UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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: 001-39263

Zentalis Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-3607803**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10275 Science Center Dr. Suite 200 San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (858) 263-4333

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	ZNTL	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $66.9 million based on the closing price of $1.16 as reported on The Nasdaq Global Market on such date. Solely for the purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the registrant as of such date have been excluded because such holders may be deemed to be affiliates.

The number of shares of registrant's common stock outstanding as of March 20, 2026 was 70,931,016.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025 are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

		Page
PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	20
Item 1B.	Unresolved Staff Comments	66
Item 1C.	Cybersecurity	67
Item 2.	Properties	68
Item 3.	Legal Proceedings	68
Item 4.	Mine Safety Disclosures	68
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	69
Item 6.	[Reserved]	70
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	71
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	82
Item 8.	Financial Statements and Supplementary Data	82
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosures	82
Item 9A.	Controls and Procedures	82
Item 9B.	Other Information	84
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	84
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	84
Item 11.	Executive Compensation	84
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	84
Item 13.	Certain Relationships and Related Transactions, and Director Independence	84
Item 14.	Principal Accounting Fees and Services	84
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	84
Item 16.	Form 10-K Summary	87

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “design,” “aim,” “support,” “advance,” “on track,” “strive,” "opportunity," "upcoming," or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our competitive position, including information relating to our competitors and their products and product candidates in our industry;
- our expectations, projections and estimates regarding our capital requirements, need for additional capital, financing our future cash needs, costs, expenses, revenues, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth, contractual obligations, the period of time our cash resources will fund our current operating plan, our internal control over financial reporting and disclosure controls and procedures;
- our expectations regarding the impact of our January 2025 strategic restructuring, including anticipated cost savings, workforce reductions, and our ability to execute our business strategy with reduced personnel;
- our prioritization of azenosertib (ZN-c3) and the potential for azenosertib to be first-in-class and best-in-class;
- the ability of our clinical trials to demonstrate safety and efficacy of azenosertib and other positive results;
- the global macroeconomic environment and increased inflation;
- our plans for, including the timing and focus of, our ongoing and future clinical trials of azenosertib, including the reporting of data from those studies and trials and the timing thereof and the timing of initiation of enrollment in our clinical trials, including our Phase 3 ASPENOVA confirmatory study of monotherapy azenosertib in Cyclin E1-positive platinum-resistant ovarian cancer ("PROC") patients and our plans to enroll concurrently with DENALI Part 2b;
- the design of our clinical trials, such as for DENALI Part 2 and ASPENOVA, including our estimates of the number of patients that we will enroll in our clinical trials;
- the potential benefits of the measures in the DENALI Part 2 and ASPENOVA protocols for enhanced patient monitoring, guidance and supportive care;
- the beneficial characteristics, safety, efficacy and therapeutic effects of azenosertib;
- our and our collaborators' strategy, plans and expectations with respect to the development, manufacturing, supply, approval and commercialization of azenosertib and the timing thereof;
- the designs of our studies and the type of information and data expected from our studies and the expected benefits thereof;
- our ability to obtain and maintain any marketing authorizations and our ability to complete post-marketing requirements with respect thereto;
- the timing and amounts of payments from or to our collaborators, licensors and purchasers of assets, and the anticipated arrangements and benefits under our collaboration and license agreements, including with respect to milestones and royalties;
- our plans and ability to raise additional capital, including under our at-the-market offering program, and the terms and timing thereof;
- our pipeline, including its potential, and our related research and development activities;
- our plans relating to a companion diagnostic to identify patients with Cyclin E1-positive PROC and other potential biomarkers to identify patients, and the costs thereof;
- our plans relating to the further development of azenosertib, including program timelines, potential paths to registration, and additional indications we may pursue;
- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms and processes on a timely basis, or at all, with third-party payors for azenosertib and any future product candidates, if approved;
- our plans to evaluate additional strategic opportunities to maximize the value of our pipeline;
- our plans to develop azenosertib in combination with other therapies, resources allowing;
- our ability to obtain, and negotiate favorable terms of any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize azenosertib;
- timing and likelihood of success of our development and commercialization efforts;
- timing of expected milestones and results, and the announcement thereof;
- the broad franchise potential of azenosertib;

- the estimated size of the market opportunity for azenosertib, including the market opportunity for azenosertib in Cyclin E1-positive PROC, and our underlying assumptions thereof, including our estimate of the limited overlap between FRα-high PROC patients and those that have Cyclin E1 overexpression, and our belief that there is additional market opportunity for azenosertib outside of ovarian cancer across other solid tumors;
- our expectations regarding the approval and use of azenosertib;
- the timing or likelihood of regulatory filings and approvals;
- our ability to obtain and maintain regulatory approval of azenosertib and any future product candidates;
- our regulatory strategy, including the potential for DENALI Part 2, if successful, to support an accelerated approval for azenosertib;
- existing laws, regulations and regulatory developments in the United States, the European Union, or the EU, and other jurisdictions;
- our intellectual property position, including obtaining and maintaining patents, and the timing, outcome and impact of administrative, regulatory, legal and other proceedings relating to our patents and other proprietary and intellectual property rights, and the timing and resolution thereof;
- our facilities and lease commitments;
- accounting standards and estimates, their impact, and their expected timing of completion;
- cybersecurity and information security;
- expected ongoing reliance on third parties, including with respect to the development, manufacturing, supply and commercialization of azenosertib and any future product candidates;
- insurance coverage;
- estimated periods of performance of key contracts; and
- the potential need to hire personnel and our ability to attract and retain personnel, and our ability to provide competitive compensation and benefits.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties, assumptions and other important factors, including those described under "Summary Risk Factors" below and in the sections in this Annual Report on Form 10-K entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K.

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, they may turn out to be inaccurate and you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results, financial condition, performance or achievements could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan 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.

INDUSTRY AND OTHER DATA

This Annual Report on Form 10-K contains industry, market and competitive position data from our own internal estimates and research as well as industry and general publications and research surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the markets in which we operate and our management’s understanding of industry conditions. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions are appropriate, neither such research nor definitions have been verified by an independent source.

The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in Part I, Item 1A., “Risk Factors” in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A., "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- We are substantially dependent on the success of azenosertib, which is currently our only product candidate in clinical development. If we are unable to complete development of, obtain approval for and commercialize azenosertib in a timely manner, our business will be harmed.
- The clinical trials of azenosertib or any future product candidates may not demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or FDA, or ex-U.S. regulatory authorities or otherwise produce positive results.
- We expect to be required by the FDA and ex-U.S. regulatory authorities to obtain approval of a companion diagnostic in connection with approval of our lead indication for azenosertib, and additional biomarkers may be required for the development and commercialization of azenosertib outside of our lead indication and for future product candidates. If regulatory approval is not obtained or there are delays in obtaining regulatory approval of any such companion diagnostic, we will not be able to commercialize azenosertib and, potentially, future product candidates, and our ability to generate product revenue will be materially impaired.
- The regulatory approval processes of the FDA and ex-U.S. regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for azenosertib or any future product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- Our success depends on our ability to protect our intellectual property and our proprietary platform. If we are unable to adequately protect our intellectual property and our proprietary platform, or to obtain and maintain issued patents which are sufficient to protect azenosertib or any future product candidates, then others could compete against us more directly, which would negatively impact our business.
- Our existing collaborations are important to our business and future licenses may also be important to us and, if we are unable to maintain any of these collaborations, or if these arrangements are not successful, our business could be adversely affected.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations, or CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize azenosertib or any future product candidates and our business could be substantially harmed.
- We contract with third parties for the manufacture of azenosertib for preclinical studies and ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of azenosertib or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, then we may not be able to sustain or grow our business when needed.

- Unfavorable U.S., global, political or economic conditions could adversely affect our business, financial condition or results of operations.

- Business interruptions could adversely affect our operations.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company developing azenosertib (ZN-c3), an investigational, potentially first-in-class and best-in-class WEE1 inhibitor, for patients with ovarian cancer and other tumor types. In clinical trials, azenosertib has been well tolerated and has demonstrated anti-tumor activity as a single agent across multiple tumor types. We are currently focused on advancing the clinical development of azenosertib in Cyclin E1-positive platinum-resistant ovarian cancer, or PROC. We believe that our DENALI (ZN-c3-005) Part 2 clinical trial of azenosertib in patients with Cyclin E1-positive PROC, if successful, has the potential to support an accelerated approval, subject to U.S. Food and Drug Administration, or FDA, review. Azenosertib also has broad franchise potential beyond Cyclin E1-positive PROC. We exclusively in-license or solely own worldwide development and commercialization rights to azenosertib.

Strategy

Our strategy includes the following key components:

- ***Rapidly advance the clinical development of azenosertib as a monotherapy toward first regulatory approval in Cyclin E1-positive PROC***. We believe azenosertib has the potential to set a new standard of care in patients with Cyclin E1-positive PROC. Many patients with PROC receive single-agent chemotherapy, which has modest clinical benefits. In January 2025, we disclosed a significant amount of clinical data showing an objective response rate, or ORR, of over 30% and a manageable safety profile in patients with Cyclin E1-positive PROC who received azenosertib at our primary dose-of-interest, 400 mg QD 5:2 (single daily dose on an intermittent schedule of five days on and two days off). We completed enrollment in Part 2a of our Phase 2 DENALI clinical trial of azenosertib in patients with Cyclin E1-positive PROC in 2025 and anticipate a topline readout from the trial by year end 2026. DENALI Part 2, if successful, has the potential to support an accelerated approval, subject to FDA review.
- ***Advance the development of azenosertib outside of Cyclin E1-positive PROC, as resources allow.*** We believe that the opportunity for azenosertib is broad, and we plan to advance the clinical development of azenosertib outside of Cyclin E1-positive PROC, as our resources allow. We are evaluating azenosertib in combination with bevacizumab as maintenance therapy in patients with ovarian cancer in our MUIR (ZN-c3-002) Phase 1 clinical trial. In addition, we are leveraging our extensive experience and capabilities to translate our science to advance research on additional areas of opportunity for azenosertib in other tumor types beyond ovarian cancer.
- ***Evaluate additional strategic opportunities to maximize the value of our pipeline***. We previously had development collaborations for azenosertib with Pfizer Inc., GSK plc, and Dana-Farber Cancer Institute. While these collaborations have completed, we will continue to selectively evaluate new collaborations for azenosertib with partners whose assets and capabilities complement our own.

