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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 September 30, 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 October 31, 2025, there were 53,679,166 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 our product candidates for multiple immunology and inflammation ("I&I") diseases;
- our ability to develop and, if approved, ultimately commercialize our product candidates 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;
- the impact of current and future healthcare reforms, including those affecting the delivery of or payment for healthcare products and services;
- our expectations regarding federal, state and foreign regulatory requirements;
- other governmental legislation and regulation, as well as adverse effects from the U.S. government shutdown;
- 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, to obtain marketing approval, or to 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") and InnoCare Pharma Inc. ("InnoCare"). 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 obexelimab drug substance and drug product, WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") and our collaboration partner, InnoCare, which are both 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)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 115,565	$ 319,742
Short-term investments	175,319	31,024
Restricted cash	—	90
Prepaid expenses and other current assets	5,758	5,067
Total current assets	296,642	355,923
Property and equipment, net	50	185
Operating lease right-of-use assets, net	807	1,004
Long-term investments	10,717	—
Other non-current assets	13,802	12,856
Total assets	$ 322,018	$ 369,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,444	$ 17,136
Accrued expenses	45,359	39,371
Operating lease liabilities, current	618	785
Total current liabilities	52,421	57,292
Long-term liabilities:		
Royalty obligation	72,989	—
Operating lease liabilities, less current portion	180	218
Total long-term liabilities	73,169	218
Total liabilities	125,590	57,510
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share; 25,000,000 shares authorized and no shares issued and outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock, par value $0.0001 per share; 175,000,000 shares authorized; 42,213,465 and 41,793,412 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	4	4
Additional paid-in capital	721,179	699,651
Accumulated other comprehensive (loss) income	(69)	194
Accumulated deficit	(524,686)	(387,391)
Total stockholders' equity	196,428	312,458
Total liabilities and stockholders' equity	$ 322,018	$ 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)

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Revenue:				
License and collaboration revenue	$ —	$ —	$ 10,000	$ —
Total revenue	—	—	10,000	—
Operating expenses:				
Research and development	34,402	33,530	112,343	89,982
General and administrative	13,178	7,454	37,730	18,283
Acquired in-process research and development	5,000	—	5,000	—
Total operating expenses	52,580	40,984	155,073	108,265
Loss from operations	(52,580)	(40,984)	(145,073)	(108,265)
Other income (expense), net:				
Fair value adjustments to convertible notes	—	—	—	(846)
Other income, net	1,081	2,378	7,593	4,727
Total other income (expense), net	1,081	2,378	7,593	3,881
Loss before income taxes	(51,499)	(38,606)	(137,480)	(104,384)
Income tax (provision) benefit	—	—	185	—
Net loss to common stockholders	$ (51,499)	$ (38,606)	$ (137,295)	$ (104,384)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.22)	$ (5.02)	$ (3.27)	$ (28.83)
Weighted-average common stock outstanding - basic and diluted	42,159,340	7,697,695	41,943,160	3,621,276
Comprehensive loss:				
Net loss to common stockholders	$ (51,499)	$ (38,606)	$ (137,295)	$ (104,384)
Other comprehensive income (loss):				
Unrealized gain on investments	35	—	77	—
Foreign currency translation adjustment	(10)	(50)	(340)	16
Comprehensive loss	$ (51,474)	$ (38,656)	$ (137,558)	$ (104,368)

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

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

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	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
Exercises of common stock options	266,810	—	1,722	—	—	1,722
Stock-based compensation expense	—	—	6,045	—	—	6,045
Unrealized gain on investments	—	—	—	30	—	30
Foreign currency translation adjustment	—	—	—	(265)	—	(265)
Net loss	—	—	—	—	(52,223)	(52,223)
Balance as of June 30, 2025	42,088,697	$ 4	$ 712,903	$ (94)	$ (473,187)	$ 239,626
Exercises of common stock options	82,000	—	664	—	—	664
Stock-based compensation expense	—	—	7,336	—	—	7,336
Purchases of common stock under the Employee Stock Purchase Plan	42,768	—	276	—	—	276
Unrealized gain on investments	—	—	—	35	—	35
Foreign currency translation adjustment	—	—	—	(10)	—	(10)
Net loss	—	—	—	—	(51,499)	(51,499)
Balance as of September 30, 2025	42,213,465	$ 4	$ 721,179	$ (69)	$ (524,686)	$ 196,428

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

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

	Convertible Preferred Stock												
	Seed Series		Series A		Series B		Series C		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (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)
Issuance of Series C convertible preferred stock, net of $619 issuance cost	—	—	—	—	—	—	116,275,239	199,526	—	—	—	—	—	—
Exercises of common stock options	—	—	—	—	—	—	—	—	15,655	—	124	—	—	124
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,536	—	—	1,536
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	30	—	30
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(37,977)	(37,977)
Balance as of June 30, 2024	1,785,714	$ 956	17,589,380	$ 55,840	81,242,587	$ 193,290	116,275,239	$ 199,526	1,578,372	$ —	$ 7,294	$ 104	$ (296,180)	$ (288,782)
Conversion of convertible preferred stock upon closing of initial public offering	(1,785,714)	(956)	(17,589,380)	(55,840)	(81,242,587)	(193,290)	(116,275,239)	(199,526)	24,978,715	2	449,610	—	—	449,612
Issuance of common stock from initial public offer, net of underwriting discounts, commissions and other issuance costs	—	—	—	—	—	—	—	—	15,220,588	2	234,384	—	—	234,386
Exercises of common stock options	—	—	—	—	—	—	—	—	3,263	—	32	—	—	32
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,843	—	—	2,843
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	(50)	—	(50)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(38,606)	(38,606)
Balance as of September 30, 2024	—	$ —	—	$ —	—	$ —	—	$ —	41,780,938	$ 4	$ 694,163	$ 54	$ (334,786)	$ 359,435

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)

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (137,295)	$ (104,384)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	5,000	—
Depreciation expense	46	104
Loss on disposal of property and equipment	107	—
Net amortization of premiums and accretion of discounts on investments	(1,510)	—
Non-cash interest expense on royalty obligation	1,679	—
Stock-based compensation expense	18,767	5,326
Change in fair value of convertible notes	—	846
Non-cash lease expense	651	423
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(799)	475
Accounts payable	(11,159)	6,319
Accrued expenses	5,251	10,200
Operating lease liabilities	(657)	(429)
Net cash used in operating activities	(119,919)	(81,120)
Cash flows from investing activities:		
Purchases of property and equipment	(18)	(57)
Purchases of investments	(284,862)	(26,760)
Proceeds from sales and maturities of investments	131,358	—
Product candidate license acquisitions	(5,000)	—
Net cash used in investing activities	(158,522)	(26,817)
Cash flows from financing activities:		
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	—	178,381
Payment of initial public offering costs	—	(1,861)
Payment of deferred offering costs	(3,324)	—
Proceeds from royalty obligation	75,000	—
Proceeds from exercise of stock options	2,485	198
Proceeds from issuance of common stock under employee stock purchase plan	276	—
Proceeds from initial public offering, net of underwriting discount and commissions	—	234,387
Net cash provided by financing activities	74,437	411,105
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(263)	16
Net (decrease) increase in cash, cash equivalents and restricted cash	(204,267)	303,184
Cash, cash equivalents and restricted cash at beginning of period	319,832	56,943
Cash, cash equivalents and restricted cash at end of period	$ 115,565	$ 360,127
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained under operating lease arrangements	$ 445	$ —
Conversion of BMS Note into Series C convertible preferred stock	$ —	$ 21,146
Deferred offering costs in accounts payable and accrued expenses	$ 1,204	$ 4,389
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 115,565	$ 360,038
Restricted cash	—	89
Total cash, cash equivalents and restricted cash	$ 115,565	$ 360,127

The accompanying notes are an integral part of these 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"), license agreement with Zai Lab (Hong Kong) Limited ("Zai"), and a royalty purchase agreement with Royalty Pharma Investments ("Royalty Pharma") (please see *Note 7, License and Collaboration Revenue and Note 9, Royalty Obligation*, 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 $51.5 million and $38.6 million for the three months ended September 30, 2025 and 2024, respectively, and $137.3 million and

$104.4 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, the Company had an accumulated deficit of $524.7 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 $301.6 million as of September 30, 2025, together with the $120.0 million of gross proceeds from the Private Investment in Public Equity ("PIPE") received in October 2025 (*Note 16, Subsequent Events*) will be sufficient to fund its operating and capital expenditures into the fourth quarter of 2026, however it will not be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date these condensed consolidated financial statements were issued. Therefore, the Company has concluded that substantial doubt exists with respect to its ability to continue as a going concern. As a result, the Company will need to raise additional capital to finance its operations. The Company's ability to fund operations is subject to substantial risks and uncertainties.

Until such time that 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. If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects, and the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

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, other than disclosed herein, 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 September 30, 2025, and the results of operations and its cash flows for the three and nine months ended September 30, 2025 and 2024. The financial

data and other information disclosed in these notes related to the three and nine months ended September 30, 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, pre-initial public offering ("IPO") valuations of common stock and the liability related to the sale of future royalties including the estimation of future payments and the related non-cash interest expense.

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.

Royalty Obligation

In September 2025, the Company and Royalty Pharma Investments 2019 ICAV ("Royalty Pharma") entered into the Revenue Participation Right Purchase and Sale Agreement (the "Royalty Purchase Agreement"). See *Note 9, Royalty Obligations,* for further details of the agreement.

When the Company maintains significant continuing involvement in generating the underlying cash flows, royalty financings are recognized as obligations. Payments received are recorded as the principal amount of the obligation on the consolidated balance sheet as long-term liabilities. The carrying amount of the obligation is accreted to reflect the total expected royalty and related payments due to Royalty Pharma, using the effective interest method. As royalties and other related payments are made, the outstanding royalty obligation will be reduced over the estimated term of the arrangement.

The royalty obligation, effective interest rate, and corresponding interest expense are determined based on the Company's estimate of future anticipated royalty payments under the arrangement. These estimates are reassessed at the end of each reporting period according to the Company's latest projections. Should these estimated cash flows change as a result of this review, the Company will recalculate the effective interest rate and adjust the accretion of interest on the royalty obligation prospectively. Any additional funding received from Royalty Pharma will also be treated as an obligation, with a prospective adjustment to the effective interest rate applied upon receipt of such funds.

Recent Accounting Pronouncements

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

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

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 September 30, 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	$ 100,852	$ 100,852	$ —	$ —
Money market funds	14,713	14,713	—	—
Short-term investments:				
Commercial paper	6,338	—	6,338	—
Corporate debt securities	38,944	—	38,944	—
Government securities	130,037	130,037	—	—
Long-term investments:				
Government securities	10,717	10,717	—	—
Total assets	$ 301,601	$ 256,319	$ 45,282	$ —

	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 September 30, 2025 and December 31, 2024. In addition, there have been no changes in valuation techniques as of September 30, 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 nine months ended September 30, 2025 and year ended December 31, 2024, there were no transfers between levels.

The short and long-term investments are classified as available-for-sale securities. As of September 30, 2025, the remaining contractual maturities of the available-for-sale securities were 1 to 16 months, and 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 and nine months ended September 30, 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 September 30, 2025, which the Company does not intend to sell and has concluded it 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 September 30, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 6,334	$ 4	$ —	$ 6,338
Corporate debt securities	38,914	31	(1)	38,944
Government securities	140,680	77	(3)	140,754
Total	$ 185,928	$ 112	$ (4)	$ 186,036

	As of December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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):

	September 30, 2025	December 31, 2024
Clinical trial deposits	$ 12,882	$ 12,639
Deferred offering costs	837	—
Other	83	217
Total other assets	$ 13,802	$ 12,856

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
External research, development and manufacturing expenses	$ 34,102	$ 29,338
Employee compensation and benefits	8,757	8,308
Professional and consultant fees	1,920	1,265
Income taxes payable	—	211
Other	580	249
Total accrued expenses	$ 45,359	$ 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 three months)	$ 239
2026	457
2027	138
Thereafter	—
Total future minimum lease payments	834
Less: imputed interest	(36)
Total operating lease liabilities	$ 798

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.

As of September 30, 2025 and 2024, the Company recorded $1.3 million and $1.8 million, respectively, as a receivable included in prepaid expenses and other current assets. The Company recorded $1.3 million and $1.8 million for the three months ended September 30, 2025 and 2024, respectively, as a reduction to research and development expense for global development costs to be reimbursed by BMS. The Company recorded $4.2 million and $3.9 million for the nine months ended September 30, 2025 and 2024, respectively, as a reduction of 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 and nine months ended September 30, 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 nine months ended September 30, 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 September 30, 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 nine months ended September 30, 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 nine months ended September 30, 2025 and 2024, the Company recorded no reimbursable patent-related costs.

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 and nine months ended September 30, 2025, the Company recognized no expense related to Viridian contract manufacturing organization ("CMO") costs. During the three and nine months ended September 30, 2024, the Company recognized no expense and $0.1 million in expense related to Viridian CMO costs, respectively. 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 and nine months ended September 30, 2025, the Company recorded an immaterial amount and $0.2 million in reimbursable expenses, respectively. During the three and nine months ended September 30, 2024, the Company recorded $0.5 million and $1.5 million in reimbursable expenses, respectively. Additionally, during the nine months ended September 30, 2025 and 2024, no milestones were achieved.

9. Royalty Obligation

In September 2025, the Company and Royalty Pharma entered into the Royalty Purchase Agreement. Pursuant to the Royalty Purchase Agreement, the Company received a $75.0 million upfront payment in exchange for which Royalty Pharma purchased the right to receive, for each calendar quarter, (i) 5.5% of net sales of obexelimab products sold by the Company and its affiliates worldwide, (ii) 5.5% of net sales of obexelimab products sold by licensees of Zenas and its affiliates in the U.S., the United Kingdom and the European Union, (iii) 25% of royalty income payable to Zenas or any of its affiliates on sales of obexelimab products in countries other than the U.S., the United Kingdom, and in the European Union by its licensees pursuant to out-licenses less royalty payments payable by Zenas to Xencor Inc. and (iv) 25% of non-royalty income attributable to obexelimab products payable to Zenas or any of its affiliates by its licensees (other than certain milestone payments payable by Bristol-Myers Squibb) pursuant to out-licenses and allocated to countries other than the U.S., the United Kingdom and in the European Union.

The Royalty Purchase Agreement provides for an additional $225.0 million of payments to be paid to the Company by Royalty Pharma upon the occurrence of certain triggering events which includes (1) $75.0 million payable upon the achievement of certain milestones with respect to Zenas' INDIGO Phase 3 Trial of obexelimab for the treatment of patients with IgG4-Related Disease on or before a specified date, (2) $75.0 million payable following receipt of marketing approval for obexelimab from the U.S. Food and Drug Administration (the "FDA") for the treatment of IgG4-Related Disease on or before a specified date and (3) $75.0 million payable following receipt of marketing approval for obexelimab from the FDA for the treatment of systemic lupus erythematosus on or before a specified date.

The Company accounted for the Royalty Purchase Agreement as a debt financing, primarily because it has significant continuing involvement in generating the future revenue on which the royalty payments are based. The $75.0 million upfront payment received was recorded as a liability, net of issuance costs of $3.7 million. The effective interest rate was determined based on the Company's projections of future royalty payments. The Company will evaluate the estimated timing and amount of future royalty payments for each reporting period and will revise the effective interest rate prospectively if those estimates change materially.

The fair value of the liability approximates the carrying value and was determined based on the current estimate of the timing and amount of expected future royalty payments expected to be paid over the estimated term of the Royalty

Purchase Agreement, which are subject to significant estimation uncertainty and are based on various assumptions made by the Company. These assumption inputs are determined to be Level 3 inputs in the fair value hierarchy as they involve significant unobservable inputs and judgment.

The following table shows the activity for the royalty obligation during the three and nine months ended September 30, 2025 (in thousands):

		Amount
Proceeds from royalty obligation	$	75,000
Issuance costs		(3,690)
Interest expense related to royalty obligation		1,679
Royalty obligation as of September 30, 2025	$	72,989
Effective interest rate		30.7%

10. 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 common stock $0.0001 par value. 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:

	September 30, 2025	December 31, 2024
Options to purchase common stock	10,507,497	8,706,197
Remaining shares reserved for future issuance	507,134	359,399
RSUs	525,350	—
Employee stock purchase plan	773,122	397,956
Total	12,313,103	9,463,552

11. 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 September 30, 2025, 507,134 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.

From time to time, the Company grants equity awards to newly hired employees as an inducement to enter into employment with the Company. The grants constitute "employment inducement grants" in accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules and are issued outside of the 2024 Plan. The inducement grants include non-statutory stock options to purchase shares of the Company's common stock. The inducement grants have terms and conditions consistent with those set forth under the 2024 Plan and vest under the same respective vesting schedules as stock option awards granted under the 2024 Plan. The inducement grants are included in the stock option award tables below. As of September 30, 2025, the Company granted 762,000 non-statutory stock options as inducement grants. No inducement grants were awarded during 2024.

