenses.

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.

On January 24, 2025, the Company entered into the Zai License Agreement, with 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.

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 March 31, 2025, we have financed our operations primarily with the proceeds from the issuance of convertible preferred stock, our convertible notes, payments received under our license and collaboration agreements 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 three months ended March 31, 2025 and 2024, were $33.6 million and $27.8 million, respectively. As of March 31, 2025, we had an accumulated deficit of $421.0 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 March 31, 2025, we had $314.2 million in cash, cash equivalents and investments. We believe that our cash, cash equivalents and investments as of March 31, 2025 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 geopolitical, trade, regulatory and economic environment, including, but not limited to the imposition of new tariffs or increases in tariff rates and other trade measures, may materially affect our business and operating results by increasing the costs of our clinical trial materials and supplies, which in turn increase our overhead costs. 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. Such economic conditions could increase our operating costs, including our labor costs and research and development costs. For example, we import drug products and other

components from and into China for use in the manufacturing process and in our clinical studies, and such components and products are subject to tariffs, which we anticipate will result in increased costs. Our operating and labor costs and research and development 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.

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 BMS Agreement, our Tenacia Agreement and our Zai License 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.

Pursuant to the Zai License Agreement, 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.

For a more detailed description of these agreements, see *Note 7, License and Collaboration Revenue,* to our condensed consolidated financial statements in this Quarterly Report.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, and (ii) general and administrative 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 condensed 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;
- 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, as well as tariffs that impact the biopharmaceutical industry generally;

- 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. We will also incur pre-commercialization expenses to facilitate commercial readiness, if a product candidate is approved.

Total Other Income (Expense), Net

Other Income (Expense), Net

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

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 Three Months Ended March 31, 2025 and 2024

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

	Three Months Ended March 31,		
	2025	2024	Increase (Decrease)
Revenue:			
License and collaboration revenue	$ 10,000	$ —	$ 10,000
Total revenue	10,000	—	10,000
Operating expenses:			
Research and development	$ 34,915	$ 22,645	$ 12,270
General and administrative	12,415	4,933	7,482
Total operating expenses	47,330	27,578	19,752
Loss from operations	(37,330)	(27,578)	(9,752)
Other income (expense), net:			
Fair value adjustments to convertible notes	—	(694)	694
Other income, net	3,552	472	3,080
Total other income (expense), net	3,552	(222)	3,774
Loss before income taxes	(33,778)	(27,800)	(5,978)
Income tax benefit	205	—	205
Net loss	$ (33,573)	$ (27,800)	$ (5,773)

Revenue

We recognized license and collaboration revenue of $10.0 million for the three months ended March 31, 2025, related to the one-time non-refundable upfront cash payment under the Zai License Agreement that was recognized upon delivery of the license and related technology transfer. We did not recognize any license and collaboration revenue during the three months ended March 31, 2024.

Research and Development Expenses

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

	Three Months Ended March 31,		
	2025	2024	Increase (Decrease)
Direct research and development expenses by program:			
Obexelimab	$ 23,491	$ 12,295	$ 11,196
Other programs (ZB002 & ZB004)	203	894	(691)
Partnered regional programs (ZB001 & ZB005)	99	1,588	(1,489)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	10,779	7,563	3,216
Other expenses	343	305	38
Total research and development expenses	$ 34,915	$ 22,645	$ 12,270

Research and development expenses were $34.9 million for the three months ended March 31, 2025, compared to $22.6 million for the three months ended March 31, 2024. The increase of $12.3 million was primarily attributable to the following:

- a $11.2 million increase in costs related to the development of obexelimab, our lead product candidate, driven by a $7.4 million increase in clinical trial costs and a $3.6 million increase in manufacturing costs for clinical trial materials;
- a $1.5 million decrease in costs related to our partnered regional programs, including a $0.9 million decrease related to ZB005, largely driven by a decrease in clinical activities and a $0.6 million decrease related to ZB001 as the ongoing clinical studies were out licensed; and
- a $3.2 million increase in personnel costs, including a $1.9 million increase in salary and benefit related expense, primarily due to an increase in headcount, a $1.2 million increase in stock-based compensation expense, and a $0.1 million increase in external contractor expense and other personnel costs.

General and Administrative Expenses

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

	Three Months Ended March 31,		
	2025	2024	Increase (Decrease)
Personnel related expenses (including stock-based compensation)	$ 8,349	$ 2,890	$ 5,459
Legal and professional fees	2,153	1,175	978
Facilities	902	507	395
Other expenses	1,011	361	650
Total general and administrative expenses	$ 12,415	$ 4,933	$ 7,482

General and administrative expenses were $12.4 million for the three months ended March 31,2025, compared to $4.9 million for the three months ended March 31,2025. The increase of $7.5 million was primarily attributable to the following:

- a $5.5 million increase in personnel costs, including a $3.3 million increase in stock-based compensation expense, a $1.8 million increase in salary and benefit related expense, primarily due to an increase in headcount, personnel associated with pre-commercialization activities, and a $0.5 million increase in recruiting expense;
- a 1.0 million increase in professional fees, including legal, audit and tax expenses, primarily attributable to operating as a public company; and
- a $1.0 million increase in facilities and other expenses, is primarily attributable to facility, insurance and other variable costs related to operating as a public company.