Azenosertib (WEE1 Inhibitor)

Mechanism of Action

Azenosertib is an investigational, potentially first-in-class and best-in-class oral, small molecule WEE1 inhibitor. The inhibition of WEE1, a DNA damage response kinase, drives cancer cells into mitosis without being able to repair damaged DNA, resulting in cell death and thereby preventing tumor growth and potentially causing tumor regression. We have designed azenosertib to have advantages over other investigational therapies targeting WEE1, including superior selectivity and pharmacokinetic, or PK, properties.

Cyclin E1 Expression as a Sensitive and Specific Predictive Biomarker

Cells with Cyclin E1 activation are exquisitely sensitive to WEE1 inhibition via azenosertib because Cyclin E1 activation further accelerates cancer cells into the DNA replication phase without adequate DNA repair. As a result, we have used retrospective analyses to establish Cyclin E1 as a sensitive and specific predictive biomarker that can be used to identify patients who might benefit from azenosertib. In addition, based on published retrospective analyses, Cyclin E1 alteration is a biomarker of poor prognosis and low benefit from standard-of-care single-agent chemotherapy in PROC patients.

We are working with a diagnostic partner to validate a companion diagnostic test that will identify patients with PROC that overexpress the Cyclin E1 protein using our proprietary immunohistochemistry, or IHC, cutoff. A prototype of this test is being used in DENALI Part 2 and is ready for use in our Phase 3 trial, ASPENOVA.

Market Opportunity

In 2022, the global ovarian cancer market was approximately $3 billion, with significant growth expected over the next several years. PROC is a subset of the ovarian cancer market. Based on our analysis utilizing our IHC cutoff, we estimate that approximately 50% of PROC patients overexpress Cyclin E1 protein, which accounts for approximately 21,500 patients on an annual basis in the United States, EU4 (France, Germany, Italy, Spain) and the United Kingdom, based on 2024 estimates. As a result, we believe there is a large market opportunity for azenosertib in Cyclin E1-positive PROC patients. Moreover, the successful launch of mirvetuximab in PROC patients with high folate receptor alpha, or FRα-high, expression underscores the demand for biomarker-directed therapies for PROC patients. The limited overlap between FRα-high PROC patients and those that have Cyclin E1 overexpression is estimated to be less than 20%, which highlights the significant unmet need in patients with Cyclin E1-positive PROC.

We believe there is additional market opportunity for azenosertib in earlier lines of treatment for ovarian cancer, and across other solid tumor types.

Clinical Development Program

The following ongoing and planned studies constitute the current clinical development program for azenosertib:

- ***Monotherapy – Phase 2 Clinical Trial in PROC (DENALI - ZN-c3-005).***

    - **DENALI Part 1b** is a single-arm study that evaluated azenosertib monotherapy at our primary dose-of-interest, 400 mg QD 5:2, in 102 patients with PROC. Tissue collection for biomarker assessment was mandated in the study and upon a retrospective analysis, approximately 50% of the patients were Cyclin E1-positive per our IHC cutoff. In January and March of 2025, we announced clinical data from this study, which is described in the next section below titled “Clinical Data – DENALI Part 1b”.

    - **DENALI Part 2** is designed to enroll approximately 100 patients with Cyclin E1-positive PROC at the selected dose who have received one to three prior lines of therapy, or for patients whose tumors are also FRα-high and who have received mirvetuximab soravtansine, one to four prior lines of therapy. We have aligned with the FDA on the design of our DENALI Part 2 study in patients with Cyclin E1-positive PROC, which allows for seamless enrollment across Parts 2a and 2b. DENALI Part 2a is designed to confirm 400 mg QD 5:2 as the recommended pivotal study dose by enrolling approximately 30 patients at each of two dose levels, 400 mg QD 5:2 and 300 mg QD 5:2. DENALI Part 2b is designed to enroll approximately 70 patients at a single dose, the selection of which will be informed by the Part 2a results and FDA interaction. In April 2025, we announced that the first patient was dosed in DENALI Part 2a. In January 2026, we announced that the enrollment for Part 2a was completed in 2025 and we plan to announce dose selection from Part 2a in the first half of 2026. We anticipate a topline readout for DENALI Part 2 by year end 2026. We believe that DENALI Part 2, if successful, has the potential to support an accelerated approval, subject to FDA review. The FDA has granted Fast Track Designation to azenosertib for the treatment of patients with PROC who are positive via IHC for Cyclin E1 protein levels.

- ***Monotherapy – Phase 3 Clinical Trial in Cyclin E1-positive PROC (ASPENOVA).*** We have aligned with the FDA on the trial design for ASPENOVA, a randomized Phase 3 confirmatory clinical trial of azenosertib versus standard-of-care chemotherapy for the treatment of patients with Cyclin E1-positive PROC designed to support a full approval of azenosertib in this setting. We plan to initiate ASPENOVA in the first half of 2026 and enroll concurrently with DENALI Part 2b.

- ***Combination – Phase 1b Clinical Trial of Azenosertib and Chemotherapy or Bevacizumab in Ovarian Cancer (MUIR - ZN-c3-002).*** We are currently enrolling patients in an arm of our ZN-c3-002 Phase 1b clinical trial that is evaluating azenosertib in combination with bevacizumab as maintenance therapy in ovarian cancer. The dose expansion portion will enroll second-line platinum-sensitive ovarian cancer (PSOC) patients for maintenance treatment, whose disease progressed while on a PARP inhibitor.

We also completed enrollment in a Phase 2 clinical trial evaluating azenosertib as a monotherapy in patients with uterine serous carcinoma, or USC (TETON - ZN-c3-004). We plan to publish results from this trial in the future. We do not plan further development of azenosertib in USC.

Clinical Data

DENALI Part 1b

In January 2025, we announced data from DENALI Part 1b (n=102). As of the December 2, 2024 data cutoff, in patients with Cyclin E1-positive PROC tumors who were response-evaluable (patients who had at least one scan after receiving azenosertib), an ORR of 34.9% (15/43; 95% confidence interval, or CI: 21.0 - 50.9) was observed. In the intent-to-treat patients with Cyclin E1-positive PROC (patients who received at least one dose of azenosertib), the ORR was 31.3% (15/48; 95% CI: 18.7 - 46.3). As of the December 2, 2024 data cutoff, the median duration of response, or mDOR, for the intent-to-treat population was still maturing and was approximately 5.5 months (95% CI: 2.7 - not estimable).

As of the December 2, 2024 data cutoff, azenosertib was observed to have a safety and tolerability profile that is favorable compared to published data from standard-of-care single-agent chemotherapy. Treatment-related serious adverse events occurred in 22 patients (21.6%).

The most common treatment-related adverse events of special interest or clinical significance for azenosertib, were nausea (65.7% all grades; 3.9% Grade 3+), fatigue (59.8% all grades, 15.7% Grade 3+), diarrhea (50.0% all grades; 6.9% Grade 3+), thrombocytopenia (34.3% all grades; 11.8% Grade 3+), and anemia (30.4% all grades, 10.8% Grade 3+). In addition, Grade 3+ sepsis occurred in 3 patients (2.9%), Grade 3+ febrile neutropenia occurred in 3 patients (2.9%), and Grade 3+ pancytopenia occurred in 1 patient (1.0%). Treatment-related adverse events led to dose reductions in 43 patients (42.2%), dose interruptions in 60 patients (58.8%) and discontinuations in 22 patients (21.6%). There were two previously reported treatment-related Grade 5 events in the study (2.0%). The DENALI Part 2 protocol contains measures for enhanced patient monitoring, guidance and supportive care, which could potentially improve discontinuation rates.

In March 2025 at the Society of Gynecologic Oncology 2025 Annual Meeting on Women's Cancer, or SGO, we disclosed updated data from DENALI Part 1b reflecting a January 13, 2025 data cutoff. As of the January 13, 2025 data cutoff, the ORR in patients with Cyclin E1-positive PROC tumors who were response-evaluable remained at 34.9% (15/43; 95% CI: 21.0 - 50.9). The safety and tolerability profile presented at SGO reflected treatment-related adverse events occurring in 10% or greater of patients and was consistent with the safety and tolerability profile reflected in the December 2, 2024 data cutoff, with no new safety findings. As previously disclosed in January 2025, the mDOR for the intent-to-treat population in DENALI Part 1b was still maturing. As of the January 13, 2025 data cutoff, the ongoing mDOR had increased to approximately 6.3 months (95% CI: 2.7 - not estimable). Since patients remain on study in DENALI Part 1b, the mDOR continues to mature.

MAMMOTH (ZN-c3-006) – Monotherapy

In January 2025, we announced data from the monotherapy arm of our Phase 1/2 clinical trial of azenosertib in patients with PARP-inhibitor resistant ovarian cancer. In the monotherapy arm of the study (n=61), patients who were PARPi refractory were treated with azenosertib at 300 mg QD 5:2 or 400 mg QD 5:2. As of the December 2, 2024 data cutoff, among Cyclin E1-positive patients treated at the primary dose-of-interest, 400 mg QD 5:2 (n=16), an ORR of 31.3% (5/16; 95% CI: 11.0 - 58.7) and an mDOR of 4.2 months (95% CI: 3.0, not estimable) were observed, and among Cyclin E1-positive patients treated at the 300 mg QD 5:2 dose level (n=14), an ORR of 21.4% (3/14; 95% CI: 4.7 - 50.8) and an mDOR of 4.9 months (95% CI: 3.0 - not estimable) were observed. The upper end of the mDOR confidence interval was not estimable due to the small number of patients and events.