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	2,703,600	$ 10.82		
Exercised	(377,285)	$ 6.59		$ 1,731
Forfeited or cancelled	(525,015)	$ 12.59		
Outstanding - September 30, 2025	10,507,497	$ 12.86	8.81	$ 98,133
Options vested and exercisable as of September 30, 2025	2,833,037	$ 12.12	8.12	$ 28,548
Options vested and expected to vest as of September 30, 2025	10,507,497	$ 12.86	8.81	$ 98,133

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 September 30, 2025.

Restricted Stock Units

The Company granted to certain employees restricted stock units ("RSUs") that are subject to time-based vesting conditions, that vest equally over four years, assuming continued employment. RSUs with time-based vesting conditions are valued on the grant date using the grant date market value price of the underlying shares of the Company's common stock. The Company did not grant any RSU's in 2024. The following table summarizes the Company's RSU activity:

	Number of Shares	Weighted - Average Grant Date Fair Value
Unvested as of December 31, 2024	—	$ —
Granted	538,550	$ 12.15
Vested	—	$ —
Forfeited	(13,200)	$ 11.94
Unvested as of September 30, 2025	525,350	$ 12.16

No RSUs vested during the current or prior year periods.

As of September 30, 2025, there was $81.2 million of unrecognized stock-based compensation related to unvested stock options, granted RSU's and the Employee Stock Purchase Plan (the "ESPP"), which is expected to be recognized over a weighted-average period of 3.0 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 2,403	$ 1,257	$ 6,097	$ 2,378
General and administrative	4,933	1,586	12,670	2,948
Total stock-based compensation expense	$ 7,336	$ 2,843	$ 18,767	$ 5,326

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 September 30, 2025, a total of 773,122 shares were available for future issuance under the ESPP. During the three and nine months ended September 30, 2025, there were 42,768 shares issued under the ESPP.

12. Net Loss Per Share

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 September 30, 2025 and 2024 because including them would have had an anti-dilutive effect:

	September 30,	
	2025	2024
Unvested restricted stock units	525,350	—
Options to purchase common stock	10,507,497	8,630,075

13. 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.

Royalty Obligation

The Company entered into a royalty purchase agreement under which it is obligated to make contingent payments related to future net sales and royalty income of obexelimab; see *Note 9, Royalty Obligation* 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 September 30, 2025, our total non-cancellable clinical manufacturing contract payment obligations are $18.7 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 September 30, 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 September 30, 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.

14. 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 September 30, 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 September 30, 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.

15. 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, and 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 investment balances. Revenue is primarily attributed to individual countries based on the entity owning the license. During the three months ended September 30, 2025, the Company did not recognize revenue and for nine months ended September 30, 2025, $10.0 million was recognized as revenue which was attributed to Zenas HK. The Company did not recognize revenue during the three or nine months ended September 30, 2024.

The following table presents certain financial data for the Company's reportable segment for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Revenue	$ —	$ —	$ 10,000	$ —
Less:				
Direct research and development expenses:[1]				
Obexelimab	20,753	21,326	74,006	56,408
Other programs (ZB002 & ZB004)	467	384	1,204	1,850
Partnered regional programs (ZB001 & ZB005)	172	2,344	134	6,367
Unallocated research and development[2]	10,607	8,219	30,902	22,979
General and administrative[3]	8,245	5,868	25,060	15,335
Acquired in-process research and development	5,000	—	5,000	—
Stock-based compensation	7,336	2,843	18,767	5,326
Other segment items[4]	(1,081)	(2,378)	(7,778)	(3,881)
Segment net loss	$ (51,499)	$ (38,606)	$ (137,295)	$ (104,384)

[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, interest expense related to the royalty obligation and realized and unrealized gains and losses on foreign currency transactions.

16. Subsequent Events

License Agreement with InnoCare Pharma Inc.

In October 2025, the Company entered into a License Agreement (the "InnoCare License Agreement") with InnoCare Pharma Inc. ("InnoCare"). Under the InnoCare License Agreement, InnoCare granted the Company exclusive rights to develop, manufacture, and commercialize: i) orelabrutinib, in the multiple sclerosis ("MS") field worldwide, and in all non-oncology indications outside Greater China and Brunei, Burma, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam ("Southeast Asia"), ii) ZB021 (an IL-17AA/AF inhibitor) in all fields of use worldwide, excluding Greater China and Southeast Asia and iii) ZB022 (a TYK2 inhibitor) in all fields of use worldwide. The Company also obtained certain non-exclusive rights to perform development and manufacturing activities in Greater China and Southeast Asia to support each program in its respective licensed territories.

Pursuant to the InnoCare License Agreement, the Company agreed to make a one-time non-refundable upfront cash payment of $35.0 million, $5.0 million of which was paid as of September 30, 2025, prior to the transaction closing and was recorded in the condensed consolidated statement of operations and comprehensive loss as acquired in-process research and development. The Company also agreed to issue upfront, 5,000,000 shares of common stock to InnoCare in a private placement in exchange for these rights.

The Company is also required to make an additional one-time non-refundable cash payment of $25.0 million and issue an additional 2,000,000 shares of common stock through a private placement upon the occurrence of Zenas' initiated Phase 3 clinical trial for orelabrutinib in any indication other than primary progressive MS, or by March 31, 2026, upon the occurrence of certain specified events, whichever comes first. In addition, the Company has agreed to make one-time, potential near-term milestone payments of $20 million each, upon the achievement of certain regulatory milestones for ZB021 and ZB022 (the "Regulatory Milestones").

The Company is further obligated to pay future regulatory and commercial milestones of up to $723.0 million related to orelabrutinib, and future development, regulatory, and commercial milestones of up to $656.0 million, inclusive of the two $20.0 million Regulatory Milestones specified above, for each preclinical compound if certain milestones are successfully achieved. In addition, the Company may be obligated to pay royalties on net sales at rates ranging from high-single digits to high-teens for orelabrutinib, and mid-single digits to mid-teens for the preclinical compounds.

The Company is obligated to reimburse InnoCare approximately $4.0 million, for certain costs related to the acquired programs which were incurred prior to and after the effective date of the InnoCare License Agreement, including clinical trial startup costs and Investigational New Drug ("IND") enabling activities.

The Company simultaneously entered into a Subscription Agreement and Registration Rights Agreement with InnoCare related to the shares of common stock issued and to be issued in the private placement. The Subscription Agreement provides transfer restrictions on the InnoCare shares and other customary representations, warranties and covenants that were made solely for the benefit of the parties to the Securities Purchase Agreement.

PIPE

In October 2025, the Company entered into a Securities Purchase Agreement and Registration Rights Agreement related to the PIPE transaction, pursuant to which the Company sold (i) 6,262,112 shares of common stock to certain institutional and accredited investors at a price of $19.00 per share and (ii) 48,918 shares of common stock to certain directors and officers of the Company at a price of $20.85 per share for gross proceeds of approximately $120.0 million, before deducting placement agent fees and other offering expenses.

At- the-Market ("ATM") Program

In October 2025, the Company filed a registration statement on Form S-3 (the "Registration Statement") with the SEC, which registered the offering, issuance and sale of common stock, preferred stock, warrants and debt securities, or any combination thereof, in an amount and on terms that the Company will determine at the time of the respective offering. The Company simultaneously entered into a sales agreement with Jefferies LLC as sales agent to provide for the issuance and sale by the Company of up to $200.0 million of common stock from time to time in ATM offerings under the Registration Statement.

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 (the "INDIGO" trial), systemic lupus erythematosus ("SLE") through an ongoing Phase 2, double-blind, randomized, placebo-controlled trial (the "SunStone" trial), and relapsing multiple sclerosis ("RMS") through an ongoing Phase 2, double-blind, randomized, placebo-controlled trial (the "MoonStone" trial).

On October 27, 2025, we announced topline data from the MoonStone trial. Obexelimab met the primary endpoint, demonstrating a statistically significant 95% relative reduction in the cumulative number of new gadolinium-enhancing T1 hyperintense lesions, which are markers of active inflammation, over week 8 and week 12 compared with placebo (p=0.0009). The Company expects to report 24-week data from the MoonStone trial in the first quarter of 2026, which will include additional secondary and exploratory endpoints. The 24-week data from additional secondary and exploratory endpoints may inform obexelimab's potential impact on disability progression and help the Company determine next steps for future development of obexelimab in RMS. In the fourth quarter of 2024, we completed the target enrollment of the INDIGO trial and expect to report topline results from the INDIGO trial around year-end 2025. If the topline results are positive, we expect to file a Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA") in the first half of 2026, followed by a Marketing Authorization Application with the European Medicines Agency ("EMA"), and, if approved, commence the commercial launch initially in the U.S. and then in Europe. We expect to report topline results from the SunStone trial in mid-2026. Based on the outcome of the SunStone trial, and considering other factors, we may initiate a Phase 3 program in patients with SLE in the first half of 2027.

On October 7, 2025, we entered into a License Agreement with InnoCare Pharma Inc. pursuant to which we were granted exclusive rights to develop, manufacture, and commercialize orelabrutinib, a Bruton's Tyrosine Kinase inhibitor ("BTK"),

for multiple sclerosis worldwide, and in all non-oncology indications worldwide excluding mainland China, Hong Kong, Macau and Taiwan ("Greater China"), and Brunei, Burma, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam ("Southeast Asia"), as well as two early-development product candidates: ZB021, an IL-17AA/AF inhibitor, in all fields of use worldwide excluding Greater China and Southeast Asia, and ZB022, a TYK2 inhibitor, in all fields of use worldwide.

Orelabrutinib is a highly selective and central nervous system ("CNS")-penetrant, oral small molecule BTK inhibitor. Orelabrutinib is designed to bind irreversibly to BTK with minimal off-target effects, which may potentially reduce certain side effects. We believe orelabrutinib is designed to efficiently cross the blood-brain barrier, reaching therapeutic levels within the CNS to directly target inflammation in diseases like MS.

In September 2025, the Phase 3 clinical trial of orelabrutinib in patients with Primary Progressive Multiple Sclerosis ("PPMS") was initiated. The Phase 3 trial of orelabrutinib in patients with PPMS is a global, multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating the safety and efficacy of orelabrutinib dosed 80 mg once daily ("QD") compared to placebo in patients with PPMS, with a primary endpoint of time to onset of 12-week composite confirmed disability progression ("cCDP"). In the first quarter of 2026, we plan to initiate a second global, Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating orelabrutinib dosed 80 mg QD compared to placebo in patients with Secondary Progressive Multiple Sclerosis ("SPMS"), with a primary endpoint of time to onset of 24-week CDP.

ZB021 is an oral IL-17AA/AF inhibitor designed to block both IL-17AA homodimer and IL-17AF heterodimer signaling. Preclinical studies for ZB021 have shown favorable PK and ADME properties. ZB021 achieved comparable activity in vivo to a reference anti-IL-17 biologic in a rat CIA model. Subject to the results of Investigational New Drug ("IND")-enabling studies, we expect to submit an IND application for ZB021, and if cleared, initiate a Phase 1 clinical study in 2026.

ZB022 is an oral, brain-penetrant TYK2-JH2 inhibitor, currently in IND-enabling studies. Subject to the results of IND-enabling studies, we expect to submit an IND application for ZB022, and if cleared, initiate a Phase 1 clinical study in 2026.

Beyond our lead product candidates, 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.

On September 2, 2025, the Company and Royalty Pharma Investments 2019 ICAV ("Royalty Pharma") entered into the Revenue Participation Right Purchase and Sale Agreement (the "Royalty Purchase Agreement"), pursuant to which

Royalty Pharma purchased the right to receive, for each calendar quarter, (i) 5.5% of net sales of obexelimab products sold by Zenas and its affiliates worldwide, (ii) 5.5% of net sales of obexelimab products sold by licensees of Zenas and its affiliates in the U.S., the United Kingdom and the European Union, (iii) 25% of royalty income payable to Zenas or any of its affiliates on sales of obexelimab products in countries other than the U.S., the United Kingdom, and in the European Union by its licensees pursuant to out-licenses less royalty payments payable by Zenas to Xencor Inc. and (iv) 25% of non-royalty income attributable to obexelimab products payable to Zenas or any of its affiliates by its licensees (other than certain milestone payments payable by Bristol-Myers Squibb) pursuant to out-licenses and allocated to countries other than the U.S., the United Kingdom and in the European Union.

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 September 30, 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. Additionally, on October 9, 2025, we closed our private investment in public equity ("PIPE") of 6,311,030 shares of common stock for gross proceeds of approximately $120.0 million, before deducting placement agent fees and other expenses.

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 and nine months ended September 30, 2025 were $51.5 million and $137.3 million, respectively, and we recorded net loss of $38.6 million and $104.4 million, for the three and nine months ended September 30, 2024. As of September 30, 2025, we had an accumulated deficit of $524.7 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, orelabrutinib and our other programs;
- advance our obexelimab and orelabrutinib programs 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.

We had $301.6 million in cash, cash equivalents and investments as of September 30, 2025. Based on our current operating plans, including $120.0 million of gross proceeds from the PIPE received in October 2025 (*Note 16, Subsequent Events*), we expect that our existing cash, cash equivalents and investments will be sufficient to fund our capital and operating expenditures into the fourth quarter of 2026, however it will not be sufficient to fund our operations and capital expenditure requirements for at least twelve months from the date our condensed consolidated financial statements are issued and accordingly have concluded that there is substantial doubt with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments or changes in classification of assets or liabilities that may result from our possible inability to continue as a going concern. However, we expect to finance our operations through private or public equity financing, debt financing or other capital resources. 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 our product candidates, 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 clinical studies and other research and development activities associated with the development of our current 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 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 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.

Acquired In-Process Research and Development Expense

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

Total Other Income (Expense), Net

Other Income (Expense), Net

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

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 September 30, 2025 and 2024

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

	Three Months Ended September 30,		
	2025	2024	Increase (Decrease)
Operating expenses:			
Research and development	$ 34,402	$ 33,530	$ 872
General and administrative	13,178	7,454	5,724
Acquired in-process research and development	5,000	—	5,000
Total operating expenses	52,580	40,984	11,596
Loss from operations	(52,580)	(40,984)	(11,596)
Other income (expense), net:			
Other income, net	1,081	2,378	(1,297)
Total other income (expense), net	1,081	2,378	(1,297)
Net loss	$ (51,499)	$ (38,606)	$ (12,893)

Research and Development Expenses

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

	Three Months Ended September 30,		
	2025	2024	Increase (Decrease)
Direct research and development expenses by program:			
Obexelimab	$ 20,753	$ 21,326	$ (573)
Other programs (ZB002 & ZB004)	467	384	83
Partnered regional programs (ZB001 & ZB005)	172	2,344	(2,172)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	12,467	9,049	3,418
Other expenses	543	427	116
Total research and development expenses	$ 34,402	$ 33,530	$ 872

Research and development expenses were $34.4 million for the three months ended September 30, 2025, compared to $33.5 million for the three months ended September 30, 2024. The increase of $0.9 million was primarily attributable to

the following:

- a $0.6 million decrease in costs related to the development of obexelimab, our lead product candidate, primarily driven by a $3.6 million decrease in manufacturing costs for clinical trial materials and partially offset by a $2.8 million increase in clinical trial and regulatory costs;

- a $2.2 million decrease in costs related to our partnered regional programs, including a $1.9 million decrease related to ZB005 and a $0.3 million decrease related to ZB001, as a result of transitioning these programs to Tenacia and Zai, respectively; and

- a $3.4 million increase in personnel costs, including a $2.2 million increase in salary and benefit related expense, primarily due to an increase in headcount, a $1.1 million increase in stock-based compensation expense, and a $0.1 million increase in external contractor expenses 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 September 30,		
	2025	2024	Increase (Decrease)
Personnel related expenses (including stock-based compensation)	$ 8,804	$ 4,866	$ 3,938
Legal and professional fees	2,608	1,512	1,096
Facilities	789	507	282
Other expenses	977	569	408
Total general and administrative expenses	$ 13,178	$ 7,454	$ 5,724

General and administrative expenses were $13.2 million for the three months ended September 30, 2025, compared to $7.5 million for the three months ended September 30, 2024. The increase of $5.7 million was primarily attributable to the following:

- a $3.9 million increase in personnel costs, including a $3.3 million increase in stock-based compensation expense, and a $0.7 million increase in salary and benefit related expenses, primarily due to an increase in headcount associated with pre-commercialization activities partially offset by a $0.1 million decrease in contractor-related expenses.

- a $1.1 million increase in professional fees, including legal, audit and tax expenses, primarily attributable to operating as a public company; and

- a $0.7 million increase in facilities and other expenses, primarily attributable to facility, insurance and other variable costs related to operating as a public company.