Total Other Income (Expense), Net

For the three months ended March 31, 2025, total other income (expense), increased from the comparable period in the prior year primarily due to interest income as a result of higher cash, cash equivalents and investments.

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 March 31, 2025, we had $314.2 million in cash, cash equivalents, and investments and we had an accumulated deficit of $421.0 million. Through March 31, 2025, 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 $65.0 million through our BMS Agreement, Tenacia Agreement and Zai Agreement, and most recently, from the sale of common stock in our IPO for which we received $234.3 million in net proceeds, after deducting underwriting discounts, commissions and other offering expenses.

Future Funding Requirements:

We believe that our available cash, cash equivalents and investments, as of March 31, 2025, are sufficient to fund our operations and capital expenditure requirements for at least the next 12 months from the filing of this Quarterly Report. We estimate that our existing cash, cash equivalents and investments will be sufficient to fund our projected operations and capital expenditure requirements into the fourth quarter of 2026. Our primary uses of capital are, and we expect to continue to be, compensation and related expenses, third-party clinical research and development services, manufacturing 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 licenses, 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, and 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 licenses, 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 additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market 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):

	Three Months Ended March 31,	
	2025	**2024**
Net cash used in operating activities	$ (37,051)	$ (19,102)
Net cash used in investing activities	(86,274)	(22)
Net cash provided by (used in) financing activities	99	(614)
Effect of exchange rate changes on cash and restricted cash	(52)	36
Net decrease in cash, cash equivalents and restricted cash	$ (123,278)	$ (19,702)

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2025 was $37.1 million, and was primarily due to our net loss of $33.6 million, partially offset by $5.4 million of stock-based compensation expense, $2.9 million increase in accounts payable, a $0.4 million increase in prepaid expenses and other assets and a $11.2 million decrease in accrued expenses. The net decrease in accounts payable and accrued expenses was primarily due to the timing of vendor payments.

Net cash used in operating activities for the three months ended March 31, 2024 was $19.1 million, and was primarily due to our net loss of $27.8 million, partially offset by a $3.4 million increase in accounts payable, a $1.8 million increase in prepaid expenses and other assets, a $1.5 million increase in other current liabilities, $0.9 million of stock-based compensation expense, $0.7 million increase in the fair value of our BMS Note Liability and a $0.3 million increase in accrued expenses. The increase in accrued expenses and accounts payable was primarily due to an increase in research and development expenses, while the increase in prepaid expenses and other assets was primarily due to the timing of vendor payments.

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2025 was $86.3 million and consisted primarily of proceeds from sales and maturities of investments of $12.9 million, offset by purchases of investments of $99.1 million.

Net cash used in investing activities for the three months ended March 31, 2024 was less than $0.1 million and consisted of purchases of property and equipment.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2025 was $0.1 million, resulting from $0.1 million of proceeds received from the exercise of stock options.

Net cash used in financing activities for the three months ended March 31, 2024 was $0.6 million, resulting from a $0.7 million in payment of offering costs, partially offset by less than $0.1 million of proceeds received from the exercise of stock options.

Material Cash Requirements for Known Contractual and Other Obligations

During the three months ended March 31, 2025, there were no material changes to our contractual obligations and commitments from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these condensed consolidated financial statements requires us to make judgements, 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 condensed consolidated financial statements, and the reported amounts of expenses during the reported periods. On an ongoing basis, we evaluate our judgments, assumptions 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 condensed consolidated financial statements prospectively from the date of change in estimates.

There have been no material changes to our critical accounting policies from those described under our "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

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 this Quarterly Report on Form 10-Q.

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 Jumpstart Our Business Startups Act of 2012, as amended (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. 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 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to interest rate risk in the ordinary course of our business. As of March 31, 2025, we had cash, cash equivalents and investments in marketable securities of $314.2 million.

Foreign Currency Exchange Risk

Our reporting currency is the U.S. dollar ("USD"). Our functional currency for Zenas BioPharma (HK) Limited, our wholly owned subsidiary in Hong Kong, is the USD, and our functional currency for Shanghai Zenas Biotechnology Co. Limited, our wholly-owned subsidiary in China, is the Chinese Yuan. Our functional currency for Zenas BioPharma GmbH, our wholly-owned subsidiary in Switzerland, is the Swiss Franc. The functional currency of our wholly-owned U.S. subsidiaries, Zenas BioPharma (USA) LLC and Zenas BioPharma Securities Corp., is the USD. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss as incurred. Realized foreign currency transaction gains (losses) were immaterial for the three months ended March 31, 2025.

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

Effects of Inflation

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

Item 4. 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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of March 31, 2025. 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 submit 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 our management, including our principal executive officer and principal financial officer, or person performing similar functions, as appropriate to allow timely decisions regarding required disclosures.