As of the December 2, 2024 data cutoff, in the monotherapy arm of the MAMMOTH study at both 300mg QD 5:2 and 400mg QD 5:2 regardless of biomarker status, similar rates of treatment-related serious adverse events were observed across dose levels. There was a low rate of treatment-related Grade 3+ hematological toxicity with the majority being Grade 3 events, and only one Grade 4 febrile neutropenia event and one Grade 4 sepsis event. There was a low rate of treatment-related adverse events leading to treatment discontinuation: 16% in the 300 mg arm (n=4) and 5.6% in the 400 mg arm (n=2). There was one previously reported treatment-related Grade 5 event in the study.

ZN-c3-001

ZN-c3-001 is a Phase 1, dose-escalation study that evaluated azenosertib monotherapy in solid tumors across continuous and intermittent dosing schedules. ZN-c3-001 is fully enrolled (n=274). Greater anti-tumor activity was seen with intermittent dose schedules and in Cyclin E1-positive patients.

There were 23 patients with Cyclin E1-positive PROC who were dosed at intermittent schedules at total daily doses of ≥300 mg. In these patients as of the December 2, 2024 data cutoff, an ORR of 34.8% (8/23; 95% CI: 16.4 - 57.3) and an mDOR of 5.2 months (95% CI: 2.8, 6.9) were observed.

There were 11 patients with Cyclin E1-positive USC who were dosed at intermittent schedules at total daily doses of ≥300 mg. In these patients as of the December 2, 2024 data cutoff, an ORR of 36.4% (4/11; 95% CI: 10.9 - 69.2) and an mDOR of 5.5 months (95% CI: 5.4, not estimable) were observed. The upper end of the mDOR confidence interval was not estimable due to the small number of patients and events.

There were 193 patients in ZN-c3-001 at total daily doses of ≥300 mg across all tumor types and regardless of biomarker status. In these patients as of the December 2, 2024 data cutoff, azenosertib was shown to be tolerable with no Grade 3+ gastrointestinal treatment-related adverse events observed and low rates of Grade 3+ hematological toxicity, with the majority of hematological toxicity events being Grade 3. In these patients, there was also a low rate of treatment-related adverse events leading to discontinuation (n=10, 5.2%). There was one previously disclosed treatment-related Grade 5 event in the study (n=1, 0.5%).

Manufacturing

We currently do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We require that our CMOs produce active drug substance and finished drug product in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We maintain agreements with our CMOs that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We have engaged CMOs to manufacture, package, label and distribute azenosertib for preclinical and clinical use. We obtain our clinical trial supplies from these CMOs on a purchase order basis and do not have long-term supply arrangements in place. Although we do not currently have contractual arrangements in place for redundant supply for each component of the supply chain, we currently mitigate potential supply risks for azenosertib through inventory management. More broadly, we intend to identify and qualify additional manufacturers to provide the raw materials, active drug substance and drug product following the potential approval for azenosertib.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. While we believe that our product candidate azenosertib as a potential biomarker-directed, oral, non-chemotherapy treatment, development capabilities, experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Azenosertib, and any product candidate that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic 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 commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any medicines we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly

than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market. We believe that the key competitive factors affecting the success of any of our product candidates, if approved, will include efficacy, combinability, safety profile, convenience, cost, level of promotional activity devoted to them and intellectual property protection.

WEE1 Inhibitors

Currently, there are no WEE1 inhibitors approved by the FDA. Debiopharm Research & Manufacturing SA has disclosed that it is clinically evaluating a WEE1 inhibitor, Debio 0123, as both a monotherapy and in combination, for the treatment of advanced solid tumors. Bristol-Myers Squibb has disclosed it is evaluating a WEE1 degrader, BMS-986463, in select malignant tumors. Aprea Therapeutics, Inc., or Aprea, has disclosed that it is clinically evaluating a WEE1 inhibitor, APR-1051 (formerly ATRN-W1051) for advanced solid tumors. Schrödinger, Inc., or Schrödinger, has disclosed that it is evaluating multiple WEE1 inhibitors, including SGR-3515, a WEE1/Myt1 inhibitor, as potential monotherapy or combination therapy approaches for the treatment of gynecological cancers and other solid tumors. Acrivon Therapeutics, Inc. has disclosed that it is developing and evaluating a dual WEE1/PKMYT1 inhibitor, ACR-2316, currently in a Phase 1 trial as monotherapy for the treatment of solid tumors. Impact Therapeutics has disclosed that it is investigating IMP7068, a WEE1 inhibitor, currently in a Phase 1 trial for advanced solid tumors. Shouyao Holdings has disclosed that it is investigating SY-4835, a WEE1 inhibitor, in a Phase 1 trial for patients with advanced solid tumors. WuXi AppTec has disclosed that SC0191, a WEE1 inhibitor, is currently in Phase 2 development as a monotherapy or combination in advanced colorectal cancer. Wigen Biomedicine Technology (Shanghai) Co., Ltd has disclosed WJB001 is being evaluated as monotherapy or combination in advanced solid tumors. Other companies or institutions may have WEE1 inhibitors in preclinical development; however, to our knowledge none of these other companies or institutions have publicly disclosed information or timelines for an investigational new drug, or IND, filing.

Other

There are also other therapies available or in development, such as CDK2 inhibitors, antibody-drug conjugates and taxane-based combination therapies against various targets, that may compete with azenosertib as a treatment for PROC, if approved, and any other indications that azenosertib may be approved for.

Intellectual Property

We strive to protect the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on know-how and trade secret relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. In addition, we plan to rely on data exclusivity, market exclusivity and patent term extensions or adjustments when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to defend and enforce our proprietary rights, including any patents and trade secrets that we may own in the future; and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. Intellectual property rights may not address all potential threats to our competitive advantage.

With respect to our product candidates and processes we intend to develop and commercialize in the normal course of business, we intend, or understand that our licensors intend, to pursue patent protection covering, when possible, composition of matter, methods of use, dosing and formulations. We or our licensors also may pursue patent protection with respect to manufacturing and drug development processes and technologies. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies. We or our licensors may not be able to obtain patent protections for our composition of matter, methods of use, dosing and formulations, manufacturing and drug development processes and technologies throughout the world. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest non-provisional or PCT filing date. In addition, in certain instances, the term of an issued U.S. patent that is directed to or claims an FDA-approved product can be extended to recapture a portion of the term effectively lost due to the time spent on clinical trials and the FDA regulatory review, which is called “patent term extension.” The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the jurisdiction, but typically is also 20 years from the earliest non-provisional or PCT filing date plus any extensions of term that may be available under national law. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal

remedies in a particular country, and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biopharmaceuticals has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated, deemed unenforceable or circumvented, which could limit our ability to stop competitors from marketing-related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent directed to such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

In-licensed Patents and Patent Applications

Our wholly owned subsidiary, Zeno Management, Inc., or ZMI, has exclusively in-licensed or is the owner/assignee of issued patents and patent applications directed to our technology across our pipeline in the United States and many other major jurisdictions worldwide, including Europe, Japan and China. Certain issued patents and patent applications directed to azenosertib have been exclusively in-licensed from Recurium IP Holdings, LLC, or Recurium IP. For additional information on our license agreement with Recurium IP, see Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations—License Agreements and Strategic Collaborations" in this Annual Report.

The expected expiration dates for issued patents, or patents that may issue from any patent applications, directed to our WEE1 inhibitor program, including azenosertib, are between 2038 and 2047 plus any extensions or adjustments of term available under national law. However, there can be no assurance that any of the pending patent applications will issue. Furthermore, there can be no assurance that we will benefit from any patent term extension or favorable adjustments to the term of any of the issued patents or patents that may issue from any pending patent applications in the future. The applicable authorities, including the FDA in the United States and the U.S. Patent and Trademark Office, or USPTO, may not agree with our assessment of whether such patent term extensions or adjustments should be granted, and, if granted, they may grant more limited extensions or adjustments than we request.

Trademarks

Our trademark portfolio includes the ZENTALIS mark and the stylized “Z” mark, both of which are registered in the United States as well as in major foreign markets, including the EU, the United Kingdom, Japan and China.

Furthermore, we rely upon know-how, trade secret, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees, and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any such breach. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

License Agreements and Strategic Collaborations

Recurium IP Holdings, LLC License Agreement

In December 2014, our wholly owned subsidiary, Zeno Pharmaceuticals, Inc., entered into a license agreement, or the Recurium Agreement, with Recurium IP, which was subsequently amended, under which Zeno Pharmaceuticals, Inc. was granted an exclusive worldwide license to certain intellectual property rights owned or controlled by Recurium IP to develop and commercialize pharmaceutical products for the treatment or prevention of disease, other than for providing pain relief. Following a corporate restructuring disclosed elsewhere in this Annual Report on Form 10-K, our wholly owned subsidiary, ZMI, became the Zentalis contracting party to the Recurium Agreement. The intellectual property rights exclusively licensed by ZMI under the Recurium Agreement include certain intellectual property covering azenosertib. Under the terms of the Recurium Agreement, ZMI is obligated to make certain development and regulatory milestone payments with respect to azenosertib. See Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations—License Agreements and Strategic Collaborations" in this Annual Report for additional information.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the New Drug Application, or NDA, or Biologics License Application, or BLA, process before it may be legally marketed in the United States.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's Good Laboratory Practice, or GLP, requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA/BLA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and potential inspection of selected clinical investigation sites and the sponsor to assess compliance with GCPs; and
- FDA review and approval of the NDA/BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for allowance from the FDA to administer an investigational new drug product to humans. The IND includes results of animal and *in vitro* studies assessing the toxicology, PK, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND

automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include among other things, the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, or AEs, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of post-marketing studies, including Phase 4 studies, as a condition of approval of an NDA or BLA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 1, at the end of Phase 2, and before an NDA/BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach alignment on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug. Alternatively, sponsors planning for a Phase 2 registration study will utilize the meetings at the end of the Phase 1 trial to discuss Phase 1 clinical results and present plans for the Phase 2 registration study that they believe will support approval of the new drug.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, including results from preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA/BLA requesting approval to market the product. The submission of an NDA/BLA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs/BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of an NDA/BLA within the first 60 days after submission, before accepting the application for filing, to determine whether it is sufficiently complete to permit a substantive review. The FDA may request additional information rather than accept an NDA/BLA for filing. In this event, the NDA/BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA/BLA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA/BLA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee if they feel there is an issue regarding the benefit/risk of the drug. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA/BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA/BLA, the FDA will typically inspect the sponsor and one or more clinical sites to assure compliance with GCPs.