Acquired In-Process Research and Development

Acquired in-process research and development was $5.0 million for the three months ended September 30, 2025 related to a deposit paid toward the $35.0 million upfront payment for the exclusive rights to develop and manufacture product candidates under the License Agreement with InnoCare.

Total Other Income (Expense), Net

Total other income (expense), net was $1.1 million for the three months ended September 30, 2025, was due to an increase in interest income related to our cash equivalents and investments, partially offset by interest expense related to our royalty obligation.

Comparison of the Nine Months Ended September 30, 2025 and 2024

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

	Nine Months Ended September 30,		
	2025	2024	Increase (Decrease)
Revenue:			
License and collaboration revenue	$ 10,000	$ —	$ 10,000
Total revenue	10,000	—	10,000
Operating expenses:			
Research and development	$ 112,343	$ 89,982	$ 22,361
General and administrative	37,730	18,283	19,447
Acquired in-process research and development	5,000	—	5,000
Total operating expenses	155,073	108,265	46,808
Loss from operations	(145,073)	(108,265)	(36,808)
Other income (expense), net:			
Fair value adjustments to convertible notes	—	(846)	846
Other income, net	7,593	4,727	2,866
Total other income (expense), net	7,593	3,881	3,712
Loss before income taxes	(137,480)	(104,384)	(33,096)
Income tax benefit	185	—	185
Net loss	$ (137,295)	$ (104,384)	$ (32,911)

Revenue

For the nine months ended September 30, 2025, revenue increased $10.0 million, compared to the same period in 2024. The increase is 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 nine months ended September 30, 2024.

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2025	2024	Increase (Decrease)
Direct research and development expenses by program:			
Obexelimab	$ 74,006	$ 56,408	$ 17,598
Other programs (ZB002 & ZB004)	1,204	1,850	(646)
Partnered regional programs (ZB001 & ZB005)	134	6,367	(6,233)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	35,548	24,210	11,338
Other expenses	1,451	1,147	304
Total research and development expenses	$ 112,343	$ 89,982	$ 22,361

Research and development expenses were $112.3 million for the nine months ended September 30, 2025, compared to $90.0 million for the nine months ended September 30, 2024. The increase of $22.4 million was primarily attributable to the following:

- a $17.6 million increase in costs related to the development of obexelimab, our lead product candidate, primarily driven by a $11.2 million increase in clinical trial and regulatory costs and a $5.6 million increase in manufacturing costs for clinical trial materials;
- a $6.2 million decrease in costs related to our partnered regional programs, including a $4.6 million decrease related to ZB005 and a $1.6 million decrease related ZB001, as a result of transitioning these programs to Tenacia and Zai, respectively; and
- a $11.3 million increase in personnel costs, including a $7.2 million increase in salary and benefit related expenses, primarily due to an increase in headcount, a $3.7 million increase in stock-based compensation expense, and a $0.4 million increase in external contractor expenses 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):

	Nine Months Ended September 30,		
	2025	2024	Increase (Decrease)
Personnel related expenses (including stock-based compensation)	$ 25,261	$ 10,961	$ 14,300
Legal and professional fees	6,834	4,332	2,502
Facilities	2,494	1,557	937
Other expenses	3,141	1,433	1,708
Total general and administrative expenses	$ 37,730	$ 18,283	$ 19,447

General and administrative expenses were $37.7 million for the nine months ended September 30, 2025, compared to $18.3 million for the nine months ended September 30, 2024. The increase of $19.4 million was primarily attributable to the following:

- a $14.3 million increase in personnel costs, primarily including a $9.7 million increase in stock-based compensation expense, a $4.4 million increase in salary and benefit related expense, primarily due to an increase in headcount

associated with pre-commercialization activities, a $0.6 million increase in recruiting expense partially offset by a $0.4 million decrease in contractor-related expenses;

- a $2.5 million increase in professional fees, including legal, audit and tax expenses, primarily attributable to operating as a public company; and

- a $2.6 million increase in facilities and other expenses, primarily attributable to facility, insurance and other variable costs related to operating as a public company.

Acquired In-Process Research and Development

Acquired in-process research and development was $5.0 million for the nine months ended September 30, 2025, related to a deposit paid toward the $35.0 million upfront payment for the exclusive rights to develop and manufacture product candidates under the License Agreement with InnoCare.

Total Other Income (Expense), Net

Total other income (expense), net was $7.6 million for the nine months ended September 30, 2025, was due to an increase in interest income related to our cash equivalents and investments, partially offset by interest expense related to our royalty obligation.

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 September 30, 2025, we had $301.6 million in cash, cash equivalents, and investments and we had an accumulated deficit of $524.7 million. Additionally, on October 9, 2025, we closed a PIPE of 6,311,030 shares of common stock for gross proceeds of approximately $120.0 million, before deducting placement fees and other expenses. Through September 30, 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, collectively, $75.0 million through our Royalty Purchase Agreement, and 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 expect that our available cash, cash equivalents and investments, as of September 30, 2025, together with the $120.0 million of gross proceeds from the PIPE received in October 2025 (*Note 16, Subsequent Events*), will be sufficient to fund our operating and capital expenditures into the fourth quarter of 2026, however it will not be sufficient to fund our operations and capital expenditure requirements for at least the next 12 months from the filing of this Quarterly Report and accordingly have concluded that there is substantial doubt with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments or changes in classification of assets or liabilities that may result from our possible inability to continue as a going concern. However, we expect to finance our operations through private or public equity financing, debt financing or other capital resources.

Our primary uses of capital are, and we expect to continue to be, third-party clinical research and development services, manufacturing costs, compensation and related expenses, 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 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):

	Nine Months Ended September 30,	
	2025	**2024**
Net cash used in operating activities	$ (119,919)	$ (81,120)
Net cash used in investing activities	(158,522)	(26,817)
Net cash provided by financing activities	74,437	411,105
Effect of exchange rate changes on cash and restricted cash	(263)	16
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (204,267)	$ 303,184

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2025 was $119.9 million, and was primarily due to our net loss of $137.3 million and a decrease of $11.2 million in accounts payable and a decrease of $0.8 million in prepaid expenses and other assets, partially offset by $18.8 million of stock-based compensation expense, a $5.0 million increase in accrued expenses, an adjustment to cash used in operations of $5.0 million related to acquired in-process research and development expense for a deposit paid toward the $35.0 million upfront payment under the License Agreement with InnoCare. The net increase in accrued expenses was primarily due to an increase in clinical study expenses, while the decrease in accounts payable was primarily due to the timing of vendor payments.

Net cash used in operating activities for the nine months ended September 30, 2024 was $81.2 million, and was primarily due to our net loss of $104.4 million, partially offset by $6.3 million increase in accounts payable, a $10.2 million increase in accrued expenses, a $0.5 million increase in prepaid expenses and other assets, a $0.8 million increase in the fair value of our BMS Note liability and $5.3 million of stock-based compensation expense. The increase in accrued expenses and accounts payable was primarily attributable to an increase in research and development expenses, while the increase in prepaid expenses and other assets was primarily due to the timing of vendor payments.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2025 was $158.5 million and consisted primarily of purchases of investments of $284.9 million and $5.0 million payment as a deposit toward the $35.0 million

upfront payment under the License Agreement with InnoCare, partially offset by proceeds from sales and maturities of investments of $131.4 million.

Net cash used in investing activities for the nine months ended September 30, 2024 was $26.8 million and consisted of purchases of investments of $26.8 million and purchases of property and equipment of $0.1 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2025 was $74.4 million, resulting from $75.0 million in gross proceeds received in connection with the royalty obligation and $2.5 million of proceeds received from the exercise of stock options, offset by $3.3 million of payments related to deferred offering costs.

Net cash provided by financing activities for the nine months ended September 30, 2024 was $411.1 million, resulting from $178.4 million in net proceeds received from the issuance and sale of shares of our Series C Preferred Stock, net proceeds from our IPO of $234.4 million, and $0.2 million of proceeds received from the exercise of stock options, partially offset by a $1.9 million payment of offering costs.

Material Cash Requirements for Known Contractual and Other Obligations

During the three months ended September 30, 2025, except as disclosed at *Note 13 – Commitments and Contingencies*, 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 September 30, 2025, we had cash, cash equivalents and investments of $301.6 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 and nine months ended September 30, 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 September 30, 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 September 30, 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 September 30, 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 September 30, 2025 and 2024, were $51.5 million and $38.6 million, respectively, and $137.3 million and $104.4 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $524.7 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, orelabrutinib and our other programs;
- advance our obexelimab and orelabrutinib programs 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 CROs and CMOs; and
- incur additional costs associated with being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance with an exchange listing and the Securities and Exchange Commission (the "SEC") requirements, director and officer insurance premiums and investor relations costs.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial expenditures to develop and market additional product candidates.

We 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, orelabrutinib and other product candidates.

As of September 30, 2025, we had $301.6 million in cash, cash equivalents and investments. Based on our current operating plans, we do not expect that our existing cash, cash equivalents and investments will be sufficient to fund our operations and capital expenditure requirements for at least twelve months from the date of our condensed consolidated financial statements are issued and accordingly have concluded that there is substantial doubt with respect to our ability to continue as a going concern. Our financial statements do not include any adjustments or changes in classification of assets or liabilities that may result from our possible inability to continue as a going concern. However, we expect to finance our operations through private or public equity financing, debt financing or other 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 and orelabrutinib 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. For example, we entered into the Royalty Purchase Agreement with Royalty Pharma, pursuant to which we are eligible for certain milestone payments. 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, impose 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. For example, on October 9, 2025, we closed our private placement of 6,311,030 shares of common stock for gross proceeds of approximately $120.0 million, before deducting placement agent fees and other expenses. 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.

The Royalty Pharma Agreement contains covenants that impose on us certain obligations, including with respect to royalty payments, advancement of our obexelimab program and reporting of clinical, regulatory and commercial updates to Royalty Pharma and includes restrictions on intellectual property transfers and out-licenses. The Royalty Pharma Agreement also limits our ability to incur certain types of indebtedness prior to the consummation of a change of control and limits our ability to create or incur liens or dispose of certain assets related to obexelimab. Compliance with these covenants limits our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us. The Agreement may only be terminated by mutual written agreement of Royalty Pharma and us.

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

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

- the FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies or impose additional requirements before permitting us to initiate a clinical trial;

- the FDA or comparable foreign regulatory authorities, Institutional Review Boards ("IRBs") or ethics committees may disagree with our study design, may require that we modify or amend our clinical trial protocols, or may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;

- clinical investigators or clinical trial sites may deviate from trial protocols or Good Clinical Practice requirements ("GCPs") or drop out of a trial, and we may need to add new investigators or sites;

- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, if at all;

- the number of participants required for clinical trials may be larger than expected, enrollment in clinical trials may be slower than expected or participants may drop out or fail to return for post-treatment follow-up at a higher rate than expected;

- we may observe unexpectedly high placebo response rates;

- the cost of clinical trials and preclinical studies may be greater than we anticipate, or we may have insufficient funds to conduct such trial or study or to pay the substantial user fees required by the FDA upon the submission of a BLA or a New Drug Application ("NDA");

- 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 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 serious adverse events ("SAEs") in our clinical trials of obexelimab administered through IV infusion.

Our clinical trials of obexelimab are administered through subcutaneous ("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 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. 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.

The known potential risks of orelabrutinib, as observed in clinical trials in patients with B-cell malignancies and autoimmune disease, include those associated with BTK inhibitor treatment such as hepatotoxicity, hemorrhage, cytopenia, infection, malignancy, hypertension, and arrhythmia. In previous trials, two cases of elevated liver enzymes and bilirubin met Hy's Law criteria. Both affected patients were asymptomatic and their liver markers normalized after treatment was discontinued. The FDA issued a partial clinical hold for the conduct of the ongoing RMS trial. Three other BTK inhibitors, including some those currently in development for progressive MS, were also placed on a partial clinical hold while under development in the U.S. for RMS. No development restrictions were placed by the EMA.

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. 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 and InnoCare, 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) an 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 clinical trials of our product candidates, even if successfully completed, may not be sufficient for marketing approval 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 development strategies for any of our product candidates, the FDA may ultimately require us to conduct additional Phase 3 clinical trials prior to approval of that product candidate for a particular 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 integration of any business or assets, including the InnoCare programs, may be disruptive, complex, risky and costly;
- 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 NDA 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 candidates, obexelimab, for the treatment of IgG4-RD, MS and SLE and orelabrutinib, for the treatment of PPMS and SPMS. 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 or NDA 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, to obtain marketing approval, or to provide commercial supply of our products, if approved, could be delayed or halted.

Our product candidates include 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, increasing 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 rights to develop and commercialize orelabrutinib, ZB021 and ZB022 from InnoCare in October 2025. Additionally, we in-licensed the exclusive 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, InnoCare, 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 U.S. 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, and from InnoCare related to orelabrutinib, ZB021 and ZB022, 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. In addition, under our license agreement with InnoCare, InnoCare is responsible for patent prosecution of certain licensed intellectual property in Greater China and Southeast Asia. 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 our current 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 our current 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. In addition, the patent covering orelabrutinib's composition of matter expires in September 2034, excluding any extensions 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 may face competition from biosimilar or generic products approved through abbreviated regulatory pathways.

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 biological products that are biosimilar to or 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, a 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.

With respect to drugs, including small molecule products, the Federal Food Drug and Cosmetic Act ("FDCA") provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of a NDA for a new chemical entity ("NCE"), including small molecule products. A drug is a NCE if the FDA has not previously approved an NDA for any other new drug containing the same active ingredient. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right to reference all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving Abbreviated New Drug Applications ("ANDAs") or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Laws regarding exclusivity protections are complex and continue to be interpreted by the FDA. Any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any 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 and that any product candidate we develop that is approved as a NCE under an NDA should qualify for the 5-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 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 or a generic 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 or generics referencing our product candidates, our product candidates may become subject to competition from such biosimilars or generics, 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. However, the patent linkage system is still in its early stage and the impact remains uncertain. 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 could 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, orelabrutinib or any of our other product candidates or any future product candidates.

Further, the FDA and its foreign counterparts may respond to any BLA or NDA 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 or NDA 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, including government shutdowns, 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 small molecules or modifications to approved or licensed biologics or small molecules 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. Although it has not been reported that there have been reductions in the workforce, at the review or inspection divisions of the FDA, any such reductions could extend BLA and NDA 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 the current government shutdown continues or 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, healthcare reform efforts have been an ongoing focus. 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. More recently, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs and increasing drug importation. As another example, in May 2025, President Trump issued another Executive Order

that directed government agencies and officials to identify most-favored-nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients), prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the U.S., and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. Many of these reform initiatives will require additional legal and/or administrative action to implement. Other healthcare reform efforts or actions under the current presidential administration may affect access to healthcare coverage or the funding of healthcare benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the budget reconciliation legislation known as the "Big Beautiful Bill Act," including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace, will increase the number of uninsured by 16 million by 2034. The nature and extent of future healthcare reforms cannot be predicted. There is significant uncertainty regarding the nature or impact of any drug pricing or broader healthcare reform implemented by the current presidential administration through executive act or by Congress and the extent to which such action may be subject to litigation or other challenges.

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 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 for obexelimab, 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 for obexelimab, WuXi Biologics, and our collaboration partner InnoCare for supply of orelabrutinib, which provide 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 single third-party manufacturers, WuXi Biologics, and our collaboration partner, InnoCare, 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 single third-party manufacturers, WuXi Biologics for supply of obexelimab, and our collaboration partner, InnoCare for supply of orelabrutinib, both of which are located in China, to manufacture and supply the drug substances and drug products for our product candidates, and we currently do not have any redundant supply outside of WuXi Biologics, and InnoCare, for drug substance and drug product. Reliance on third-party manufacturers 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 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 or NDA 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, InnoCare 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 and InnoCare. 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 and InnoCare for certain intellectual property relating to the development and commercialization of orelabrutinib, ZB021 and ZB022. 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 or InnoCare 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 or InnoCare, 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 InnoCare 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, and our collaboration partner, InnoCare, both of which are 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, and our collaboration partner, InnoCare, both of which provide 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, or our clinical supply arrangement with InnoCare, 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 initially 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. While prior versions of the BIOSECURE Act, named WuXi Biologics as a "biotechnology company of concern," the most recent version of the BIOSECURE Act, which was passed by the Senate in October 2025, does not specifically name WuXi Biologics.

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 if they are 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, and our collaboration partner, InnoCare, 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 October 31, 2025, the closing price per share of our common stock on Nasdaq has ranged from $6.43 to $31.80. 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 October 31, 2025, we had 53,679,166 shares of common stock outstanding. Of these shares, 48,679,166 may be resold in the public market immediately, including 6,311,030 shares of common stock issued in a PIPE that we have registered on Form S-3 ASR for resale, unless the shares are held by our affiliates who are subject to 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.