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 judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2025, 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.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting for the quarter ended March 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may 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 1A. Risk Factors

Investors should carefully consider the risks described below, together with the other information contained in this Quarterly Report, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our unaudited condensed consolidated financial statements and related notes contained in this Quarterly 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. Our net losses for the three months ended March 31, 2025 and 2024, were $33.6 million and $27.8 million, respectively. As of March 31, 2025, we had an accumulated deficit of $421.0 million. 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 March 31, 2025, we had $314.2 million in cash, cash equivalents and investments. Based upon our current operating plan, we believe that our cash, cash equivalents and investments as of March 31, 2025, 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 retain personnel and hire additional personnel and consultants as our business grows, including additional 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. In April 2025, FDA approved UPLIZNA (inebilizumab-cdon) and anti-CD19 antibody, which is the first FDA-approved therapy for the treatment of IgG4-RD in adult patients. There are also 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.

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, Head of Research and Development and Chief Medical Officer, Lisa von Moltke, 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 continue 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 risks and uncertainties, including the changing trade policies and tariffs, 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.

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 any 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 United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or the claims in any of our or our licensors' issued patents may not be considered valid and enforceable by courts in the 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 affect 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 and Allergan v. MSN Laboratories 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, reductions in the workforce, particularly in the review or inspection divisions, could extend BLA review timelines, delay or prevent pre-approval inspections, and limit opportunities for FDA feedback on pending applications. 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 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 Inflation Reduction Act of 2022 (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 potential 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. For example, in March and April 2025, the U.S. imposed tariffs on, or increased the tariff rates applicable to, imports from many foreign countries. In response to these tariffs, a number of other countries have threatened or implemented retaliatory tariffs on U.S. goods. Political tensions resulting from trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Further, supply chain disruptions and delays as a result of tariff policies or trade restrictions could also negatively impact our cost of materials and processes. Such changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or 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, could restrict our ability or make it more costly to obtain needed supplies of products and materials from 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 Congress in 2024, 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 most recent version of the BIOSECURE Act, which passed in the House of Representatives in 2024 named WuXi Biologics as a "biotechnology company of concern." The BIOSECURE Act has not yet been re-introduced in Congress in 2025, but it could be.

If adopted into law, the BIOSECURE Act in its most recent 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 have 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 April 30, 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 changing trade policies, military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control; and

- the other factors described in this "Risk Factors" section and elsewhere in this Quarterly 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 may be sold into the market, 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 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 April 30, 2025, we had 41,834,182 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.

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. 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 56% of our outstanding common stock as of March 31, 2025. 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, high interest rates, the impact of increased tariffs and trade policy, 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 continue to incur, increased costs as a result of operating as a public company, and our management will continue to 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 continue to need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations have, and we expect them to continue 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 in the future. 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 quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on 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.

Securities class action litigation imposes costs on our business.

Securities class action litigation often is instituted against issuers following periods of volatility or declines in the market prices of an issuer's securities. As an example, in April 2025, a putative securities class action was filed against us and certain of our directors and officers, as well as the underwriters in our IPO. The action, purportedly brought on behalf of a putative class of purchasers of our common stock in, or traceable to, our IPO, asserts claims under Sections 11, 12, and 15 of the Securities Act of 1933, as amended. The action seeks compensatory damages, attorneys' fees and costs, and any other relief that the court determines is just and proper. Often multiple plaintiffs' attorneys file similar complaints and, at a future point, a consolidated amended complaint is filed. We do not anticipate providing updates for similar complaints or developments in this litigation, absent a legal obligation. Securities litigation results in costs and diversion of management's time and attention. The underwriting agreement from our IPO contemplates that we cover certain litigation expenses incurred by the underwriters in connection with the suit referenced above. Costs we incur addressing securities litigation harm our business, operating results, and financial condition, potentially with significant impact. Securities litigation also often raises the cost of directors' and officers' liability insurance. We factor those costs into the policy limits and scope of coverage we obtain, with those costs a key factor in determining the extent to which we rely on our balance sheet, rather than insurance, to cover defense costs, any settlement amounts, or any damages awarded to plaintiffs in litigation.

Changes in tax rates, the adoption of new tax legislation or other exposure to tax liabilities, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

(b) Use of Proceeds from Public Offering of Common Stock

On September 16, 2024, the Company's registration statement on Form S-1 (File No.333-281713) (the "IPO Prospectus") relating to our IPO became effective.

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

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During our fiscal quarter ended March 31, 2025, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

See Exhibit Index.

EXHIBIT INDEX

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)
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
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.

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

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: May 15, 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)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leon O. Moulder, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Zenas BioPharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2025

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

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jennifer Fox, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Zenas BioPharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2025

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

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Zenas BioPharma, Inc. (the "Company") hereby certifies, to the best of my knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 15, 2025

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

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Zenas BioPharma, Inc. (the "Company") hereby certifies, to the best of my knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 15, 2025

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