After the FDA evaluates an NDA/BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications and outlines post-marketing requirements with milestone dates. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA/BLA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA/BLA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA/BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for a particular indication(s) and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also approve the NDA/BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication

guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA may also mandate post-marketing requirements, including one or more post-market studies and/or surveillance programs, to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs/BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates.

Fast Track Designation

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development. With regard to a fast track product, the FDA may consider for review sections of the NDA/BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA/BLA, the FDA agrees to accept sections of the NDA/BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA/BLA.

Breakthrough Therapy Designation

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers at FDA.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority Review

An NDA/BLA is eligible for priority review if the product candidate has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the FDA's acceptance for filing date as compared to ten months for review of new molecular entity NDAs or original BLAs under its current PDUFA review goals.

Accelerated Approval

In addition, depending on the design of the applicable clinical studies, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such confirmatory clinical trials be underway prior to granting accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner, or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the U.S. Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. An applicant must request orphan drug designation before submitting an NDA/BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for limited grant funding towards clinical trial costs, research tax advantages, and user fee waivers. If a product that has orphan designation subsequently receives the first FDA approval within the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity. This means the FDA may not approve any other applications, including full NDAs/BLAs, to market the same drug, as defined by the FDA, for the same approved use or indication with the applicable rare disease or condition for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity within the relevant indication or use. Competitors, however, may receive approval of either a different product for the same indication or use of the same product for a different indication or use. Orphan exclusivity also could block the approval of a product for seven years in the relevant indication or use if a competitor obtains approval of the "same drug," as defined by the FDA, or if such drug is determined to be contained within the competitor's product. If a drug designated as an orphan product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs relating to the approved indication or use of patients with the rare disease or condition.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to 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 to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an 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, for example new indications, dosages or strengths of an existing

drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. 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 any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of exclusivity attached to another existing patent term or period of regulatory exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

The Affordable Care Act, or the ACA, which was enacted in 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. This 12-year exclusivity period is referred to as the reference product exclusivity period and bars approval of a biosimilar but notably does not prevent approval of a competing product pursuant to a full BLA (i.e., containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the product). The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity, and enforceability prior to the approval of the biosimilar.

Foreign Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, marketing authorization, post-marketing requirements and any commercial sales and distribution of our product candidates.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or prior to marketing of the product candidates in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines or operating restrictions.

Non-Clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union, or EU, are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the GLP principles, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide "no fault" compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, repealed the EU Clinical Trials Directive and became applicable on January 31, 2022. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a clinical trials information system, which contains a centralized EU portal and database. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in trials must be made following good manufacturing practice, or GMP. Other national and EU rules may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. In the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs (i.e., centralized and national MAs). Our product candidate is expected to be subject to the centralized MA procedure. Centralized MAs are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops. The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Other Healthcare Laws

Pharmaceutical and medical device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, fraud and abuse, false claims, consumer fraud, pricing reporting, and transparency laws and regulations as well as similar state and foreign laws in the jurisdictions outside the United States. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, apply to companion diagnostics.

Third-party payors are increasingly reducing reimbursements for pharmaceutical products and services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are more and more frequently challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. The ACA, was enacted in 2010, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, absent additional congressional action. In addition, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in executive orders, several U.S. 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 drug products. The Inflation Reduction Act, or the IRA, was enacted in 2022. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; redesigns the Medicare Part D benefit; and replaces the Part D coverage gap discount program with a new manufacturer discount program. The Centers for Medicare & Medicaid Services, or CMS, has published the negotiated prices

for the initial ten drugs, which became effective in 2026, and the subsequent fifteen drugs, which will first be effective in 2027. CMS has also published the next set of fifteen drugs that will be subject to negotiation. Additional drugs will become subject to the Medicare price negotiation program in each following year. The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The current U.S. presidential administration is pursuing a two-fold strategy to reduce drug costs in the United States. While it is unclear whether and how the administration's proposals will be implemented, the proposed policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for product candidates that receive approval. On the one hand, the administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price of drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the current administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the United States that is based on drug prices outside the United States would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that ultimately do not go into effect or are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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, designed to encourage importation from other countries and bulk purchasing. Some states have also enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA or ex-U.S. regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, new and changing laws, regulations, executive orders and other governmental actions, as well as changing interpretations by government of laws and regulations, may also create uncertainty about how to comply with laws and regulations. Changes in binding legal standards that materially affect our business may be announced, and we may be unable to effectively mitigate all adverse impacts from such measures. If we are found to have violated binding legal standards, we could face significant fines, government investigations, litigation, and reputational harm, which could materially adversely affect our business, reputation, results of operations, and financial condition.

FDA Approval and Regulation of Companion Diagnostics

If safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of *in vitro* companion diagnostics in conjunction with the review of our therapeutic treatments for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance.

Unless an exemption applies, each medical device commercially distributed in the United States generally requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval, or a PMA application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. While most Class I devices—devices that generally pose a low risk to users—are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are automatically placed in Class III, requiring approval of a PMA unless down-classified in accordance with the "*de novo*" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

To obtain 510(k) clearance, a manufacturer must submit to the FDA a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or request down-classification of the device through the "*de novo*" process.

The PMA process is more demanding than the 510(k) premarket notification process, and can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality Management System Regulation, or QMSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the

PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QMSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing

Human Capital Resources

As of December 31, 2025, Zentalis had a total of 106 employees all of whom were full-time employees. In 2025 Zentalis completed a strategic restructuring, which included a workforce reduction by approximately 40%, to support the execution of late-stage development for azenosertib and extend its cash runway. None of our employees are represented by labor unions or covered by any collective bargaining agreements.

Zentalis aims to drive positive social impact, including by improving the lives of cancer patients through our therapeutics. Below are a couple of initiatives that demonstrate our focus on social impact:

- We prioritize the safety and well-being of our patients and our employees. Our employees receive annual trainings on general safety, quality assurance and standard operating procedures to help ensure that we are managing risks and operating safely. We continue to evaluate our practices to address our employees' health and well-being.

- We are committed to being an equal opportunity employer and enhancing diversity and inclusivity, including diversity of thought and experience. We are proud of the diversity we have cultivated throughout the company and our management team. We intend to continue to develop our workforce in compliance with all applicable laws in an equitable fashion based on performance and merit. Our Code of Business Conduct and Ethics prohibits discrimination of any protected group, and our employees participate in regular anti-harassment training.

- We are dedicated to supporting a talented team and strive to offer competitive compensation, including salaries, bonuses and equity awards, and benefits in order to support our business objectives, assist in the achievement of our strategic goals and create value for our stockholders. We formally review employee performance annually and provide merit increases, bonus payments and annual equity awards, subject to achievement of certain goals. In addition to offering benefits such as medical, dental, vision, 401(k) with company matching, flexible spending for healthcare and dependent care, life insurance and both short and long-term disability, we offer work / life balance benefits and

employee development opportunities. These include flexible time off, voluntary life-illness-accident insurance, wellness challenges and healthy food options onsite. We also have a variety of company-wide events designed to support camaraderie and encourage teamwork and collaboration. We maintain the Zentalis Pharmaceuticals, Inc. 2020 Employee Stock Purchase Plan for all full-time employees who elected to participate—a benefit we are proud to offer and that we believe helps to foster our corporate culture and encourage collaboration towards our shared business success.

Zentalis prioritizes governance systems and policies that promote fair, transparent and efficient business practices. Here are a few initiatives that demonstrate our focus on good governance:

- Our Board of Directors and Executive Leadership Team oversee all material human capital resource decisions.
- We have employee trainings, procedures and policies in place to train our employees on data privacy and cybersecurity. Trainings take place at regular intervals and cover threats and phishing risk. We also have a defined information security incident response plan that is designed to assist Zentalis in detecting and managing cybersecurity incidents. See Part I, Item 1C. "Cybersecurity" for additional information
- We have adopted a Code of Business Conduct and Ethics, and we conduct regular trainings on a variety of related topics, including insider trading compliance and anti-harassment.

Corporate Information

We were initially formed as Zeno Pharmaceuticals, Inc., a Delaware corporation, in December 2014. In conjunction with a corporate restructuring, Zeno Pharma, LLC, a Delaware limited liability company, was formed, and in December 2017 acquired Zeno Pharmaceuticals, Inc., pursuant to a merger agreement. As a result of this merger, Zeno Pharmaceuticals, Inc. became a wholly-owned subsidiary of Zeno Pharma, LLC. In December 2019, Zeno Pharma, LLC changed its name to Zentalis Pharmaceuticals, LLC. In April 2020, in connection with our initial public offering, Zentalis Pharmaceuticals, LLC was converted to a Delaware corporation pursuant to a statutory conversion and changed its name to Zentalis Pharmaceuticals, Inc.

Available Information

Our Internet address is www.zentalis.com. At our investor relations website, https://ir.zentalis.com/, we make available free of charge a variety of information for investors, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements for our annual meetings of stockholders, and any amendments to those reports, as soon as reasonably practicable after we electronically file that material with or furnish it to the SEC. Additionally, we routinely post additional important information, including press releases, on our investor relations website and on LinkedIn and recognize our investor relations website and LinkedIn as channels of distribution to reach public investors and as means of disclosing material non-public information for complying with disclosure obligations under Regulation FD.The information found on our website is not part of this Annual Report on Form 10-K or any other report we file with, or furnish to, the SEC. The SEC also maintains a website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is https://www.sec.gov.