Further, pursuant to the terms of the InnoCare Registration Rights Agreement, we are obligated to file a registration statement prior to October 7, 2026 to register for resale the aggregate of 7,000,000 shares of our common stock currently issued and expected to be issued to InnoCare in connection with our collaboration with InnoCare (the "InnoCare Shares"). However, InnoCare may not sell any of the InnoCare Shares until October 7, 2026, and thereafter may not transfer InnoCare Shares during any one month in an amount that exceeds the greater of (i) one percent of the outstanding common stock as most recently reported by us publicly and (ii) the average weekly reported volume of trading in the common stock during the four preceding calendar weeks.

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 67% of our outstanding common stock as of September 30, 2025 and approximately 64% as of October 31, 2025, post InnoCare and PIPE transactions. 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 being 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 September 30, 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)
10.1+	Revenue Participation Right Purchase and Sale Agreement, by and between Zenas BioPharma, Inc. and Royalty Pharma Investments 2019 ICAV, dated September 2, 2025
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.

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

* This certification will not be deemed "filed" for purposes of Section 18 of the 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: November 12, 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 10.1

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) THE TYPE THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE AND CONFIDENTIAL.

Revenue Participation Right

Purchase and Sale Agreement

By and Between

Zenas BioPharma, Inc.

and

Royalty Pharma Investments 2019 ICAV

Dated as of September 2, 2025

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REVENUE PARTICIPATION RIGHT PURCHASE AND SALE AGREEMENT

This REVENUE PARTICIPATION RIGHT PURCHASE AND SALE AGREEMENT (this "Agreement"), dated as of September 2, 2025 (the "Effective Date"), is made and entered into by and between Royalty Pharma Investments 2019 ICAV, an Irish collective asset-management vehicle (the "Buyer"), and Zenas BioPharma, Inc., a Delaware corporation (the "Seller").

W I T N E S S E T H:

WHEREAS, the Seller is in the business of, among other things, developing and commercializing pharmaceutical products, including the Product; and

WHEREAS, the Buyer desires to purchase the Revenue Participation Right and receive the Revenue Payments from the Seller, and the Seller desires to sell the Revenue Participation Right and make the Revenue Payments to the Buyer, in each case on the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Seller and the Buyer hereby agree as follows:

ARTICLE 1
DEFINITIONS

Section 1.1 Definitions. The following terms, as used herein, shall have the following meanings:

[***].

"Additional Purchase Price Payment" is defined in Section 3.6.

"Affiliate" means, with respect to any particular Person, any other Person directly or indirectly controlling, controlled by or under common control with such particular Person. For purposes of the foregoing sentence, the term "control" means direct or indirect ownership of (a) fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such Person, firm, trust, corporation, partnership or other entity or combination thereof, or (b) the power to direct the management of such Person, firm, trust, corporation, partnership or other entity or combination thereof, by contract or otherwise. For purposes hereof, any Person shall be deemed to control a partnership, limited liability company, association or other business entity if such Person, directly or indirectly through one or more intermediaries, shall be allocated a majority of partnership, limited liability company, association or other business entity gains or losses or shall be or control the managing director or general partner of such partnership, limited liability company, association or other business entity.

"Aggregated Licensee Payment" is defined in Section 7.7(a).

"Agreement" is defined in the preamble.

[***] is defined in the definition of [***].

"Audit Arbitrator" is defined in Section 7.4(d).

"Back-Up Security Interest" is defined in Section 2.4.

"Bankruptcy Laws" means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws affecting the enforcement of creditors' rights generally.

"Bill of Sale" is defined in Section 3.3.

"BMS Agreement" means the License Agreement between Seller and Bristol-Myers Squibb Company dated as of August 30, 2023, as in effect on the date hereof.

"Business Day" means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York are permitted or required by applicable law or regulation to remain closed.

"Buyer" is defined in the preamble.

"Buyer Indemnified Parties" is defined in Section 8.1(a).

"Calendar Quarter" means a period of three (3) consecutive months ending at midnight, New York City time on the last day of March, June, September, or December, respectively, provided that the first Calendar Quarter shall commence on the Effective Date and end on September 30, 2025.

"Calendar Year" means a period of twelve (12) consecutive months commencing on January 1 of any year, provided that the first Calendar Year shall commence on the Effective Date and end on December 31, 2025.

"Change of Control" means (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of the Seller's and its Affiliates' assets, on a consolidated basis; (b) a merger or consolidation of the Seller (or a parent entity) with a Third Party in which the Seller (or a parent entity) is not the surviving corporation or in which, if the Seller (or its parent entity) is the surviving corporation, the stockholders of the Seller (or its parent entity) immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, and acting jointly, a majority of the voting power of all of the surviving entity's outstanding stock and other securities and the power to elect a majority of the members of the Seller's (or its parent entity's) board of directors (or equivalent governing body); or (c) a transaction or series of related transactions with one or more Third Parties (which may include a tender offer for the Seller's (or its parent entity's) stock or the issuance, sale or exchange of stock of the Seller (or its parent entity)) if the stockholders of the Seller (or its parent entity) immediately prior to such transaction(s) do not, immediately after consummation of such transaction(s), possess, directly or indirectly through one or more intermediaries, and acting jointly, a majority of the voting power of all of the Seller's (or its parent entity's) or its successor's

outstanding stock and other securities and the power to elect a majority of the members of the Seller's (or its parent entity's) or its successor's board of directors (or equivalent governing body).

"Clinical Trial" means a clinical study involving patients or healthy volunteers intended to support the Marketing Approval or Commercialization of a Product.

"Clinical Updates" means, [***].

"CMC Activities" means those manufacturing activities and regulatory activities designed to support preparation of the chemistry, manufacturing and controls sections of any regulatory materials or Marketing Approval for any Product.

"Combination Product" means [***].

"Commercial Updates" means, [***].

"Commercialization" means any and all activities directed to the marketing, detailing, promotion, commercial launching, selling and securing of reimbursement of a product (including using, importing, selling and offering for sale of the product), and shall include Post-Approval Studies, post-launch marketing, promoting, detailing, marketing research, customer service, selling a product, importing, exporting, and regulatory compliance with respect to the foregoing. When used as a verb, "Commercialize" and "Commercializing" shall mean to engage in Commercialization. For clarity, "Commercialization" excludes Manufacturing activities.

"Commercially Reasonable Efforts" means, [***].

"Confidential Information" is defined in Section 9.1.

"Contract Manufacturing Agreement" means any agreement or arrangement (including any memorandum of understanding regarding a future agreement) between the Seller or any of its Affiliates, on the one hand, and any Third Party, on the other hand, for the Manufacture of a Product (including bulk drug product, bulk drug substance and finished product).

"Customary Intercreditor Agreement" means a customary intercreditor agreement between the Buyer and a Third Party providing [***]; and (f) any other provisions reasonably satisfactory to such Third Party secured debt provider and the Buyer consistent with clauses (a)-(e) above and consistent with the premise that (i) [***], and (ii) the Buyer shall not interfere with such Third Party secured debt provider enforcing its rights and remedies as a secured creditor under the UCC, any Bankruptcy Laws and any other applicable law (to the extent such enforcement is not inconsistent with clauses (a)-(e) above or other customary protections applicable to junior creditors).

"Data Room" is defined in Section 7.9.

"Disclosing Party" is defined in Section 9.1.

"Disclosure Schedule" means the Disclosure Schedule, dated as of the Effective Date, set forth on Exhibit H.

"Effective Date" is defined in the preamble.

"EMA" means the European Medicines Agency, or any successor agency thereto.

"European Union" means the countries of the European Union, as it is constituted on the date of this Agreement and as it may be modified from time to time after the date of this Agreement.

"Excluded Product" means any compound, molecule or other pharmaceutical product developed or licensed by the Seller or any of its Affiliates that is not a Product.

"Excluded Product Assets" means, collectively, the Seller's and its Affiliates' rights, title and interests in any Excluded Product (including all inventory, raw material and work in progress of such Excluded Product) and product rights solely related to Excluded Products (including, (a) any intellectual property rights, (b) regulatory filings, submissions and approvals with or from any regulatory authorities, including any clinical data thereunder, (c) any in-licenses, and (d) out-licenses, in each case, solely related to Excluded Products) owned, licensed or otherwise held by the Seller or any of its Affiliates and any proceeds thereof, including (i) all accounts receivable and payment intangibles solely resulting from the sale, license or other disposition of such Excluded Product by the Seller or its Affiliates, (ii) cash and cash equivalents to the extent traceable solely from such sale, license or deposition in the foregoing clause (i), and (iii) any deposit or securities accounts holding such cash and equivalents and/or proceeds of such accounts receivable and payment intangibles in the foregoing clauses (i) and (ii).

"Existing Agreements" means the BMS Agreement, each Existing Contract Manufacturing Agreement, and each Existing In-License.

"Existing Contract Manufacturing Agreement" means the agreements set forth on Exhibit E.

"Existing In-Licenses" means the agreements set forth on Exhibit F.

"Existing Patent Rights" is defined in Section 4.9(a).

"Exploitation" means any and all activities directed to the research, development, importation, exportation, use, registration, modification, enhancement, improvement, optimization, seeking of Marketing Approvals and pricing and reimbursement approvals for, Commercialization or other exploitation of a Product. "Exploit" shall mean to engage in Exploitation. For clarity, "Exploitation" excludes Manufacturing activities.

"FCPA" is defined in Section 4.14.

"FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

"First Commercial Sale" means the first sale that will result in any Net Sales of a Product in any jurisdiction of the world.

"GAAP" means generally accepted accounting principles in the United States as consistently applied by the applicable Related Party in accordance with its implemented accounting policies.

"Governmental Entity" means any: (a) nation, principality, republic, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or other entity and any court, arbitrator or other tribunal); (d) multi-national organization or body; or (e) individual, body or other entity exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

"Gross Sales" is defined in the definition of "Net Sales".

[***].

"Indebtedness" means (a) any indebtedness for borrowed money, (b) any obligation evidenced by a note, bond, debenture or similar instrument, (c) any obligation to pay the deferred purchase price of property in connection with the purchase of a business or product line (other than, for the avoidance of doubt, "earnouts" and other similar payments based on performance of the acquired business or product line) or (d) any guarantee of any of the foregoing. [***].

"Indemnified Party" is defined in Section 8.2.

"Indemnifying Party" is defined in Section 8.2.

"INDIGO Phase 3 Trial" means the Phase 3 Clinical Trial entitled "*A Phase 3 Study of Obexelimab in Patients with IgG4-Related Disease"*, clinicaltrials.gov identifier # NCT05662241.

"Initial Purchase Price" means seventy-five million dollars ($75,000,000).

"In-License" means [***].

"In-Licensed Intellectual Property Rights" means all Intellectual Property Rights in-licensed by Seller or any of its Affiliates pursuant to any In-License.

"In-Licensed Patent Rights" means all Patent Rights in-licensed by Seller or any of its Affiliates pursuant to any In-License.

"Intellectual Property Rights" means any and all of the following (a) owned by the Seller or its Affiliates or their respective Licensees or (b) in-licensed by the Seller or its Affiliates or their respective Licensees, in each case ((a) and (b)), as they exist throughout the world at any time: (i) the Patent Rights; [***]; (v) any and all other intellectual property rights and/or proprietary rights, whether or not patentable, specifically relating to any of the foregoing ((i)-(iv)); [***].

"Intellectual Property Updates" means [***].

"Judgment" means any judgment, order, writ, injunction, citation, award or decree of any nature.

"Key Out-License" is defined in Section 7.7(a).

"Know-How" means any and all proprietary or confidential information, know-how and trade secrets, including processes, formulae, models and techniques, rights in research in progress, algorithms, data, databases, data collections, chemical and biological materials (including any compounds, DNA, RNA, clones, vectors, cells and any expression product, progeny, derivatives or improvements thereto), and the results of experimentation and testing, and samples.

"Knowledge of the Seller" means the actual knowledge of [***], after reasonable due inquiry.

"Licensee" means any Third Party that is a counterparty to an Out-License, or any downstream (sub)licensee of such Third Party under such Out-License.

"Licensee Income" means:

(a) for each Calendar Quarter, all royalty payments payable to the Seller or its Affiliates in respect of Net Sales of the Products by any and all Licensees in the Licensee Income Territory attributable to such Calendar Quarter, less any royalty payments payable by the Seller to Xencor pursuant to Section 9.3 of the Xencor In-License in respect of Net Sales (as defined in the Xencor In-License) of such Products in the Licensee Income Territory in such Calendar Quarter (such net amount, the "Licensee Royalty Income"); plus

(b) for each Calendar Quarter, all consideration other than Licensee Royalty Income, in whatever form, payable to the Seller or its Affiliates by any and all Licensees to the extent attributable (in accordance with Section 7.7(a)) to one or more Products in the Licensee Income Territory in such Calendar Quarter, including upfront payments, license maintenance fees, minimum annual royalty payments, milestone payments, option exercise fees, and other similar payments ("Licensee Non-Royalty Income").

[***].

Licensee Non-Royalty Income expressly excludes: (a) milestone payments payable to the Seller pursuant to Section 8.2 of the BMS Agreement, [***].

"Licensee Income Percentage" means twenty-five percent (25%).

"Licensee Income Territory" means worldwide other than the Royalty Territory.

[***] is defined in the definition of [***].

[***] is defined in the definition of [***].

"Licensor" means a Third Party that is a party to any In-License.

"Lien" means any mortgage, lien, pledge, participation interest, charge, adverse claim, security interest, encumbrance or restriction of any kind, including any restriction on use, transfer or exercise of any other attribute of ownership of any kind, whether voluntarily incurred or arising by operation of law or otherwise.

"Logistics Agreement" means any agreement between the Seller or any of its Affiliates, on the one hand, and a Third Party acting solely as a Logistics Provider, on the other hand.

"Logistics Provider" means a Third Party that has the right, option or obligation to distribute, transport, warehouse, package, import, or provide similar logistics services with respect to a Product on behalf of a Related Party, including a Wholesale Distributor.

"Loss" means any and all Judgments, damages, losses, claims, costs, liabilities and expenses, including reasonable fees and out-of-pocket expenses of counsel.

"Major European Markets" means [***].

"Manufacturer" means a Third Party that is a party to any Contract Manufacturing Agreement.

"Manufacturing" means manufacturing, production, formulating, processing, filling, finishing, quality control, quality assurance, stability testing, packaging, labeling, shipping, importing, storage and similar activities with respect to a Product (and components thereof or therefor) and regulatory compliance with respect to the foregoing. "Manufacture" shall mean to engage in Manufacturing. For clarity, "Manufacturing" excludes Development and Commercialization activities.

"Marketing Approval" means, with respect to any product, any and all approvals (including drug and/or device approval applications), licenses, registrations or authorizations sufficient to Commercialize such product in accordance with applicable laws, including, if applicable, pricing or reimbursement approvals.

"Market Capitalization" means, with respect to any entity, an amount equal to the product of (a) the total number of issued and outstanding shares of equity interests of the entity (or any successor entity) on the date of determination and (b) the arithmetic mean of the closing prices per share of such equity interests for the [***] consecutive trading days immediately preceding the date of determination.

"Material Adverse Effect" means [***].

"MHRA" means the United Kingdom Medicines and Healthcare products Regulatory Agency.

"Net Sales" means the gross amount invoiced, billed or otherwise recorded or recognized for sales of [***]:

[***].

Net Sales shall be determined in U.S. dollars.

[***]

Net Sales will not include [***].

Net Sales shall also include [***].

"Net Sales Percentage" means five and one-half percent (5.5%).

"Obexelimab" means the antibody with heavy and light chains having the amino acid sequences set forth on Exhibit C.

"Out-License" means [***].

"Patent Right" means [***].

"Patents" means any and all patents and patent applications, including any continuation, continuation-in-part, division, provisional or any substitute applications, any patent issued with respect to any of the foregoing patent applications, any certificate, reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent or other governmental actions that extend any of the subject matter of a patent, and any substitution patent, confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

"Payment Triggering Event" is defined in Section 3.6.

[***].

"Permitted Entity" means a global biopharmaceutical company with a Market Capitalization of at least [***].

"Permitted Indebtedness" means [***].

"Permitted Lien" means [***].

[***].

[***].

[***].

"Person" means any individual, firm, corporation, company, partnership, limited liability company, trust, joint venture, association, estate, trust, Governmental Entity or other entity, enterprise, association or organization.

"Phase 3 Clinical Trial" means a Clinical Trial that incorporates accepted endpoints for confirmation of safety and statistical significance of efficacy with the aim to generate data and results that can be submitted to obtain Marketing Approval as described in 21 C.F.R. 312.21(c),

or a comparable Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States.