Item 1A. Risk Factors

You should carefully consider the risks and uncertainties described below and the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain important factors, including those set forth below.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing potential product candidates, securing related intellectual property rights, and conducting preclinical studies and clinical trials of our product candidates, including the ongoing clinical trials of azenosertib. We have not yet demonstrated our ability to obtain marketing approvals, supply a product at commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred net losses in almost every reporting period since our inception, we have not generated any revenue from product sales to date, and we have financed our operations principally through private financings, our initial public offering, or IPO, and follow-on public offerings of our common stock. We have incurred net losses of $137.1 million and $165.9 million for the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $1.2 billion. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of azenosertib and any future product candidates. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

Our ability to generate product revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Our business depends entirely on the successful discovery, development and commercialization of azenosertib and any future product candidates. We currently generate no revenues from sales of any products. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate product revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve a number of objectives, including:

- successful and timely completion of the clinical development of azenosertib as a monotherapy for the treatment of Cyclin E1-positive PROC, successful and timely completion of the development of a companion diagnostic with a diagnostic partner to identify patients with Cyclin E1-positive PROC, and meeting the associated costs thereof, including any unforeseen costs we have incurred and may continue to incur as a result of delays including due to public health emergencies, U.S. and global economic issues, such as rising inflation, or ongoing military conflicts, among other causes;
- successful and timely completion of the clinical development of azenosertib for additional oncology indications and of any future product candidates, resources allowing;
- if applicable, the availability or successful development of diagnostic tools for biomarkers for any future product candidates or for additional biomarkers for azenosertib;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development, both in the United States and internationally, of azenosertib and any future product candidates, resources allowing;
- timely receipt of marketing approvals from applicable regulatory authorities for azenosertib for the treatment of Cyclin E1-positive PROC and, resources allowing, additional oncology indications for azenosertib and any future product candidates, in each case for which we successfully complete clinical development;
- timely receipt by our diagnostic partner of a marketing approval for a companion diagnostic to identify patients with Cyclin E1-positive PROC and, if applicable, marketing approval of diagnostic tools for biomarkers for any future product candidates and any additional biomarkers for azenosertib;
- maintaining marketing approvals, including our diagnostic partner's maintaining its marketing approval of a companion diagnostic to identify patients with Cyclin E1-positive PROC, and making any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding our intellectual property rights, including patents, trade secrets and know how, and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining adequate pricing, coverage and reimbursement by hospitals, government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel, especially in the current labor market.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations. Additionally, our current prioritization of a single product candidate means that our financial prospects are closely tied to the success of azenosertib. Any setbacks in its development or commercialization could have a material adverse effect on our financial condition and ability to continue operations.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. If our azenosertib development program continues to advance successfully, we expect our expenditures to increase as we initiate and execute our planned Phase 3 confirmatory clinical trial and prepare for potential commercialization. Even if azenosertib or any future product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. We are incurring costs related to collaborating with a diagnostic company for the development, manufacturing and supply of a companion diagnostic to identify patients with Cyclin E1-positive PROC, and we may in the future incur costs relating to additional diagnostic tools for biomarkers associated with azenosertib and any future product candidates. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, including azenosertib, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We have also incurred, and expect to continue to incur, costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2025, we had cash and cash equivalents and marketable securities of $245.9 million. Based on current business plans, we believe that our existing cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund our operating expenses and capital expenditure requirements into late 2027, but will not be sufficient to fund all of the activities that are necessary to complete the development of azenosertib and any future product candidates. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Market volatility resulting from public health emergencies, U.S. and global economic issues, global supply chain disruptions, international political instability, rising inflation or other factors could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our clinical trials or future commercialization efforts.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of azenosertib, which is currently our only product candidate in clinical development. If we are unable to complete development of, obtain approval for and commercialize azenosertib in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our only product candidate in clinical development, azenosertib. We are investing significant efforts and financial resources in the research and development of azenosertib, which will require additional clinical development, additional clinical, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote any product candidate before we receive marketing approval from the FDA and/or ex-U.S. regulatory authorities, and we may never receive such marketing approvals.

The success of azenosertib will depend on several factors, including the following:

- the successful and timely completion of our ongoing and planned clinical trials;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of azenosertib both in the United States and internationally;
- the frequency and severity of AEs observed in clinical trials;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA and/or any ex-U.S. regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the successful development, in collaboration with our diagnostic partner, of a companion diagnostic for our lead indication for azenosertib and the availability or successful development of diagnostic tools for any additional biomarkers for azenosertib;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug substance and drug product suppliers and manufacturers for clinical development of azenosertib;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of azenosertib, if approved, including for supplies of drugs that we are testing in combination with azenosertib;
- obtaining and maintaining our intellectual property rights, including patents, trade secrets and know how, and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights, and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize azenosertib or any future product candidates, which would materially harm our business. If we do not receive marketing approvals for azenosertib, or any future product candidates, we may not be able to continue our operations.

We have and in the future may enter into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any of these collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We have in the past and in the future may seek third-party collaborators for the research, development and commercialization of one or more of our product candidates. For example, we have collaborated with Pfizer, GSK and Dana Farber on the development of azenosertib. Our likely collaborators in any future collaboration arrangements include large and mid-size pharmaceutical companies and biotechnology companies. If we were to enter into any collaboration arrangements with third parties, those agreements may limit our control over the amount and timing of resources that our collaborators dedicate to the development and commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration in which we have entered or may enter. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations involving azenosertib and any future research programs or product candidates we may develop pose risks to us, including the following:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in

the collaborator's strategic focus or market considerations, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition or business combination that diverts resources or creates competing priorities. If this were to happen, we may need additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, use our product candidates in clinical trials in an unsafe manner, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Subject to certain diligence obligations, collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products.
- Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use proprietary information in a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in cases where that applies, we would not have the exclusive right to commercialize the collaboration intellectual property.
- Disputes may arise between our collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.
- Collaborators may be unable to maintain compliance with applicable laws, regulations and guidance, including good practice quality guidelines and regulations, including GLP, GCP, and cGMP, or similar ex-U.S. requirements or to secure approval for clinical development plans from the FDA or ex-U.S. regulatory authorities.
- We may require certain regulatory, clinical, manufacturing, financial and other information from our collaborators, which, if not provided in a timely manner or at all, could affect our ability to meet our business objectives and/or comply with applicable laws, regulations and guidance.

If we do not receive the funding or other resources we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, marketing approval and commercialization described in this report apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These and other similar relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of those transactions if we are unable to successfully integrate them with our existing operations and company culture.

Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Following our January 2025 strategic restructuring, we are primarily focused on the late-stage clinical development of azenosertib. However, our long-term success may also depend on our ability to successfully discover, develop, obtain regulatory approval for and commercialize additional product candidates beyond azenosertib. Our future operating results are

dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond azenosertib. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- AEs in the clinical trials.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other product candidates.

The regulatory approval processes of the FDA and ex-U.S. regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for azenosertib or any future product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Ex-U.S. regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and ex-U.S. regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and ex-U.S. regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that neither azenosertib nor any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or ex-U.S. regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or ex-U.S. regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or ex-U.S. 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 support the submission of a New Drug Application, or NDA, or Biologics License Application, or BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or ex-U.S. regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

- the FDA or ex-U.S. regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- if the FDA or ex-U.S. regulatory authority requires approval or clearance of a companion diagnostic for a particular product candidate, which we expect to be the case for monotherapy azenosertib for the treatment of patients with Cyclin E1-positive PROC, and the FDA or comparable regulatory authority does not provide such approval or clearance, then the product candidate may not be approved for marketing; and/or
- the approval policies or regulations of the FDA or ex-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, the policies and practices of the FDA and ex-U.S. regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For example, in recent years the FDA has issued guidance and launched programs aiming to reform and modernize the dose optimization procedures used by clinical trial sponsors during the development of oncology drugs. Since these guidelines are new and can potentially evolve during the conduct of our clinical trials, changes in the FDA's thinking with respect to dose selection and optimization could require us to change the design of our planned or ongoing clinical trials or otherwise conduct additional preclinical, clinical or manufacturing studies beyond those we currently anticipate, which could increase our costs and/or delay the development of our product candidates.

In addition, the regulatory landscape related to clinical trials in the EU has evolved in the last few years. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR three-year transition period ended on January 31, 2025, and all clinical trials (including related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us, our collaborators and third-party service providers, such as CROs, may impact our development plans.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings and precautions, or a Risk Evaluation and Mitigation Strategy, or REMS, or similar risk management measures. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

The clinical trials of azenosertib or any future product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA or ex-U.S. regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from the FDA or ex-U.S. regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials, including that potential biomarkers, even if validated preclinically or in early-stage clinical trials, may not be functionally validated in later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. We cannot guarantee that the FDA or ex-U.S. regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates, which may require us to expend significant resources that may not be available to us and/or cause delays in our planned timelines. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, we may rely in part on preclinical, clinical and quality data generated by CROs, our collaborators and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing our relationships with these third parties, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, do not make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or ex-U.S. regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs, or ethics committees;
- IRBs or ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which a product candidate is being developed, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related AEs;
- occurrence of serious AEs in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or ex-U.S. regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or similar ex-U.S. requirements or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- the imposition of a clinical hold by the FDA, such as the azenosertib partial clinical hold we announced in June 2024 that was lifted in September 2024 without any changes required by FDA to the azenosertib clinical development plan;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; and/or
- if we are collaborating with a third party on a clinical trial, our collaborator may not devote sufficient resources to or prioritize our clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or ex-U.S. regulatory authorities. Such a suspension or termination may be due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or ex-U.S. regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects resulting in the imposition of a clinical hold, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments will require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in ex-U.S. countries, as we do for azenosertib, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in ex-U.S. countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with ex-U.S. regulatory schemes, as well as political and economic risks relevant to such ex-U.S. countries.

Moreover, 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. Under certain circumstances, we may be required to report some of these relationships to the FDA or ex-U.S. regulatory authorities. The FDA or ex-U.S. regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or ex-U.S. regulatory authority 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 or ex-U.S. regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We expect to be required by the FDA and ex-U.S. regulatory authorities to obtain approval of a companion diagnostic in connection with approval of our lead indication for azenosertib, and additional biomarkers may be required for the development and commercialization of azenosertib outside of our lead indication and for future product candidates. If regulatory approval is not obtained or there are delays in obtaining regulatory approval of any such companion diagnostic, we will not be able to commercialize azenosertib and, potentially, future product candidates, and our ability to generate product revenue will be materially impaired.

We are working with a diagnostic partner to develop a companion diagnostic to identify patients with Cyclin E1-positive PROC in connection with our clinical development of monotherapy azenosertib for the treatment of patients with Cyclin E1-positive PROC, and we expect the FDA and ex-U.S. regulatory authorities to require approval of this companion diagnostic in connection with approval of monotherapy azenosertib for this indication. In addition, in the future, we may develop diagnostic tools for additional biomarkers for azenosertib and future product candidates for which the FDA and ex-U.S. regulatory authorities may require us or a third party collaborator to obtain marketing approval.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Many ex-U.S. regulatory authorities have similar requirements as the FDA for companion diagnostics. If there is not a satisfactory companion diagnostic commercially available for a particular biomarker, which is the case for Cyclin E1-positive PROC, we would be required to develop or obtain such diagnostic, which would be subject to regulatory approval requirements. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates, which we have done for our development of monotherapy azenosertib for the treatment of Cyclin E1-positive PROC. The process of obtaining or creating a companion diagnostic is time consuming and costly and may not result in any future income. This could require us to raise additional funds, which could dilute our current investors or impact our ability to continue our operations in the future.

In addition, we may have difficulty in establishing or maintaining development relationship with diagnostic partners, and we will face competition from other companies in establishing and maintaining these partnerships. We face similar risks

with our relationships with diagnostic partners as we face with other collaborations - see "We have and in the future may enter into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any of these collaborations is not successful, we may not be able to capitalize on the market potential of those product candidates" above for more information.

There are also several risks associated with biomarker identification and validation. We, in collaboration with any diagnostic partners, may not be able to identify predictive biomarkers for one or more of our programs. We may not be able to validate potential biomarkers (e.g., certain genomic mutations) or their functional relevance preclinically in relevant *in vitro* or *in vivo* models. Data analytics and information from databases that we rely on for identifying or validating some of our biomarker-target relationships may not accurately reflect potential patient populations or may be based on incorrect methodology. Potential biomarkers, even if validated preclinically, may not be functionally effective or validated in human clinical trials. There are also risks associated with diagnostics that are commercially available, including that we may not have access to reliable supply for such diagnostics, and that such diagnostics may not be reimbursed without obtaining regulatory approval.

If we, in collaboration with our diagnostic partner, are unable to successfully develop a Cyclin E1-positive PROC companion diagnostic for azenosertib, or experience delays in doing so, including delays in obtaining regulatory approvals, the development of monotherapy azenosertib for patients with Cyclin E1-positive PROC will be adversely affected, which will have a material adverse effect on our business. In addition, if additional indications of azenosertib or any future product candidates require a companion diagnostic or other diagnostic tool and we, in collaboration with diagnostic partners, are unable to successfully develop such tools, or such tools are not available commercially, or we experience delays in doing so, then the development of such product candidates will be adversely affected, which could have a material adverse effect on our business.

We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for a companion diagnostic, such as the one our diagnostic partner is developing for identifying patients with Cyclin E1-positive PROC, or in transferring that process to commercial partners, if applicable, or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing azenosertib and any future product candidates, if approved, on a timely or profitable basis, if at all.

Interim, initial, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We may publicly disclose initial, preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or 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 initial, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Certain of these data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, initial, topline and preliminary data should be viewed with caution until the final data are available. For example, in January 2025, we announced monotherapy azenosertib clinical data in patients with Cyclin E1-positive PROC, who were identified using a proprietary immunohistochemistry cutoff defined by retrospective tissue analysis utilizing a Cyclin E1 biomarker assay. In our DENALI Part 2 clinical trial, we are identifying patients using our proprietary immunohistochemistry cutoff with a prospective tissue analysis utilizing the Cyclin E1 biomarker assay. If we have not identified the optimal immunohistochemistry cutoff, or if our Cyclin E1 biomarker assay does not function as it functioned previously, or if the historical correlation between retrospective tissue analysis and response rates is not replicated with prospective tissue analysis, then the clinical data we announced in January 2025 may be materially different in DENALI Part 2 and in future studies.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the

particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the initial, interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Even if approved, azenosertib and any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if azenosertib and any future product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- if applicable (which we expect to be the case for monotherapy azenosertib in Cyclin E1-positive PROC), the availability and/or reimbursement of diagnostic tools such as companion diagnostics for biomarkers associated with our product candidates or any other future product candidates;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, or similar risk management measures, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of the product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- for combination therapies, the availability of the combination product ;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If azenosertib or any future product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

If we experience delays or difficulties in the enrollment and/or continuing participation of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for azenosertib and any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to each such trial's conclusion as required by the FDA or ex-U.S. regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;

- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials; and
- geopolitical changes may impact the ability to enroll in countries selected for clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining such patients on trial.

A fast track designation from the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive regulatory approval.

The FDA has granted fast track designation for azenosertib for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who are positive via Cyclin E1 immunohistochemistry for protein levels. We intend to seek such fast track designation for some or all of our future product candidates when applicable. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, drugs and biologics are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA or BLA is submitted, the application may be eligible for priority review. An NDA or BLA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even where we do receive fast track designation for any of our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that azenosertib or any other product candidate that may be granted fast track designation will receive regulatory approval in the United States. Many product candidates that have received fast track designation have ultimately failed to obtain approval.

We are developing azenosertib in combination with other therapies, which exposes us to additional risks.

We are developing azenosertib in combination with one or more other approved therapies to treat cancer and may in the future develop azenosertib or additional product candidates in combination with other approved or unapproved therapies. If we were to experience an unexpected loss of supply of any of those approved or unapproved therapies, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or ex-U.S. regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the

standard of care for the indications we choose for any of our product candidates, the FDA or ex-U.S. regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

In the event we evaluate azenosertib or other future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or ex-U.S. regulatory authorities, we will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product candidate. In addition, unapproved therapies face the same risks described herein with respect to product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of regulatory approval.

If the FDA or ex-U.S. regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

If the market opportunity for azenosertib or any future product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

Our projections of addressable patient populations that may benefit from treatment with azenosertib and any future projections we may make with respect to any future product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population for azenosertib and any future product candidates may not ultimately be amenable to treatment with such product candidate. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates proves to be inaccurate, the market opportunity for such product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with azenosertib and any future product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the indications for which we are currently developing azenosertib and for the indications for which we may attempt to develop azenosertib and any future product candidates. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

In particular, there is intense competition in the fields of oncology we are pursuing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We have chosen to initially address well-validated biochemical targets, and therefore expect to face competition from existing products and products in development for each of our product candidates. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may

also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or other comparable ex-U.S. regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA or ex-U.S. regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

We may expend our limited resources to pursue a particular product candidate or indication 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 on product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on and current prioritization of azenosertib, and any future product candidates for specific indications, may not yield any commercially viable products. 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.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. 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 commercialize our product candidates, if approved, and generate revenue.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to 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 products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain 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 have an adverse effect on our business and financial condition. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, may apply to diagnostic tools, such as companion diagnostics, that we or our collaborators develop.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as azenosertib and any of our future product candidates, if approved. In many countries, particularly the member states of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing authorization. To obtain 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 general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional ex-U.S. price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for azenosertib or any future product candidates, if approved, from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, we or our collaborators may develop diagnostic tests, including companion diagnostic tests, for use with azenosertib or any of our future product candidates, such as the companion diagnostic test being developed by our diagnostic collaborator to identify patients with Cyclin E1-positive PROC relating to our development of monotherapy azenosertib for patients with Cyclin E1-positive PROC. Companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to

obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

We may be unable to obtain U.S. or ex-U.S. regulatory approvals and, as a result, may be unable to commercialize azenosertib or any future product candidates.

Azenosertib and any future product candidates we may develop are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many ex-U.S. jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that azenosertib or any future product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its ex-U.S. counterparts use when evaluating clinical trial data can change during drug development, which makes it difficult to predict with any certainty how they will be applied. In addition, the FDA and its ex-U.S. counterparts may require approval or clearance of a companion diagnostic for a particular product candidate and may not approve the product candidate for marketing if such regulatory authority does not approve or clear the companion diagnostic. For example, we expect the FDA and its ex-U.S. counterparts to require regulatory approval of the companion diagnostic test being developed by our diagnostic collaborator to identify patients with Cyclin E1-positive PROC relating to our development of monotherapy azenosertib for patients with Cyclin E1-positive PROC, and any delays in obtaining approval or clearance for such companion diagnostic could similarly delay potential regulatory approval of azenosertib. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA or ex-U.S. regulatory authorities policy during the period of drug development, clinical trials and FDA or ex-U.S. regulatory authorities regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving an NDA or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. Similar requirements may exist in ex-U.S. jurisdictions. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous ex-U.S. regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The ex-U.S. regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in ex-U.S. jurisdictions. Moreover, the time required to obtain approval in ex-U.S. jurisdictions may differ from that required to obtain FDA approval.

Azenosertib or any future product candidates may cause significant AEs, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and AEs associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory

approval by the FDA or ex-U.S. regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If azenosertib or any future product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our ongoing and planned clinical trials may in the future suffer significant AEs or other side effects not observed in our preclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate AEs associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation, chemotherapy and other treatments, which can cause side effects or AEs that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant AEs or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA or ex-U.S. regulatory authorities, or an IRB (or similar body) may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects.