"Post-Approval Study" means a clinical study of a Product required by applicable law or a Regulatory Authority to be conducted after receipt of a Marketing Approval for such Product.

"Prime Rate" means the prime rate published by The Wall Street Journal, from time to time, as the prime rate.

"Product" means (a) any product that contains Obexelimab as an active ingredient, [***].

"Product Rights" means any and all of the following: (a) Intellectual Property Rights, (b) regulatory filings, submissions and approvals, including Marketing Approvals, with or from any Regulatory Authorities related to the Product, (c) In-Licenses, (d) Out-Licenses and (e) Contract Manufacturing Agreements.

"Proposed Allocation" is defined in Exhibit G.

"Purchase Price" is defined in Section 2.2.

"Quarterly Report" is defined in Section 7.2(a).

"Receiving Party" is defined in Section 9.1.

[***].

"Regulatory Authority" means any Governmental Entity, including the FDA, that has responsibility in granting a Marketing Approval.

"Regulatory Updates" means [***].

"Related Party" means each of the Seller, its Affiliates, and their respective Licensees, as applicable.

"Representative" means, with respect to any Person, (a) any direct or indirect member or partner of such Person and (b) any manager, director, trustee, officer, employee, agent, advisor or other representative (including attorneys, accountants, consultants, contractors, actual and potential lenders, investors, co-investors and assignees, bankers and financial advisers) of such Person.

[***].

"Revenue Participation Right" means the right to receive payment in full of all Revenue Payments and an undivided ownership interest of all accounts (as defined in the UCC), general intangibles (as defined in the UCC), payment intangibles (as defined in the UCC) and all other rights to payment on account of Net Sales of all Products and Licensee Income, and all proceeds thereof, in an amount equal to the Net Sales Percentage and the Licensee Income Percentage.

"Revenue Payment" means:

(a) for each Calendar Quarter, an amount payable to the Buyer equal to the product of [***]

(b) for each Calendar Quarter, an amount payable to the Buyer equal to the product of [***]

(c) for each Calendar Quarter, an amount payable to the Buyer equal to the product of [***]

(d) for each Calendar Quarter, an amount payable to the Buyer equal to the product of [***].

"Revenue Report" is defined in Section 7.3(c).

"Royalty Territory" means the United States, the United Kingdom, and the European Union.

[***] is defined in the definition of [***].

"Safety Event" means a determination by a Regulatory Authority, the Seller's clinical safety adjudication committee (acting in good faith and in accordance with its charter), or data monitoring review board (or similar entity) that a Product presents an unreasonable and significant risk of death, a life-threatening condition or a safety concern, in each case, to patients, such that such Product cannot continue to be administered to any patients.

"Safety Notices" means any recalls, field notifications, market withdrawals, warnings, "dear doctor" letters, investigator notices, safety alerts or other notices of action issued or instigated by the Seller or any of its Affiliates or any Regulatory Authority or data monitoring review board (or similar entity) relating to an alleged lack of safety or regulatory compliance of or with respect to a Product.

"Seller" is defined in the preamble.

"Seller Indemnified Parties" is defined in Section 8.1(b).

"Support Memorandum" is defined in Exhibit G.

"Tax" or "Taxes" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, abandoned property, value added, alternative or add-on minimum, estimated or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not.

"Third Party" means any Person that is not the Seller or an Affiliate of the Seller.

"Transaction Documents" means this Agreement and the Bill of Sale.

"UCC" means the Uniform Commercial Code in the State of New York; provided, that, if with respect to any financing statement or by reason of any provisions of law, the perfection, priority or the effect of perfection, priority or non-perfection of the security interests granted to the Administrative Agent pursuant to this Agreement or any related document is governed by the Uniform Commercial Code in a jurisdiction of the United States other than New York, then "UCC" means the Uniform Commercial Code in such other jurisdiction for purposes of the provisions of this Agreement, any related document and any financing statement relating to such perfection, priority or effect of perfection, priority or non-perfection.

"United States" means the United States of America, including its territories and possessions.

"Wholesale Distributor" means a non-Related Party wholesale distributor of a Product that is not required to provide consideration to a Related Party based on the value of, or otherwise attributable to, the sale of such Product by or on behalf of such distributor.

"Xencor" is defined in Exhibit F.

"Xencor In-License" is defined in Exhibit F.

Section 1.2 Certain Interpretations. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(a) "either" and "or" are not exclusive and "include," "includes" and "including" are not limiting and shall be deemed to be followed by the words "without limitation";

(b) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if";

(c) "hereof," "hereto," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;

(d) references to a Person are also to its permitted successors and assigns, and references to a Governmental Entity are also to its succeeding governing entity in the relevant jurisdiction;

(e) definitions are applicable to the singular as well as the plural forms of such terms;

(f) references to an "Article", "Section" or "Exhibit" refer to an Article or Section of, or an Exhibit to, this Agreement, references to a "Schedule" refer to the corresponding part of the Disclosure Schedule, and references to the Transaction Documents refer to any certificates, notices, schedules, exhibits, annexes or other documents or instruments delivered in connection with the Transaction Documents;

(g) provisions referring to matters that would or could have, or would or could reasonably be expected to have, or similar phrases, shall be deemed to have such result or expectation with or without the giving of notice or the passage of time, or both;

(h) accounting terms not specifically or completely defined herein shall be construed in conformity with, and all financial data (including financial ratios and other financial calculations) required to be submitted pursuant to this Agreement or any related document shall be prepared in conformity with GAAP;

(i) for covenants that are to be undertaken "reasonably" by the Seller or its Affiliates, such actions (or inactions) shall take into account the Buyer's economic interest in the Products, the Product Rights, the Revenue Participation Right and the Revenue Payments and the impact of the applicable action (or inaction) on such interest;

(j) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement;

(k) references to "$" or otherwise to dollar amounts refer to the lawful currency of the United States; and

(l) any item shall not be treated as "Indebtedness" under this Agreement [***] solely because such item is treated as debt or indebtedness under GAAP.

Section 1.3 Headings. The table of contents and the descriptive headings of the several Articles and Sections of this Agreement and the Exhibits and Schedules are for convenience only, do not constitute a part of this Agreement and shall not control or affect, in any way, the meaning or interpretation of this Agreement.

ARTICLE 2
PURCHASE, SALE AND ASSIGNMENT OF THE REVENUE PARTICIPATION RIGHT

Section 2.1 Purchase, Sale and Assignment. On the Effective Date and upon the terms and subject to the conditions of this Agreement, in exchange for the Buyer's payment of the Initial Purchase Price and the Buyer's promise to pay the Additional Purchase Price Payments if and when due hereunder, the Seller hereby sells, transfers, assigns and conveys to the Buyer, and the Buyer hereby purchases, acquires and accepts from the Seller, the Revenue Participation Right free and clear of all Liens. From and after the Effective Date, the Seller relinquishes all of the Seller's and its Affiliates' right, title and interest in and to the Revenue Participation Right, and all such right, title and interest shall vest in the Buyer. In addition, the Seller hereby agrees to pay to the Buyer the Revenue Payments on the terms and conditions set forth herein.

Section 2.2 Purchase Price and Use of Proceeds. The purchase price for the Revenue Participation Right shall consist of the Initial Purchase Price and, if payable hereunder, the Additional Purchase Price Payments (together, the "Purchase Price"). The Seller shall [***].

Section 2.3 No Assumed Obligations, Etc. Notwithstanding any provision in this Agreement to the contrary, the Buyer is, on the terms and conditions set forth in this Agreement, only purchasing, acquiring and accepting the Revenue Participation Right and is not assuming any liability or obligation of the Seller or its Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter.

Section 2.4 True Sale. It is the intention of the parties hereto that the sale, transfer, assignment and conveyance of the Revenue Participation Right contemplated by this Agreement be, and is, a true, complete, absolute and irrevocable sale, transfer, assignment and conveyance by the Seller to the Buyer of all of the Seller's rights, title and interests in and to the Revenue Participation Right. Neither the Seller nor the Buyer intends the transactions contemplated by this Agreement to be, or for any purpose characterized as, a loan from the Buyer to the Seller, a pledge, a financing transaction or a borrowing. It is the intention of the parties hereto that the beneficial interest in and title to the Revenue Participation Right and any "proceeds" (as such term is defined in the UCC) thereof shall not be part of the Seller's estate in the event of the filing of a petition by or against the Seller or any of its Affiliates under any Bankruptcy Laws. The Seller hereby waives, to the maximum extent permitted by applicable law, any right to contest or otherwise assert that the sale contemplated by this Agreement does not constitute a true, complete, absolute and irrevocable sale, transfer, assignment and conveyance by the Seller to the Buyer of all of the Seller's right, title and interest in and to the Revenue Participation Right under applicable laws, which waiver shall, to the maximum extent permitted by applicable laws, be enforceable against the Seller and its Affiliates in any bankruptcy or insolvency proceeding relating to the Seller or any of its Affiliates. Accordingly, the Seller shall treat the sale, transfer, assignment and conveyance of the Revenue Participation Right as a sale of "accounts," "payment intangibles" or "general intangibles" (as appropriate) and the proceeds thereof in accordance with the UCC, and the Seller hereby authorizes the Buyer and its representatives at any time to file one or more financing statements or any amendments to financing statements previously filed by the Buyer (and continuation statements with respect to such financing statements when applicable) naming the Seller as the "seller" and the Buyer as the "buyer" in respect of the Revenue Participation Right. Not in derogation of the foregoing statement of the intent of the parties hereto in this regard, and for the purposes of providing additional assurance to the Buyer, including in the event that, despite the intent of the parties hereto, the sale, transfer, assignment and conveyance contemplated hereby is hereafter held not to be a sale, the Seller hereby grants to the Buyer a security interest in, to and under the Revenue Participation Right, the Revenue Payments, the Products and the Seller's right, title and interest in the Product Rights, and any "proceeds" (as defined in the UCC) of each of the foregoing as security for all of the Seller's obligations under the Transaction Documents and any related documents, including the obligations to pay the Revenue Payments (the "Back-Up Security Interest"), and the Seller does hereby authorize the Buyer and its representatives, from and after the Effective Date, to file one or more financing statements (and continuation statements and any amendments with respect to such financing statements when applicable) in such manner and such jurisdictions as are necessary or appropriate to perfect such Back-Up Security Interest; provided that such Back-Up Security Interest shall be terminated without any action or notice of any party upon termination of this Agreement as provided in Section 10.2. Following the termination of this Agreement as provided in the immediately preceding sentence, upon the Seller's request and at Seller's expense, the Buyer shall file a UCC-3 termination statement terminating the security interest granted in this Section 2.4. In the event any of Seller's Affiliates obtain any right, title or interest in Product Rights, the Seller shall promptly provide notice to the Buyer and cause such Affiliates to grant to the Buyer a security interest in such Product Rights on the same terms as the Back-Up Security Interest.

ARTICLE 3
CLOSING; PAYMENT OF PURCHASE PRICE

Section 3.1 Closing. The purchase and sale of the Revenue Participation Right shall take place remotely via the exchange of documents and signatures on the date hereof or such other place, time and date as the parties hereto may mutually agree.

Section 3.2 Payment of Initial Purchase Price. On the Effective Date, the Buyer shall pay to the Seller the Initial Purchase Price by wire transfer of immediately available funds to the account specified on Exhibit A.

Section 3.3 Bill of Sale. On the Effective Date, upon confirmation of the receipt of the Initial Purchase Price, the Seller shall deliver to the Buyer a duly executed bill of sale evidencing the sale, transfer, assignment and conveyance of the Revenue Participation Right in the form attached hereto as Exhibit B (the "Bill of Sale").

Section 3.4 Seller Form W-9. On or prior to the Effective Date, the Seller shall deliver to the Buyer a valid, properly executed IRS Form W-9 certifying that the Seller is exempt from U.S. federal "backup" withholding tax.

Section 3.5 Buyer Form W-8BEN-E. On or prior to the Effective Date, the Buyer shall deliver to the Seller a valid, properly executed IRS Form W-8BEN-E or other applicable form certifying that the Buyer is exempt from U.S. federal withholding and backup withholding tax with respect to the Revenue Payments.

Section 3.6 Additional Purchase Price Payments. The Seller shall promptly (and, in any event, within five (5) Business Days) notify the Buyer upon the first occurrence of each of the events set forth in the table below (each a "Payment Triggering Event"). As long as there has not been a Material Adverse Effect of which Buyer has notified Seller in writing and that remains uncured at the time of such occurrence, and provided that Buyer has not notified the Seller of any material non-compliance with its obligations under this Agreement that remains uncured at the time of such occurrence, the Buyer shall make a one-time cash payment (each an "Additional Purchase Price Payment") in the amount corresponding to such Payment Triggering Event to the Seller by wire transfer of immediately available funds to the account specified by the Seller on Exhibit A (or such other account as specified by the Seller in a writing delivered to the Buyer in accordance with Section 11.1 of this Agreement) within [***] following the Buyer's receipt of such notice.

#	PAYMENT TRIGGERING EVENT	ADDITIONAL PURCHASE PRICE PAYMENT AMOUNT
1.	[***], the [***] criteria [***] in the INDIGO Phase 3 Trial, and the Seller delivers to Buyer a certificate and supporting documentation for such determination no later than [***] Business Days following [***].	$75,000,000
2.	[***], receipt of Marketing Approval of the Product by the FDA for the treatment of IgG4-related disease.	$75,000,000
3.	[***], receipt of Marketing Approval of the Product by the FDA for the treatment of systemic lupus erythematosus.	$75,000,000
	TOTAL	**$225,000,000**

For the avoidance of doubt, the Buyer and the Seller hereby acknowledge and agree that (a) each Additional Purchase Price Payment is a contingent payment obligation of the Buyer and there can be no assurance regarding the occurrence of any Payment Triggering Event, (b) the Buyer shall have no obligation or liability with respect to an Additional Purchase Price Payment unless and until the corresponding Payment Triggering Event timely occurs, (c) [***], (d) the aggregate Additional Purchase Price Payments payable by the Buyer hereunder shall not exceed $225,000,000 and (e) no such Additional Purchase Price Payment shall be due or payable if this Agreement has been terminated pursuant to ARTICLE 10 prior the occurrence of the applicable Payment Triggering Event. Upon the Buyer's reasonable request, the parties hereto agree to use reasonable efforts to timely negotiate in good faith (i) a separate agreement with respect to the Additional Purchase Price Payment relating to the Payment Triggering Event #1, 2 or 3 and a then-fair value portion of the Revenue Participation Right allocated to the Payment Triggering Event #1, 2 or 3, provided that such separate agreement will not (x) modify the terms set forth herein except to allocate such terms across this Agreement and such separate agreement as long as such allocation does not modify the terms as a whole or (y) otherwise adversely affect the Seller in any manner, including with respect to the Seller's Tax or financial reporting position(s) and (ii) an amendment to this Agreement to effectuate the foregoing. Unless and until the parties enter into such Agreement, the Additional Purchase Price Payment relating to the Payment Triggering Event #1, 2 or 3 (as applicable) will be due and payable upon achievement of Payment Triggering Event #1, 2 or 3 (as applicable) in accordance with the terms of this Agreement.

ARTICLE 4
REPRESENTATIONS AND WARRANTIES OF THE SELLER

Except as set forth on the Disclosure Schedule set forth on Exhibit H, the Seller represents and warrants to the Buyer that as of the Effective Date:

Section 4.1 Existence; Good Standing. The Seller is a corporation, duly organized, validly existing and in good standing under the laws of Delaware. Each of the Seller and its Affiliates is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified and in good standing has not and would not reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

Section 4.2 Authorization. The Seller has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary corporate action on the part of the Seller.

Section 4.3 Enforceability. This Agreement has been duly executed and delivered by an authorized officer of the Seller and constitutes the valid and legally binding obligation of the Seller, enforceable against the Seller in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

Section 4.4 No Conflicts. The execution, delivery and performance by the Seller of this Agreement and the consummation of the transactions contemplated hereby do not and will not (a) contravene or conflict with the organizational documents of the Seller or its Affiliates, (b) contravene or conflict with or constitute a material default under any law binding upon or applicable to the Seller, its Affiliates or the Revenue Participation Right, (c) contravene or conflict with or constitute a default under the Xencor In-License or (d) contravene or conflict with or constitute a material default under any other material agreement or any Judgment binding upon or applicable to the Seller, any of its Affiliates or the Revenue Participation Right.

Section 4.5 Consents. Except for any filings required by the federal securities laws or stock exchange rules, no consent (other than consents obtained prior to the Effective Date), approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Seller or any of its Affiliates in connection with (a) the execution and delivery by the Seller of this Agreement, (b) the performance by the Seller of its obligations under this Agreement or (c) the consummation by the Seller of any of the transactions contemplated by this Agreement.