Moreover, some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates not seen during clinical testing may also develop after such approval and may lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The FDA and ex-U.S. regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We are conducting international clinical trials for azenosertib and may in the future conduct international clinical trials for other product candidates. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or ex-U.S. regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from ex-U.S. clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of ex-U.S. data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP requirements; and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Furthermore, even where the ex-U.S. study data are not intended to serve as the sole basis for approval, if the trial was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many ex-U.S. regulatory authorities have similar approval requirements. In addition, such ex-U.S. trials would be subject to the applicable local laws of the ex-U.S. jurisdictions where the trials are conducted. There can be no assurance that the FDA or any ex-U.S. regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any ex-U.S. regulatory authority does not accept such data, it

would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in ex-U.S. jurisdictions must also approve the manufacturing processes, marketing, promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining ex-U.S. regulatory approvals and establishing and maintaining compliance with ex-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or ex-U.S. regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs or similar ex-U.S. requirements and GCP for any clinical trials that we conduct post-approval. In addition, CMOs and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations or similar ex-U.S. requirements and standards. If we or a regulatory agency discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and ex-U.S. regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials by the FDA or ex-U.S. regulatory authorities;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate product revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and ex-U.S. regulatory authorities' policies, or implementation of existing policies, may change and additional government regulations may be enacted, including as a result of the new U.S. presidential administration, that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates is approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Changes and/or disruptions at the FDA, the SEC and other government agencies, including as a result of government shutdowns, funding shortages, staffing changes or limitations, or global health concerns could prevent those agencies from performing business functions as they were previously performed, which could negatively impact our business.

The ability of the FDA and other regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, changes in presidential administrations, political fluctuations, and other events that may otherwise affect the FDA's and ex-U.S. regulatory authorities' ability to perform routine functions. Average review times at the FDA and ex-U.S. regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Changes and/or disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in 2025 and in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Further, in our operations as a public company, future or prolonged government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Further, the current U.S. presidential administration has issued certain policies and executive orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs or if there are delays and slowdowns caused by staffing limitations, funding shortages, or for other reasons, these actions and events could significantly impact the ability of the FDA or ex-U.S. regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. It could also impact our ability to access the public markets and obtain necessary capital in order to properly fund our operations.

If we are unable to obtain accelerated approval or any other form of expedited development or review from the FDA or ex-U.S. regulatory authorities, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We plan to seek accelerated approval from the FDA for monotherapy azenosertib for the treatment of Cyclin E1-positive PROC, subject to supportive clinical data and FDA review. In addition, we may in the future seek accelerated approval or another form of expedited development or review for azenosertib in another indication or future product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis. In addition the Food and Drug Omnibus Reform Act of 2022 provided the FDA statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

In the EU, under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use may perform an accelerated assessment of a marketing authorization application. Applicants requesting an accelerated assessment procedure must justify that the product candidate is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. Conditional approval is also available in the EU, which is similar to the FDA's accelerated approval program.

Prior to seeking accelerated approval or another form of expedited development or review for any of our product candidates, we intend to seek feedback from the FDA or ex-U.S. regulatory authorities and will otherwise evaluate our ability to seek and receive accelerated approval or another form of expedited development or review. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA, whichever is applicable, for accelerated approval or another form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval or another form of expedited development, review or approval for azenosertib or any future product candidate, there can be no assurance that such submission or application will be accepted or that any such expedited development, review or approval will be granted on a timely basis, or at all. The FDA or ex-U.S. regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for azenosertib would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize any approved product candidate and may adversely affect the prices we may obtain and may have a negative impact on our business and results of operations.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of azenosertib and any future product candidates and affect our ability to profitably sell our products for which we receive approval. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, including by executive order, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

New and changing laws and regulations, including by executive order, may also create uncertainty about how existing laws and regulations will be interpreted and applied, including pricing. If the Company is found to have violated laws and regulations, it could materially adversely affect the Company's business, results of operations and financial condition.

For example, the ACA was enacted in 2010, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the American Rescue Plan Act of 2021, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously

capped at 100% of a drug's average manufacturer price. It is unclear how other healthcare reform measures will impact our business.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in executive orders, several U.S. 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 drug products. The IRA was enacted in 2022. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; redesigns the Medicare Part D benefit; and replaces the Part D coverage gap discount program with a new manufacturer discount program. CMS has published the negotiated prices for the initial ten drugs, which became effective in 2026, and the subsequent fifteen drugs, which will first be effective in 2027. CMS has also published the next set of fifteen drugs that will be subject to negotiation. Additional drugs will become subject to the Medicare price negotiation program in each following year. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The current U.S. presidential administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the administration's proposals will be implemented, the proposed policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for product candidates that receive approval. On the one hand, the administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price of drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the current administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the United States that is based on drug prices outside the United States would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that ultimately do not go into effect or are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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, designed to encourage importation from other countries and bulk purchasing. Some states have also enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA or ex-U.S. regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's

approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, new and changing laws, regulations, executive orders and other governmental actions, as well as changing interpretations by government of laws and regulations, may also create uncertainty about how to comply with laws and regulations. Changes in binding legal standards that materially affect our business may be announced, and we may be unable to effectively mitigate all adverse impacts from such measures. If we are found to have violated binding legal standards, we could face significant fines, government investigations, litigation, and reputational harm, which could materially adversely affect our business, reputation, results of operations, and financial condition.

In the EU, pharmaceutical legislation has been undergoing a complete review process in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement by the European Parliament and Council of the EU on the proposed revisions was reached on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions. The proposed changes are not expected to enter into application before 2028 and may have a significant impact on the pharmaceutical industry in the long term.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to fraud and abuse laws and other healthcare laws and regulations.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal, state and ex-U.S. healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Open Payments Act (formerly known as the Physician Payments Sunshine Act) requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law, certain non-physician practitioners including physician assistants and nurse practitioners, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually; and
- analogous state and ex-U.S. laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and ex-U.S. laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or ex-U.S. laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties, but we may, however, obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. Additionally, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information, and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have passed in other states, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. To the extent that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For instance, the European Union General Data Protection Regulation, or EU GDPR, and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018, collectively the UK GDPR, and together with the EU GDPR, the GDPR, imposes strict requirements for processing the personal data of individuals within the European Economic Area, or the EEA, and the UK or in the context of our activities in the EEA, and the UK. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR, and subject to additional compliance obligations and to local law derogations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements, administrative penalties and potential fines for noncompliance of up to €20 million / £17.5 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. We currently rely on the EU standard contractual clauses, the UK Addendum to the EU standard contractual clauses and the UK International Data Transfer Agreement, as relevant, to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third party transfers. We may also rely on individual consent to transfer personal data in certain circumstances. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could incur additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

In addition, we selectively use artificial intelligence, or AI, in our business. The regulatory framework for AI is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA and other ex-U.S. authorities regulations, provide accurate information to the FDA or ex-U.S. regulatory authorities, comply with federal, state and ex-U.S. health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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 by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We have been and may in the future be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations have and may in the future involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also have and may in the future produce hazardous waste products. We have previously contracted with third parties for the disposal of these materials and wastes and were not able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain ex-U.S. export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in ex-U.S. markets and subject us to liability if we violate them.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered ex-U.S. officials under the FCPA. During the prior U.S. presidential administration, the SEC and the U.S. Department of Justice increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products and activities may be subject to U.S. and ex-U.S. export controls, trade sanctions, tariffs and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements or otherwise address the loss in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future

success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

In addition, losing employees, including as a result of a workforce reduction such as the one announced in January 2025, which was operationally completed during the year ended December 31, 2025, subjects us to a number of risks, including the failure to transition responsibilities and tasks, the need to adapt or create systems and processes, the impact on corporate culture, and the loss of historical knowledge.

If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We have never commercialized a product candidate. In order to commercialize any product candidates, if approved, for which we retain commercialization rights, we must build marketing, sales, distribution, market access, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks. In addition, for product candidates for which we do not retain commercialization rights, we will rely on the assistance of collaborators to successfully commercialize any product candidates that are approved.

Establishing internal sales, marketing and market access teams with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executives to manage. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Any failure or delay in the development of our internal sales, marketing, market access and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, especially if we also do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

In order to successfully implement our long-term plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

In order to successfully implement our long-term development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial, operational, sales, marketing, financial, legal, compliance and other personnel in the long-term. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and ex-U.S. regulatory agencies' review process for our product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize, our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization if and when we need to by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including our mobile and web-based applications. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data, and personal information, or collectively, Confidential Information, of customers and our employees and contractors.

Despite the implementation of security measures, our information systems and those of our current and any future contract research organizations, or CROs, CMOs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to attack, damage and interruption from various threat actors and thread vectors, including computer viruses and malware (e.g., ransomware), malicious code, misconfigurations, "bugs" or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failure, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are also increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Additionally, any integration of AI in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can be no assurance that our and our current and any future CROs', CMOs' and other contractors', consultants', collaborators' and third-party service provider's cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents that threaten the confidentiality, integrity and availability of our information technology systems and Confidential Information. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to our Confidential Information, it could result in a material disruption of our drug development programs. Some federal, state and ex-U.S. government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval

efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of Confidential Information, we could be exposed to litigation (such as class actions) and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Ex-U.S. pricing, drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We may seek approval to market our product candidates in both the United States and in selected ex-U.S. jurisdictions. If we obtain approval in one or more ex-U.S. jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some ex-U.S. countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national laws of EU member states, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and/or approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

Unfavorable U.S., global, political or economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the U.S. and global economy and in the U.S. and global financial markets. For example, the recent global economic downturn has caused rising inflation and has led to extreme volatility and disruptions in the capital and credit markets. A worsening or prolonged economic downturn or recession

could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, and cause the prices of our supplies to increase or cause our customers to delay making payments for our services. In addition, current military conflicts and/or civil unrest could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have and may in the future be initiated by nations including the United States, the EU or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with which we conduct business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Scrutiny and changing expectations from governments and other stakeholders with respect to Environmental, Social and Governance, or ESG, policies and practices may cause us to incur additional costs or expose us to additional risks.