Section 4.6 No Litigation. Neither the Seller nor any of its Affiliates is a party to, and, since [***], none has received any written notice of, any action, claim, suit, investigation or proceeding pending before any Governmental Entity and, to the Knowledge of the Seller, since [***], no such action, claim, suit, investigation or proceeding has been threatened against the Seller or any of its Affiliates, that, either individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

Section 4.7 Compliance.

(a) To the Knowledge of the Seller, all applications, submissions, information and data related to any Product submitted or utilized as the basis for any request to any Regulatory Authority by or on behalf of the Seller or any of its Affiliates were true and correct in all material respects as of the date of such submission or request, and any material updates, changes, corrections or modification to such applications, submissions, information or data required under applicable laws or regulations have been submitted to the necessary Regulatory Authorities.

(b) The Seller has made available to the Buyer prior to the Effective Date in the Data Room true, correct and complete copies of all material communications sent or received since

[***] by the Seller and any of its Affiliates to or from any Regulatory Authorities that relate to its or their Exploitation or Manufacture of any Product.

(c) Since [***], neither the Seller nor any of its Affiliates has committed any act, made any statement or failed to make any statement in respect of a Product that would reasonably be expected to provide a basis for the FDA to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", or any other Governmental Entity to invoke similar policies, set forth in any applicable laws or regulations.

(d) Since [***], (i) there have been no Safety Notices, (ii) to the Knowledge of the Seller, there are no unresolved material product complaints with respect to any Product, that would result in a Material Adverse Effect, and (iii) to the Knowledge of the Seller, there are no facts currently in existence that would, individually or in the aggregate, reasonably be expected to result in (1) a material Safety Notice with respect to any Product, or (2) a material change in the anticipated labeling of any Product. The Seller and its Affiliates have not experienced any significant failures in the Manufacturing of a Product that have not been resolved, or that would, individually or in the aggregate, have had or would reasonably be expected to result in, if such failure occurred again, a Material Adverse Effect.

(e) The Seller and its Affiliates are, and, since [***], have been, with respect to the Product, in compliance with all applicable laws administered or issued by the FDA or any similar Regulatory Authority in each jurisdiction where the Product has been, or is intended to be, Manufactured or Exploited, including the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, applicable requirements in FDA regulations, and any orders issued by FDA or similar Regulatory Authorities in each jurisdiction where a Product has been, or is intended to be, Manufactured or Exploited, and all other laws regarding ownership, developing, testing, Manufacturing, disposal, Commercializing, and complaint handling or adverse event reporting for the products of the Seller or its Affiliates, except to the extent that such failure to comply with such applicable laws would not reasonably be expected to result in a Material Adverse Effect.

Section 4.8 Licenses.

(a) Existing Agreements. Other than the Existing In-Licenses, there are no In-Licenses currently in effect or contemplated. [***]. The Seller has provided to the Buyer a true, accurate and complete copy of each Existing Agreement (including all written amendments, supplements or modifications thereto or written waivers thereunder). Each Existing Agreement is in full force and effect in accordance with its terms.

(b) Validity and Enforceability of Existing Agreements. Except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law), (i) each Existing Contract Manufacturing Agreement is a valid and binding obligation of and enforceable against the Seller and, to the Knowledge of the Seller, the counterparty thereto, in accordance with the terms of such agreement, and (ii) the BMS Agreement and each of the Existing In-Licenses is a valid and binding obligation of and enforceable against the parties thereto, in accordance with the terms of such agreement. Neither the Seller nor any of its Affiliates that is a party to an Existing Agreement has received any written notice in connection

with any Existing Agreement challenging the validity, enforceability or interpretation of any provision of such Existing Agreement.

(c) No Termination of Existing Agreements. Neither the Seller nor any of its Affiliates that is a party to an Existing Agreement has (1) given notice to a counterparty of the termination of any Existing Agreement (whether in whole or in part) or expressed any intention or desire to terminate such Existing Agreement, or (2) received from a counterparty thereto any notice of termination of any Existing Agreement (whether in whole or in part) or any communications from a counterparty thereto expressing any intention or desire to terminate such Existing Agreement.

(d) No Breaches or Defaults of Existing Agreements. There is no material breach or default under any provision of any Existing Agreement as of the Effective Date either by the Seller or any of its Affiliates that is a party to such Existing Agreement or, to the Knowledge of the Seller, by the counterparty (or any predecessor thereof) thereto. To the Knowledge of the Seller, there is no event that would reasonably be expected to give rise to any such breach or default by the Seller or any of its Affiliates that is a party to such Existing Agreement or the counterparty thereto.

(e) No Assignments of Existing Agreements. Neither the Seller nor any of its Affiliates that is a party to such Existing Agreement has assigned, or consented to any assignment by the counterparty to any Existing Agreement of, any rights or obligations under such agreement, and no such counterparty has provided written notice to the Seller or any of its Affiliates that is a party to such Existing Agreement that such counterparty has assigned any of its rights or obligations under any such agreement to any Person and, to the Knowledge of the Seller, no such counterparty has assigned any of its material rights or obligations under such agreement to any Person.

Section 4.9 Intellectual Property.

(a) Schedule 4.9(a) of the Disclosure Schedule lists all of the currently existing Patents included within the Patent Rights ("Existing Patent Rights"). Except as set forth on Schedule 4.9(a) of the Disclosure Schedule, the Seller is the sole and exclusive registered owner of all of the Existing Patent Rights. Schedule 4.9(a) of the Disclosure Schedule specifies the respective patent or patent application numbers as to each listed Patent within the Existing Patent Rights. Schedule 4.9(a) of the Disclosure Schedule specifies any Person other than the Seller owning or having an ownership interest in any Existing Patent Right, including the nature of such interest.

(b) None of the Seller nor any of its Affiliates is a party to any pending, and, to the Knowledge of the Seller, there is no threatened (in writing), litigation, interference, reexamination, post-grant proceeding, opposition or like procedure or proceeding involving any of the Existing Patent Rights or other existing Intellectual Property Rights.

(c) All of the issued Patents within the Existing Patent Rights are in full force and effect, have not lapsed, expired or otherwise terminated, and, to the Knowledge of the Seller, are valid and enforceable. Neither the Seller nor, to the Knowledge of the Seller, Licensors, has received any written notice relating to the lapse, expiration or other termination of any of the issued patents within the Existing Patent Rights. Neither the Seller nor, to the Knowledge of the Seller, Licensors, has received any written notice or written legal opinion that alleges that any issued

Patent within any of the Existing Patent Rights or any other existing Intellectual Property Rights are invalid or unenforceable.

(d) Neither the Seller nor, to the Knowledge of the Seller, Licensors, has received any written notice that there is any, and, to the Knowledge of the Seller, there is no, Person who is or claims to be an inventor under any of the Existing Patent Rights who is not a named inventor thereof or claims to be an owner of any other existing Intellectual Property Rights.

(e) The Seller and, to the Knowledge of the Seller, Licensors, as applicable, have paid all maintenance fees, annuities and like payments required with respect to all of the Existing Patent Rights.

(f) To the Knowledge of the Seller, (i) the Manufacture and Exploitation of each Product has not infringed, misappropriated or otherwise violated, and will not infringe, misappropriate or otherwise violate, any Patent or other intellectual property rights of any Third Party, and (ii) no Person is infringing, misappropriating or otherwise violating, or threatening to infringe, misappropriate or otherwise violate, any Existing Patent Rights or other existing Intellectual Property Rights, in each case ((i) and (ii)) without reference to any safe harbor, and evaluating all pending Patent claims as issued.

Section 4.10 Title to Revenue Participation Right; No Liens. The Seller holds all rights, interests and title necessary to sell, transfer, assign and convey the Revenue Participation Right to the Buyer. From and after the Effective Date, the Buyer will have acquired, subject to the terms and conditions set forth in this Agreement, good and marketable title to the Revenue Participation Right, Revenue Payments and the "proceeds" (as defined in the UCC) of the foregoing, in each case free and clear of all Liens (other than the Back-Up Security Interest, which shall be a first priority Lien, or Permitted Lien). None of the property or assets of the Seller or any of its Affiliates (other than the Revenue Participation Right, Revenue Payments and the "proceeds" (as defined in the UCC) of the foregoing, which are covered by the immediately preceding sentence) is subject to, or encumbered by, any Lien (other than the Buyer's Back-Up Security Interest or Permitted Lien). The Seller holds all rights, interests, and title (and has all authority) necessary to fully grant the Back-Up Security Interest.

Section 4.11 Indebtedness. Schedule 4.11 of the Disclosure Schedule sets forth a complete list of the outstanding Indebtedness of, or incurred by, the Seller and its Affiliates as of the Effective Date.

Section 4.12 Lien Related Representation and Warranties. The Seller's exact legal name (as defined in Section 9-503 of the UCC) is, and since August 2, 2023 has been, "Zenas BioPharma, Inc." From inception to August 2, 2023, the Seller's exact legal name was "Zenas BioPharma (Cayman) Limited." The Seller is, and since August 2, 2023 has been, a corporation and incorporated in Delaware. The Seller's chief executive office is (and has been since November 2024) located at 852 Winter Street, Suite 250, Waltham MA 02451.

Section 4.13 Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the

Seller or any of its Affiliate who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.14 Foreign Corrupt Practices Act. None of the Seller or its Affiliates nor, to the Knowledge of the Seller, any of its or their directors, officers, employees or agents have, directly or indirectly, made, offered, promised or authorized any payment or gift of any money or anything of value to or for the benefit of any "foreign official" (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA")), foreign political party or official thereof or candidate for foreign political office for the purpose of (a) influencing any official act or decision of such official, party or candidate, (b) inducing such official, party or candidate to use his, her or its influence to affect any act or decision of a foreign governmental authority, or (c) securing any improper advantage, in the case of (a), (b) and (c) above in order to assist the Seller or any of its Affiliates in obtaining or retaining business for or with, or directing business to, any person. None of the Seller or any of its Affiliates nor, to the Knowledge of the Seller, any of its or their directors, officers, employees or agents have made or authorized any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of funds or received or retained any funds in violation of any law, rule or regulation. The Seller further represents that it has maintained, and has caused each of its Affiliates to maintain, systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) and written policies designed to ensure compliance with the FCPA or any other applicable anti-bribery or anti-corruption law. To the Knowledge of the Seller, neither the Seller nor any of its Affiliates or its or their officers, directors or employees are the subject of any allegation, voluntary disclosure, investigation, prosecution or other enforcement action related to the FCPA or any other anti-corruption law.

ARTICLE 5
REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer hereby represents and warrants to the Seller that as of the Effective Date:

Section 5.1 Existence; Good Standing. The Buyer is an Irish collective asset-management vehicle duly organized, validly existing and in good standing under the laws of Ireland. The Buyer is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified and in good standing has not and would not reasonably be expected to have, either individually or in the aggregate, a material adverse effect on the Buyer.

Section 5.2 Authorization. The Buyer has the requisite right, power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary action on the part of the Buyer.

Section 5.3 Enforceability. This Agreement has been duly executed and delivered by an authorized person of the Buyer and constitutes the valid and legally binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, except as may be limited by

applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

Section 5.4 No Conflicts. The execution, delivery and performance by the Buyer of this Agreement and the consummation of the transaction contemplated hereby do not and will not (a) contravene or conflict with the organizational documents of the Buyer, (b) contravene or conflict with or constitute a material default under any material provision of any law binding upon or applicable to the Buyer or (c) contravene or conflict with or constitute a material default under any material contract or other material agreement or Judgment binding upon or applicable to the Buyer.

Section 5.5 Consents. Except for the filing of financial statement(s) in accordance with Section 2.4 or any filings required by the federal securities laws or stock exchange rules, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Buyer in connection with (a) the execution and delivery by the Buyer of this Agreement, (b) the performance by the Buyer of its obligations under this Agreement or (c) the consummation by the Buyer of any of the transactions contemplated by this Agreement.

Section 5.6 No Litigation. There is no action, claim, suit, investigation or proceeding pending or, to the knowledge of the Buyer, threatened before any Governmental Entity to which the Buyer is a party that would reasonably be expected to prevent or materially and adversely affect the ability of the Buyer to perform its obligations under this Agreement.

Section 5.7 Financing. The Buyer has sufficient cash, or access to sufficient immediately available cash under committed credit facilities, to pay the Initial Purchase Price on the Effective Date and will have sufficient cash, or access to sufficient immediately available cash under committed credit facilities, to pay the Additional Purchase Price Payments contemplated by Section 3.6 if and when due hereunder. The Buyer acknowledges that its obligations under this Agreement are not contingent on obtaining financing.

Section 5.8 Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the Buyer who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

ARTICLE 6
NO OTHER REPRESENTATIONS AND WARRANTIES.

EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN ANY TRANSACTION DOCUMENT, NONE OF THE PARTIES HERETO MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY

WARRANTY AS TO THE VALIDITY OF ANY PATENT RIGHTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 7
COVENANTS

Section 7.1 Seller Diligence Requirements.

[***].

Section 7.2 Reporting.

(a) From and after the Effective Date, the Seller shall provide the Buyer promptly following the end of each Calendar Quarter, but in any event no later than [***] calendar days after the end of such Calendar Quarter, a reasonably detailed report (the "Quarterly Report") setting forth, with respect to such same period, (i) the Clinical Updates, (ii) the Regulatory Updates and (iii) the Commercial Updates. The Quarterly Report provided during the last Calendar Quarter of each Calendar Year shall also include the Intellectual Property Updates and, prior to the first Marketing Approval of a Product, [***]. The Seller shall prepare and maintain, and shall cause its Affiliates and any Licensees and Manufacturers to prepare and maintain, reasonably complete and accurate records of the information to be disclosed in each Quarterly Report.

(b) In addition to the information provided in the Quarterly Report, the Seller shall:

(i) provide the Buyer with a draft of any press release or other public disclosure containing [***] (and no later than [***] prior to issuance thereof);

(ii) provide the Buyer with prompt (and in any event within [***] Business Days) written notice of any Safety Notices or the Seller obtaining knowledge of any information that would reasonably reflect the occurrence (or expected occurrence) of a Material Adverse Effect; and

(iii) provide the Buyer with such additional information [***].

(c) The Seller may use copies of internal presentations or reports and copies of presentations or reports received by the Seller from any Third Party, or portions thereof to satisfy its reporting obligations under this Section 7.2. No reports or information provided in response to this Section 7.2 will include any personally identifiable data or other information that can be attributed to a specific individual without the use of additional information.

Section 7.3 Revenue Payments; Revenue Payment Details.

(a) From and after the First Commercial Sale, the Seller shall pay to the Buyer each Revenue Payment promptly, but in any event no later than [***] calendar days after the end of each Calendar Quarter.

(b) Provided that the Buyer has provided to the Seller a valid, properly executed Internal Revenue Service Form W-8BEN-E or other appropriate form confirming that no

withholding is required for U.S. federal income tax purposes, the Seller shall make all payments required to be made by it to the Buyer pursuant to this Agreement in U.S. dollars by wire transfer of immediately available funds, without set-off, reduction or deduction, or withholding for or on account of any Taxes, to the bank account designated in writing from time to time by the Buyer.

(c) From and after the First Commercial Sale, the Seller shall provide the Buyer promptly following the end of each Calendar Quarter, but in any event no later than [***] calendar days after the end of such Calendar Quarter, a report (a "Revenue Report") setting forth in reasonable detail, on a Product-by-Product and country-by-country basis: [***].

Section 7.4 Inspections and Audits of the Seller.

(a) Upon reasonable prior written notice and during normal business hours, the Buyer may cause an inspection and/or audit, by an independent public accounting firm reasonably acceptable to the Seller, the Buyer and such independent public accounting firm, of the Seller's and its Affiliates' books of account, for the sole purpose of determining the correctness of the Revenue Payments made under this Agreement.

(b) Any such inspection and/or audit shall be permitted with respect to the Revenue Payments no more frequently than [***]. In connection with any such inspection and/or audit, upon the Buyer's request, the Seller and its Affiliates shall exercise any rights it may have under any Out-License to cause an inspection and/or audit by an independent public accounting firm to be made of the books of account of the applicable Licensee for the purpose of determining the correctness of the Revenue Payments made under this Agreement.

(c) All of the expenses of any inspection or audit requested by the Buyer hereunder (including the fees and expenses of such independent public accounting firm designated for such purpose) shall be borne (i) by the Buyer, if the independent public accounting firm determines that the Revenue Payments previously paid were deficient by an amount less than or equal to [***] of the Revenue Payments actually paid or (ii) otherwise, by the Seller. Any such independent public accounting firm shall not disclose to the Buyer the confidential information of the Seller or any of its Affiliates or their respective Licensees, except to the extent such disclosure is either necessary to determine the correctness of a Revenue Payment or otherwise would be provided pursuant this Agreement, including in a Quarterly Report or Revenue Report. All information obtained by the Buyer as a result of any such inspection or audit shall be Confidential Information subject to ARTICLE 9.

(d) Notwithstanding the foregoing, in the event Seller disputes any of the inspection or audit results of Section 7.4(a), the parties shall work in good faith to resolve the dispute. If the parties are unable to reach a mutually acceptable resolution of any such dispute within [***] days, the dispute shall be submitted for resolution to an independent certified public accounting firm jointly selected by each party's certified public accountants or to such other Person as the parties shall mutually agree (the "Audit Arbitrator"). The decision of Audit Arbitrator shall be final, and the costs of such arbitration as well as the initial audit shall be borne between the parties consistent with Section 7.4(c).

(e) Not later than [***] days after Buyer's receipt of the audit results or the decision of the Audit Arbitrator (and in accordance with such decision), as applicable, the Seller shall pay the additional amounts, with interest from the date originally due in accordance with Section 7.11, or the Buyer shall reimburse the excess payments, as applicable.

Section 7.5 Intellectual Property Matters.

(a) Third Party Infringement Notice. The Seller shall provide to the Buyer a copy of any written notice received, directly or indirectly, by any Related Party or Manufacturer from any Third Party alleging or claiming that any Manufacture or Exploitation of any Product infringes, misappropriates or otherwise violates any Patents or other intellectual property rights of such or any other Third Party, together with copies of material correspondence sent or received by any Related Party or Manufacturer related thereto, as soon as practicable and in any event not more than [***] Business Days following (i) as it relates to the Seller or any of its Affiliates, such delivery or receipt or (ii) as it relates to a Licensee or Manufacturer, the Seller's or its Affiliate's receipt of such delivered or received notice or material correspondence.

(b) Enforcement and Defense Notice. The Seller shall promptly inform the Buyer of any infringement, misappropriation, or violation by a Third Party of any Patent Right or other Intellectual Property Right, or of any allegation by a Third Party that any Patent Right or other Intellectual Property Right is invalid or unenforceable, of which the Seller or any of its Affiliates becomes aware. Without limiting the foregoing, the Seller shall provide to the Buyer a copy of any written notice of any suspected infringement, misappropriation, violation, invalidity, or unenforceability of any Patent Rights or other Intellectual Property Rights delivered or received by the Seller or its Affiliates, as well as copies of material correspondence related thereto, as soon as practicable and in any event not more than [***] Business Days following such delivery or receipt.

(c) Enforcement and Defense Actions. Subject to Section 7.5(d), the Seller shall, or shall cause another Related Party to, use its or their Commercially Reasonable Efforts to enforce and defend all Patent Rights and other Intellectual Property Rights other than the In-Licensed Intellectual Property Rights for which a Licensor is responsible for enforcement or defense in accordance with the terms of the applicable In-License; provided that Seller shall not be required to, or cause another Related Party to, enforce or defend any Patent Right or other Intellectual Property Right if, in Seller's good faith judgement, such enforcement or defense would reasonably be expected to have a material and adverse effect on the scope, enforceability or validity of such Patent Right or Intellectual Property Right. [***].

(d) Enforcement and Defense Updates. Reasonably prior to the Seller's or any of its Affiliate's initiating, or permitting a Licensee to initiate (to the extent the Seller's or its Affiliate's permission is required under the applicable Out-License), an enforcement or defense action regarding any suspected infringement, misappropriation, violation, invalidity, or unenforceability of any Patent Right or other Intellectual Property Right, the Seller shall provide the Buyer with written notice of such enforcement or defense action and thereafter shall provide the Buyer with such additional information as the Buyer may reasonably request.

(e) Recovery. If the Seller or any of its Affiliates or any Licensee recovers or receives monetary damages from a Third Party, where such damages (with respect to any Licensee, solely if the Seller or any of its Affiliates is entitled to share in such damages pursuant to the applicable Out-License), whether in the form of judgment or settlement, result from the misappropriation, infringement, or other violation of any of the Patent Rights or other Intellectual Property Rights, (i) such recovery will be allocated first to the reimbursement of any expenses incurred by the Seller or its Affiliates or Licensees in bringing such action (including all reasonable attorneys' fees) and not otherwise reimbursed (by a Licensee or otherwise), (ii) any remaining amounts [***], and (iii) and any remaining amounts [***]. Notwithstanding the forgoing, any such remaining amounts in subsection (iii) that are allocable to the misappropriation, infringement, or other violation of any of the Patent Rights or other Intellectual Property Rights in the Licensee Income Territory that are recovered or received by a Licensee shall not be treated as Net Sales, but the portion of any such remaining amounts that is payable by a Licensee to the Seller or its Affiliates shall be treated as Licensee Royalty Income.

(f) Prosecution. The Seller shall, or shall cause an Affiliate or use Commercially Reasonable Efforts to cause a Licensee to, diligently file, prosecute, and maintain all Patent Rights other than the In-Licensed Patent Rights for which a Licensor is responsible for prosecution or maintenance in accordance with the terms of the applicable In-License. Notwithstanding the foregoing, Seller shall be permitted to (i) allow Patent Rights to expire or (ii) abandon Patent Rights, in each case ((i) and (ii)), in good faith in the ordinary course for strategic reasons. The Seller shall use reasonable efforts to ensure that applicable Licensor diligently files, prosecutes and maintains all such In-Licensed Patent Rights.

Section 7.6 In-Licenses.

(a) The Seller shall promptly (and in any event within [***] Business Days) provide the Buyer with (i) executed copies of any In-License, (ii) executed copies of each amendment, supplement, modification or written waiver of any provision of any In-License, and (iii) [***]. The Seller may redact or otherwise exclude from any of the foregoing (x) any information the redaction or exclusion of which is required to comply with applicable law and (y) any information that does not relate to the Revenue Payments, the Revenue Participation Right, the Product or the Product Rights.

(b) The Seller shall, or shall cause its Affiliates (as applicable) to, comply in all material respects with its and their obligations under each In-License and shall not take any action or forego any action that would reasonably be expected to result in a material breach thereof. Promptly, and in any event within [***] Business Days, after receipt of any (written or oral) notice from the applicable Licensor or any of its Affiliates of an alleged breach under any In-License by Seller or its Affiliates, the Seller shall provide the Buyer with a copy (or, in the case of an oral notice, reasonably detailed summary) thereof. The Seller shall, or shall cause its Affiliates (as applicable) to, use its or their Commercially Reasonable Efforts to cure any breaches by it under such In-License and shall give written notice to the Buyer upon curing any such breach.

(c) The Seller shall provide the Buyer with written notice following the Seller or any of its Affiliates becoming aware of a Licensor's material breach of its obligations under any In-License. Promptly, and in any event within [***] Business Days following the Seller's or its

Affiliate's notice to a Licensor of an alleged breach by such Licensor under any such In-License, the Seller shall provide the Buyer with a copy thereof.

(d) The Seller shall not, and shall cause its Affiliates not to, amend or modify in any material respect, waive any material provision of, terminate or assign (i) the Xencor In-License without obtaining the Buyer's prior written consent (not to be unreasonably conditioned, withheld or delayed) or (ii) any In-License other than the Xencor In-License in a manner that would be reasonably expected to have a Material Adverse Effect without obtaining the Buyer's prior written consent.

(e) The Seller shall provide the Buyer with written notice promptly (and in any event within [***] Business Days) following the amendment, modification, waiver, termination or assignment of any In-License.

Section 7.7 Out-Licenses; Contract Manufacturing Agreements.

(a) Without the Buyer's prior written consent (such consent not to be unreasonably withheld, conditioned, or delayed), the Seller shall not, and shall cause its Affiliates not to, enter into any Out-License that grants a Third Party any rights to Commercialize a Product (i) in any Major European Market unless such Third Party is a Permitted Entity or (ii) in the United States ((i) and (ii), a "Key Out-License"). [***].

(b) The Seller shall promptly (and in any event within [***] Business Days) provide the Buyer with (i) executed copies of each Out-License, (ii) executed copies of each amendment, supplement, modification or written waiver of any provision of any Out-License, and (iii) copies of all royalty reports under any Out-License and material reports provided by the Seller or any of its Affiliates to the applicable Licensee or provided in writing by the applicable Licensee to the Seller or any of its Affiliates.

(c) The Seller shall, or shall cause its Affiliates (as applicable) to, comply in all material respects with its and their obligations under each Out-License and Contract Manufacturing Agreement and shall not take any action or forego any action that would reasonably be expected to result in a material breach thereof. Promptly, and in any event within [***] Business Days, after receipt of any (written or oral) notice from a counterparty to any Out-License or any of its Affiliates of an alleged breach under any Out-License by Seller or its Affiliates, the Seller shall provide the Buyer with a copy (or, in the case of an oral notice, a reasonably detailed summary) thereof. The Seller shall, or shall cause its Affiliates (as applicable) to, use its or their Commercially Reasonable Efforts to cure any breaches by it under such Out-License and shall give written notice to the Buyer upon curing any such breach.

(d) The Seller shall provide the Buyer with written notice following the Seller or any of its Affiliates becoming aware of a Licensee's breach of its obligations under any Out-License that would reasonably be expected to have a Material Adverse Effect. Promptly, and in any event within [***] Business Days following the Seller's or its Affiliate's notice to a Licensee of an alleged breach by such Licensee under any such Out-License, the Seller shall provide the Buyer with a copy thereof.

(e) The Seller shall not, and shall cause its Affiliates not to, amend or modify in any material respect, waive any material provision of, terminate or assign any Key Out-License without obtaining the Buyer's prior written consent (not to be unreasonably conditioned, withheld or delayed). [***].

(f) The Seller shall provide the Buyer with written notice promptly (and in any event within [***] Business Days) following the amendment, modification, waiver, termination or assignment of any Out-License.

(g) All Out-Licenses entered into after the Effective Date shall contain provisions permitting the Seller or its Affiliate to audit such Licensee on terms and conditions consistent in all material respects with the Buyer's rights to audit the Seller and its Affiliates set forth in Section 7.4. The Seller shall, and shall cause its Affiliates to use, Commercially Reasonable Efforts to ensure that each Out-License entered into after the Effective Date contains provisions requiring the applicable Licensee to provide to the Seller or its Affiliate a quarterly royalty report consistent in all material respects with the Seller's obligation to provide quarterly Revenue Reports set forth in Section 7.3(c).

Section 7.8 Disclosures. Except for a press release previously approved in form and substance by the Seller and the Buyer or any other public announcement using substantially the same text as such press release or other public announcement made in accordance with this Agreement, neither the Buyer nor the Seller shall, and each party shall cause its respective Representatives, Affiliates and Affiliates' Representatives not to, issue a press release or other public announcement or otherwise make any public disclosure with respect to this Agreement or the subject matter hereof without the prior written consent of the other party except as may be required by applicable law or stock exchange rule (in which case either party required to make the press release or other public announcement or disclosure shall allow the other party reasonable time to comment on, and, if applicable, reasonably request the disclosing party to seek confidential treatment in respect of portions of, such press release or other public announcement or disclosure in advance of such issuance).

Section 7.9 Post-Closing Obligation. The Seller shall deliver to the Buyer [***] a CD, USB drive or as otherwise agreed by the parties, containing copies [***]. For the avoidance of doubt, the contents of such CD or USB drive are Confidential Information of the Seller and subject to the terms and conditions of this Agreement.

Section 7.10 Further Assurances. The Seller and the Buyer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to give effect to and carry on the transactions contemplated by this Agreement.

Section 7.11 Late Payments. A late fee of the lesser of (a) [***] over the Prime Rate, and (b) the highest rate permitted under applicable law shall accrue on all unpaid amounts with respect to any payment owed to either party hereunder, including the Additional Purchase Price Payments or any Revenue Payment, from the date such obligation was due until the date payment is made. The imposition and payment of a late fee shall not constitute a waiver of the rights of either party with respect to such payment default. [***].

Section 7.12 Negative Pledge; Preservation of Assets and Liens.

(a) The Seller shall not, and shall not permit any of its Affiliates to, create, incur, assume or suffer to exist any Lien on [***], except for (i) the Back-Up Security Interest and (ii) solely with respect to the Product Rights and the Products (but not any of the other aforementioned assets), any Permitted Lien. For clarity, the Seller and its Affiliates are permitted to create, incur, assume or suffer to exist a Lien on (x) Excluded Product Assets and (y) rights that relate to such products and are not Product Rights. [***]. For the avoidance of doubt, this Section 7.12(a) shall not restrict the incurrence of (i) any Permitted Liens or (ii) any licenses (including any In-Licenses or Out-Licenses) not prohibited hereunder.

(b) The Seller agrees that it will not (and will not permit any of its Affiliate to), without giving the Buyer prior written notice as promptly as practical, and in any event at least [***], change (i) its legal name (as defined in Section 9-503(a) of the Uniform Commercial Code in effect in Delaware), (ii) its jurisdiction of organization, (iii) its legal entity structure or identity, or (iv) the location or address of its chief executive office and shall otherwise cooperate and act as reasonably requested by the Buyer so that the Buyer can (1) create, maintain, continue and protect the Buyer's enforceable perfected security interest and Lien (with the priority provided for in this Agreement) on the assets covered by the Back-Up Security Interest and (2) maintain, continue and protect the purchase and sale of the Revenue Participation Right contemplated by this Agreement.

Section 7.13 Restriction on Indebtedness. Prior to the consummation of a Change of Control [***], the Seller shall not, and shall not permit any of its Affiliates to, incur any Indebtedness except for Permitted Indebtedness. [***].

ARTICLE 8
INDEMNIFICATION

Section 8.1 General Indemnity. Subject to Section 8.3, from and after the Effective Date:

(a) The Seller hereby agrees to indemnify, defend and hold harmless the Buyer and its Affiliates and its and their directors, managers, trustees, officers, agents and employees (the "Buyer Indemnified Parties") from, against and in respect of all Losses suffered or incurred by the Buyer Indemnified Parties to the extent arising out of or resulting from (i) any breach of any of the representations or warranties (in each case, when made) of the Seller in any Transaction Document and (ii) any breach of any of the covenants or agreements of the Seller in any Transaction Document.

(b) The Buyer hereby agrees to indemnify, defend and hold harmless the Seller and its Affiliates and its and their directors, officers, agents and employees (the "Seller Indemnified Parties") from, against and in respect of all Losses suffered or incurred by the Seller Indemnified Parties to the extent arising out of or resulting from (i) any breach of any of the representations or warranties (in each case, when made) of the Buyer in any Transaction Document or (ii) any breach of any of the covenants or agreements of the Buyer in any Transaction Document.

Section 8.2 Notice of Claims. If either a Buyer Indemnified Party, on the one hand, or a Seller Indemnified Party, on the other hand (such Buyer Indemnified Party on the one hand and such Seller Indemnified Party on the other hand being hereinafter referred to as an "Indemnified Party"), has suffered or incurred any Losses for which indemnification may be sought under this ARTICLE 8, the Indemnified Party shall so notify the other party from whom indemnification is sought under this ARTICLE 8 (the "Indemnifying Party") promptly in writing describing such Loss, the amount or estimated amount thereof, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this the relevant Transaction Document in respect of which such Loss shall have occurred. If any claim, action, suit or proceeding is asserted or instituted by or against a Third Party with respect to which an Indemnified Party intends to claim any Loss under this Section 8.2, such Indemnified Party shall promptly notify the Indemnifying Party of such claim, action, suit or proceeding and tender to the Indemnifying Party the defense of such claim, action, suit or proceeding. A failure by an Indemnified Party to give notice and to tender the defense of such claim, action, suit or proceeding in a timely manner pursuant to this Section 8.2 shall not limit the obligation of the Indemnifying Party under this ARTICLE 8, except to the extent such Indemnifying Party is actually prejudiced thereby.

Section 8.3 Limitations on Liability. Except for claims arising from a breach of confidentiality obligations under ARTICLE 9 or in cases of fraud, gross negligence, or willful misconduct, no party hereto shall be liable (and no claim for indemnification hereunder shall be asserted) for any consequential, punitive, special or incidental damages under this ARTICLE 8 as a result of any breach or violation of any covenant or agreement of such party (including under this ARTICLE 8) in or pursuant to any Transaction Document. Notwithstanding the foregoing, (a) the Buyer shall be entitled to make indemnification claims, in accordance with the procedures set forth in this ARTICLE 8, for Losses that include any portion of the Revenue Payments that the Buyer was entitled to receive but did not receive timely or at all due to any indemnifiable events under any Transaction Document, and such portion of the Revenue Payments shall not be deemed consequential, punitive, special or incidental damages for any purpose of any Transaction Document and (b) any consequential, punitive, special or incidental damages awarded to a Third Party in connection with a claim pursuant to Section 8.4 shall be considered Losses for purposes of this ARTICLE 8. Notwithstanding anything in this ARTICLE 8 to the contrary, the Seller shall not be liable for any damages as a result of any breach of the last two sentences of Section 2.2.

Section 8.4 Third Party Claims. Upon providing notice to an Indemnifying Party by an Indemnified Party pursuant to Section 8.2 of the commencement of any action, suit or proceeding against such Indemnified Party by a Third Party with respect to which such Indemnified Party intends to claim any Loss under this ARTICLE 8, such Indemnifying Party shall defend such claim, at such Indemnifying Party's expense and with counsel of its choice reasonably satisfactory to the Indemnified Party. The Indemnified Party shall, at the request of the Indemnifying Party, use reasonable efforts to cooperate in such defense; provided, that the Indemnifying Party shall bear the Indemnified Party's reasonable out-of-pocket costs and expenses incurred in connection with such cooperation. The Indemnified Party may, without the request of the Indemnifying Party, retain separate co-counsel at the Indemnified Party's expense and may participate in the defense of such claim. The Indemnifying Party shall not consent to the entry of any Judgment or enter into any settlement with respect to such claim without the prior written consent of the Indemnified Party unless such Judgment or settlement (a) provides for the payment by the Indemnifying Party

of money as the sole relief (if any) for the claimant (other than customary and reasonable confidentiality obligations relating to such claim, Judgment or settlement), (b) results in the full and general release of the Indemnified Party from all liabilities arising out of, relating to or in connection with such claim and (c) does not involve a finding or admission of any violation of any law, rule, regulation or Judgment, or the rights of any Person, and has no effect on any other claims that may be made against the Indemnified Party. In the event the Indemnifying Party does not or ceases to conduct the defense of such claim in compliance with this Section 8.4, (i) the Indemnified Party may defend against, and consent to the entry of any Judgment or enter into any settlement with respect to, such claim in any manner such Indemnified Party reasonably deems appropriate, (ii) the Indemnifying Party shall reimburse the Indemnified Party promptly and periodically for the reasonable out-of-pocket costs of defending against such claim, including reasonable attorneys' fees and expenses against reasonably detailed invoices, and (iii) the Indemnifying Party shall remain responsible for any Losses the Indemnified Party may suffer as a result of such claim to the full extent provided in this ARTICLE 8.

Section 8.5 Exclusive Remedy. Except as set forth in Section 11.10, from and after the Effective Date, the rights of the parties hereto pursuant to (and subject to the conditions of) this ARTICLE 8 shall be the sole and exclusive remedy of the parties hereto and their respective Affiliates with respect to any claims (whether based in contract, tort or otherwise) resulting from or relating to any breach of the representations, warranties, covenants and agreements made under any Transaction Document or any certificate, document or instrument delivered under any Transaction Document, and each party hereto hereby waives, to the fullest extent permitted under applicable law, and agrees not to assert any other claim or action in respect of any such breach. Notwithstanding the foregoing, claims for fraud shall not be waived or limited in any way by this ARTICLE 8.

Section 8.6 Tax Treatment of Indemnification Payments. Any indemnification payments made pursuant to this ARTICLE 8 will be treated as an adjustment to the purchase price for U.S. federal income tax purposes to the fullest extent permitted by applicable law, except to the extent otherwise required pursuant to a "determination," within the meaning of Section 1313(a) of the US Code.

ARTICLE 9
CONFIDENTIALITY

Section 9.1 Confidentiality. Except as provided in this ARTICLE 9 or otherwise agreed in writing by the parties, the parties agree that, during the term of this Agreement and for [***] thereafter, each party (the "Receiving Party") shall (a) keep confidential and shall not publish or otherwise disclose, except as permitted pursuant to Section 9.2, any information furnished to it by or on behalf of the other party (the "Disclosing Party") pursuant to this Agreement (such information, "Confidential Information" of the Disclosing Party), and (b) shall not use the Confidential Information of the Disclosing Party for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder), except in each case ((a) and (b)) for that portion of such information that the Receiving Party can demonstrate by competent proof:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) is independently developed by the Receiving Party or any of its Affiliates without the use of the Confidential Information of the Disclosing Party; or

(e) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party who did not receive such Confidential Information from the Disclosing Party and without obligations of confidentiality with respect thereto.

Section 9.2 Authorized Disclosure. Either party may disclose Confidential Information to the extent such disclosure is reasonably necessary in the following situations:

(a) prosecuting or defending litigation between the parties hereto;

(b) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(c) complying with a valid order of a court or administrative body of competent jurisdiction or other Governmental Entity;

(d) for regulatory, Tax or customs purposes;

(e) for audit purposes;

(f) disclosure to its Affiliates and its and its Affiliates' Representatives; provided, that each recipient of Confidential Information must be bound by obligations of confidentiality and non-use at least as stringent as those set forth in this Agreement prior to any such disclosure;

(g) disclosure to its actual or potential investors, lenders, (sub)licensees, or acquirors, and their respective accountants, financial advisors and other professional representatives, provided, that such disclosure shall be made only to the extent customarily required to consummate such investment, financing or licensing transaction or acquisition and that each recipient of Confidential Information must be bound by obligations of confidentiality and non-use at least as stringent as those set forth in this Agreement prior to any such disclosure; or

(h) upon the prior written consent of the Disclosing Party.

Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to (a), (c) or (d), it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such

disclosure and use reasonable efforts to secure confidential treatment of such information. Without limiting the foregoing, a party may disclose the other party's Confidential Information, without the other party's prior written permission, to the extent it is required to do so by law, regulation, or a court or administrative order or an order of another Governmental Entity; however, prior to such disclosure, the compelled party shall notify the other party (which notice shall include a copy of the relevant portion of any applicable subpoena or order) as promptly as possible after it learns of such requirement to disclose, except to the extent such notification would be impractical or legally impermissible (in which event notification shall be made as soon as reasonably practicable and permissible), provide the other party with reasonable opportunity to pursue legal action to prevent or limit the required disclosure, and, if requested, provide reasonable assistance at the other party's expense in undertaking reasonable legal action to prevent or limit the required disclosure. In the event of any such required disclosure, the party required to disclose the other party's Confidential Information shall disclose only that portion of the other party's Confidential Information that it is legally required to disclose based on the advice of its counsel. The Receiving Party shall continue to hold in confidence hereunder any such disclosed Confidential Information of the Disclosing Party unless and until such information is no longer required to be held in confidence under the terms of this Agreement.

The Buyer shall not seek, because of, or based upon, any Confidential Information of the Seller, Patent or any other form of intellectual property protection with respect to, or related to, any such Confidential Information or use the Confidential Information of the Seller to obtain, or seek to obtain, a commercial advantage over the Seller. Without limiting the foregoing, the Buyer shall not file any Patent application based upon, disclosing or using any of the Confidential Information of the Seller provided hereunder.

ARTICLE 10
TERMINATION

Section 10.1 Term. This Agreement shall be effective as of the Effective Date and shall continue unless and until terminated pursuant to Section 10.2, at which time this Agreement shall terminate, except in each case with respect to any rights or obligations that accrued or arose prior to such termination. The Buyer and the Seller have carefully considered and negotiated the conditions under which this Agreement would terminate, and such conditions allocate risks between the Buyer and the Seller. The Buyer's obligation to pay the Purchase Price and the Seller's sale of the Revenue Participation Right and obligation to pay the Revenue Payments reflect this allocation of risk, and neither the Buyer nor the Seller would have entered into this Agreement without such allocation.

Section 10.2 Mutual Termination. This Agreement may only be terminated by mutual written agreement of the Buyer and the Seller.

Section 10.3 Survival. Notwithstanding anything to the contrary in this ARTICLE 10, the following provisions shall survive termination of this Agreement: ARTICLE 1 (Definitions); Section 7.3 (Revenue Payments; Revenue Payment Details) (solely to the extent a payment accrues prior to the effective date of termination); Section 7.4 (Inspections and Audits of the Seller) (solely to the extent set forth therein and as it relates to payments accrued prior to the effective date of termination); Section 7.5(e) (Recovery) (solely to the extent such action arises prior to the effective

date of termination); Section 7.11 (Late Payments); ARTICLE 8 (Indemnification); ARTICLE 9 (Confidentiality) (for the period of time set forth therein); Section 10.1 (Term); Section 10.3 (Survival); ARTICLE 11 (Miscellaneous). Termination of this Agreement shall not relieve any party of liability in respect of breaches under this Agreement by any party on or prior to termination.

ARTICLE 11
MISCELLANEOUS

Section 11.1 Notices. All notices and other communications under this Agreement shall be in writing and shall be by email with PDF attachment, courier service or personal delivery to the following addresses, or to such other addresses as shall be designated from time to time by a party hereto in accordance with this Section 11.1:

If to the Seller, to it at:

Zenas BioPharma, Inc.
852 Winter Street, Suite 250
Waltham, MA 02451
Attention: [***]
Email: [***]

With a copy to:

Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: Hannah H. England
Email: [***]

If to the Buyer, to it at:

Royalty Pharma Investments 2019 ICAV
110 E. 59th Street, Suite 3300
New York, New York 10022
Attention: [***]
Email: [***]

With a copy to:

Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
Attention: Robert M. Crawford and Jacqueline Mercier
Email: [***]

All notices and communications under this Agreement shall be deemed to have been duly given (a) when delivered by hand, if personally delivered, (b) when received by a recipient, if sent

by email, with an acknowledgement of receipt being produced by the recipient's email account, or (c) one (1) Business Day following sending within the United States by overnight delivery via commercial one-day overnight courier service.

Section 11.2 Expenses. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby shall be paid by the party hereto incurring such fees, costs and expenses.

Section 11.3 Assignment; Transfer Restrictions.

(a) Neither the Seller nor any of its Affiliates shall sell, assign or otherwise transfer, including by asset sale, merger, change of control, operation of law, or otherwise, this Agreement or any portion of the Seller's or its Affiliates' rights, title or interest in or to any Product Rights to any Person without the prior written consent of the Buyer (not to be unreasonably conditioned, withheld or delayed) except (i) to an Affiliate if such Affiliate transferee agrees in a writing that such Affiliate assumes all of the obligations of the Seller to the Buyer under the Transaction Documents and the Seller guarantees the performance of such Affiliate or (ii) in connection with a Change of Control, [***]. Further, the Seller and its Affiliates shall be permitted to assign this Agreement and all or substantially of its and their rights, title or interest in or to all of the Product Rights to a Permitted Entity if such Permitted Entity agrees in a writing that it assumes this Agreement. Prior to any such sale, assignment or transfer, the Seller shall take all actions required (or reasonably requested by the Buyer after being given a reasonable time to make such a request after written notice of such prospective sale, assignment or transfer) to (1) create, continue, maintain and protect the Buyer's perfected security interest and Lien (with the priority contemplated by this Agreement) in the assets covered by the Back-Up Security Interest, and (2) maintain, continue and protect the purchase and sale of the Revenue Participation Right contemplated by this Agreement. For clarity, nothing in this Section 11.3(a) shall prohibit any Out-Licenses permitted by and entered into in accordance with Section 7.7, or the grant of any Permitted Liens.

(b) The Buyer may assign this Agreement without the prior written consent of the Seller [***].

(c) A party assigning this Agreement as set forth in this Section 11.3 will promptly notify the other party of such assignment.

(d) Any purported sale, assignment or transfer in violation of this Section 11.3 shall be null and void.

This Agreement shall be binding upon, inure to the benefit of and be enforceable by, the parties hereto and their respective permitted successors and assigns.

Section 11.4 Amendment and Waiver.

(a) This Agreement may be amended, restated, modified or supplemented only in a writing signed by each of the Seller and the Buyer. Any provision of this Agreement may be waived only in a writing signed by the party hereto granting such waiver.

(b) No failure or delay on the part of either party hereto in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the parties hereto shall be effective to amend, modify, supplement or waive any provision of this Agreement.

Section 11.5 Entire Agreement. This Agreement, the Exhibits annexed hereto and the Disclosure Schedule constitute the entire understanding between the parties hereto with respect to the subject matter hereof and supersede all other understandings and negotiations with respect thereto.

Section 11.6 No Third Party Beneficiaries. This Agreement is for the sole benefit of the Seller and the Buyer and their permitted successors and assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the parties hereto and such successors and assigns, any legal or equitable rights hereunder, except that the Indemnified Parties shall be third party beneficiaries of the benefits provided for in ARTICLE 8.

Section 11.7 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

Section 11.8 Jurisdiction; Venue.

(a) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY SUBMITS, FOR ITSELF AND ITS RESPECTIVE PROPERTY AND ASSETS, TO THE EXCLUSIVE JURISDICTION OF ANY NEW YORK STATE COURT OR FEDERAL COURT OF THE UNITED STATES SITTING IN NEW YORK COUNTY, NEW YORK, AND ANY APPELLATE COURT THEREOF, IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR FOR RECOGNITION OR ENFORCEMENT OF ANY JUDGMENT IN RESPECT THEREOF, AND THE BUYER AND THE SELLER EACH HEREBY IRREVOCABLY AND UNCONDITIONALLY AGREE THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN ANY SUCH NEW YORK STATE COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. THE BUYER AND THE SELLER EACH HEREBY AGREE THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY APPLICABLE LAW. EACH OF THE BUYER AND THE SELLER HEREBY SUBMITS TO THE EXCLUSIVE PERSONAL JURISDICTION AND VENUE OF SUCH NEW YORK STATE AND FEDERAL COURTS. NOTHING IN THIS AGREEMENT OR IN ANY OTHER DOCUMENT SHALL AFFECT ANY RIGHT THAT THE BUYER MAY OTHERWISE HAVE TO BRING ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER DOCUMENT AGAINST THE SELLER OR ITS AFFILIATES OR ITS OR THEIR PROPERTIES IN THE COURTS OF ANY JURISDICTION. THE BUYER AND THE SELLER EACH AGREE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THAT PROCESS MAY BE SERVED ON THE BUYER OR THE

SELLER IN THE SAME MANNER THAT NOTICES MAY BE GIVEN PURSUANT TO SECTION 11.1 HEREOF.

(b) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY LEGALLY AND EFFECTIVELY DO SO, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT IN ANY NEW YORK STATE OR FEDERAL COURT. EACH OF THE BUYER AND THE SELLER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(c) EACH PARTY HERETO IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO TRIAL BY JURY WITH RESPECT TO ANY PROCEEDING ARISING OUT OF, RELATING TO OR IN CONNECTION WITH THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.

Section 11.9 Severability. If any term or provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any situation in any jurisdiction, then, to the extent that the economic and legal substance of the transactions contemplated hereby is not affected in a manner that is materially adverse to either party hereto, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect and the enforceability and validity of the offending term or provision shall not be affected in any other situation or jurisdiction.

Section 11.10 Specific Performance. Each party acknowledges and agrees that the other party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached or violated. Accordingly, notwithstanding Section 8.5, each party agrees that, without posting bond or other undertaking, the other party shall be entitled to an injunction or injunctions to prevent breaches or violations of the provisions of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action, suit or other proceeding instituted in any court of the United States or any state thereof having jurisdiction over the parties and the matter in addition to any other remedy to which it may be entitled, at law or in equity. Each party further agrees that, in the event of any action for specific performance in respect of such breach or violation, it shall not assert that the defense that a remedy at law would be adequate.

Section 11.11 Counterparts. This Agreement may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Copies of executed counterparts transmitted by telecopy, facsimile or other similar means of electronic transmission, including "PDF," shall be considered original executed counterparts, provided receipt of such counterparts is confirmed.

Section 11.12 Relationship of the Parties. The relationship between the Buyer and the Seller is solely that of purchaser and seller, and neither the Buyer nor the Seller has any fiduciary or other special relationship with the other party or any of its Affiliates. This Agreement is not a

partnership or similar agreement, and nothing contained herein shall be deemed to constitute the Buyer and the Seller as a partnership, an association, a joint venture or any other kind of entity or legal form for any purposes, including any Tax purposes. The Buyer and the Seller agree that they shall not take any inconsistent position with respect to such treatment in a filing with any Governmental Entity.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the Effective Date.

SELLER

ZENAS BIOPHARMA, INC.

By: /s/ Leon O. Moulder, Jr.
Name: Leon O. Moulder, Jr.
Title: Founder, Chief Executive Officer & Chairman

BUYER

ROYALTY PHARMA INVESTMENTS 2019 ICAV

By: Royalty Pharma Manager, LLC, its Attorney-in-Fact

By: /s/ George W. Lloyd
Name: George W. Lloyd
Title: EVP, Investments & Chief Legal Officer

Exhibit A

[***]

[***]

Exhibit C

[***]

Exhibit D

[***]

Exhibit E

[***]

Exhibit F

[***]

Exhibit G

[***]

Exhibit H

[***]

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: November 12, 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: November 12, 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 September 30, 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: November 12, 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 September 30, 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: November 12, 2025

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