There has been increasing public focus and scrutiny from investors, patients, activists, the media, governmental and nongovernmental organizations, and other stakeholders on a variety of environmental, social and related matters, including diversity and inclusion practices. Expectations regarding ESG continue to evolve rapidly. A failure, or perceived failure, to respond to related expectations could subject us to litigation or activism, cause harm to our business and reputation and have a negative impact on the market price of our securities. Additionally, we may be subject to new or varied laws or regulations which could result in new or more stringent forms of ESG oversight and disclosures, which may lead to increased expenditures for compliance or otherwise impact our business, including risk of fines, investigation and litigation.

Business interruptions could adversely affect our operations.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, public health crisis and pandemic diseases, natural disasters, man-made disasters or events beyond our control. Our facilities are located in regions that experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results due to hurricane, tornado, flood, fire, earthquake, landslide, other severe weather events, power loss, terrorist activity, public health crisis, pandemic diseases or other disasters, and do not have a comprehensive recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2025, we have U.S. federal and state net operating losses, or NOL, carryforwards of approximately $591.3 million and $336.0 million, respectively. The U.S. federal NOL carryforwards generated prior to January 1, 2018 begin to expire in 2035. The U.S. federal NOL generated after 2017 of $577.1 million can be carried forward indefinitely and be available to offset up to 80% of future taxable income each year. This limitation may require us to pay U.S. federal income taxes in future years despite generating U.S. federal NOLs in prior years. Our U.S. federal NOLs generated in tax years beginning prior to January 1, 2018 are not subject to this limitation, but are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law, and will start to expire in 2035 if not utilized. Our state NOLs begin to expire in 2035.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in its ownership by one or more "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-ownership change federal NOLs and certain other pre-change tax attributes, including tax credits, to offset its post-change taxable income and income tax liabilities may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have completed a Code Section 382 analysis through June 30, 2023 regarding the limitation of NOL carryforwards and other tax attributes. Under the Section 382 rules, we experienced ownership changes in 2015, 2019 and 2022. Additionally, several of our subsidiaries experienced an ownership change in 2020 based on the Section 382 rules for the time period prior to when we were a consolidated group for tax purposes. Our attributes are subject to annual limitations, and some could expire unused prior to expiration. There is a risk that additional ownership changes may occur in the future. If a future change in ownership occurs, our NOL carryforwards and other tax attributes could be limited or restricted. Additionally, our NOLs prior to the tax consolidation are also subject to the separate return loss year, or SRLY, rules. The SRLY rules may limit one member from offsetting taxable income with losses generated from another member prior to joining the consolidated group. Consequently, even if we attain profitability in the future, we may not be able

to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we would be subject to additional risks related to operating in ex-U.S. countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in ex-U.S. countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular ex-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- ex-U.S. taxes, including withholding of payroll taxes;
- ex-U.S. currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing ex-U.S. operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable ex-U.S. regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those ex-U.S. countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate product revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are and will continue to be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market, LLC, or Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose material changes made in our internal control over financial reporting on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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. We have invested and intend to continue to invest in resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our Audit Committee and Compensation Committee, and qualified executive officers. By disclosing information in filings required of us as a public company, our business and financial condition will continue to become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

A portion of our manufacturing of azenosertib takes place in ex-U.S. countries, including China, through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in such ex-U.S. countries, including China, could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties, and clinical quantities of azenosertib are manufactured by certain of these third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers for azenosertib. Any disruption in production or inability of our manufacturers in such ex-U.S. countries, including in China, to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of azenosertib. Furthermore, since these manufacturers are located outside the United States, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or ex-U.S. governments, political unrest or unstable economic conditions in such ex-U.S. countries, including in China. For example, the ongoing trade tensions between the United States and certain ex-U.S. governments, including China, have resulted in the imposition, expansion and periodic modification of tariffs and other trade restrictions on a broad range of imports, including chemicals and pharmaceutical inputs, and additional measures or retaliatory actions could be implemented at any time. These actions could potentially disrupt or increase costs associated with our existing supply chains for clinical quantities of azenosertib and impose additional costs on our business. Furthermore, the BIOSECURE Act was enacted in December 2025, as Section 851 of the National Defense Authorization Act for Fiscal Year 2026 and has the potential to restrict the ability of U.S. biopharmaceutical companies to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. Although we do not currently anticipate that supply of azenosertib will be affected by the implementation of the BIOSECURE Act, the impact of the BIOSECURE Act or any related legislation remains uncertain, and we are continuing to monitor regulatory developments, including the publication of the list of designated biotechnology companies of concern expected by December 2026 and subsequent implementing guidance. Any of these matters could materially and adversely affect our business and

results of operations. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position.

Further, we are exposed to fluctuations in foreign currency exchange rates in the countries in which our third-party manufacturers operate. Changes in exchange rates could increase our costs and may be difficult to predict or hedge effectively. In addition, our labor and operating costs in these countries, including China, could continue to rise due to inflationary pressures, wage rates increase due to increased demand for skilled laborers, competition for qualified labor and changes in local economic conditions which could increase the cost of manufacturing our product candidates and related materials.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary platform.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for azenosertib and any future product candidates, proprietary technologies and their uses, our and our licensors' ability to operate without infringing the proprietary rights of others, and our and our licensors' ability to successfully defend our patents, including those that we have in-licensed, against third-party challenges. If we or our licensors are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or azenosertib or any future product candidates, our competitive position could be harmed. We and our licensors generally seek to protect our proprietary position by filing patent applications in the United States and outside of the United States related to our product candidates, proprietary technologies and their uses that are important to our business. Our or our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our or our licensors' patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents, if issued, will be infringed or will not be designed around by third parties. 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. The degree of future protection for our and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our or our licensors' rights or permit us or our licensors to gain or keep any competitive advantage. These uncertainties and/or limitations in our and our licensors' ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Although we in-license issued patents in the United States and ex-U.S. countries, we cannot be certain that the claims in our other U.S. pending patent applications, corresponding international patent applications and patent applications in certain ex-U.S. countries will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in ex-U.S. countries, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our licensors or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdictions;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we or our licensors do and many of whom have made significant investments in competing technologies, may seek, may have filed patent applications, or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. and ex-U.S. governments and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing ex-U.S. competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our licensors may not identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we in-license, including those which we in-license from our licensors and from third parties. We also may require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, CMOs, consultants, advisors, licensors, and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from our licensors and third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to license agreements under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future. For example, our wholly owned subsidiary, ZMI, is party to a license agreement with Recurium IP under which we have an exclusive license to certain intellectual property rights, including certain intellectual property covering azenosertib.

This and our other existing license agreements impose on us, and we expect that any future license agreements where we in-license intellectual property will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensors may have the right to terminate the licenses, in which event we would not be able to market products covered by the licenses.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our product candidates in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and their affiliates and sublicensees and by us and our partners and sublicensees.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, if we choose to sublicense or assign to any third parties certain patent rights exclusively in-licensed under the Recurium Agreement, we will be required to pay to Recurium a specified percentage of certain sublicensing income to be received in connection with such transaction.

If the scope of our patent protection or any patent protection our licensors obtain is not sufficiently broad, or if our licensors lose any of the patent protection we license, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the existence, issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates or that effectively prevent others from commercializing competitive product candidates.

Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent issue, and claim scope can be reinterpreted after issuance. Even if patent applications we in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our or our licensors' patents by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our in-licensed patents may not cover our product candidates or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings in the USPTO or ex-U.S. patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our or our licensors' patents, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found. There is also no assurance that there is not prior art of which we or licensors were or are aware of, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or those of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of in-licensed patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The patent protection and patent prosecution for some of our product candidates may be dependent on our licensors and third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects as to form in the preparation or filing of our patents or patent applications or those of our licensors may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, written descriptions, claim scope, or requests for patent term adjustments, patent term extensions or any

foreign equivalents thereof. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our in-licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a licensee, we may rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the in-licensed intellectual property under some of our license agreements. We may not have primary control over these activities for certain of our patents or patent applications or those of our licensors and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our in-licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the in-licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to in-license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or licensees or future collaborators fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors 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 acquired or in-licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or in-licensed from various third parties, including our licensors, may be subject to retained rights. Our licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our in-licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or in-licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of in-licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidate.

Some of our intellectual property may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies if it is determined that our intellectual property has been discovered through government-funded programs. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have acquired or in-licensed or may acquire or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured

substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products relating to such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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 develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or patent application that we own or in-license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our licensors' pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- 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; and
- the patents of others may have an adverse effect on our business.
- Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit, interfere or block our ability to make, use, sell, offer for sale or import azenosertib, any future product candidates, and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation and administrative proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent invalidity and infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO, ex-U.S. patent offices and/or in a court of law. Numerous third-party U.S. and ex-U.S. issued patents and pending patent applications exist in the fields in which we are developing azenosertib and any future product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents issue, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology 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. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing azenosertib and any future product candidates until the asserted patent expires or is held finally invalid or unenforceable or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this periodic report, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful. Further, our issued patents or the patents of our licensors could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we and/or our licensors may be required to file infringement claims, which can be expensive and time-consuming. Further, our licensors may need to file infringement claims, but they may elect not file such claims. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could assert that such a patent is invalid, not infringed and/or unenforceable in whole or in part. In patent litigation, defendant allegations of invalidity and/or unenforceability of asserted patents are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including patent-ineligible subject matter, lack of utility, lack of novelty, obviousness or lack of written description, or non-enablement. Grounds for an unenforceability assertion could include an allegation of inequitable conduct that someone connected with prosecution of the patent intentionally withheld material information from the USPTO or an ex-U.S. patent office or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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 conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or our licensors, or declared by the USPTO or similar proceedings in ex-U.S. patent offices may be necessary to determine the priority of inventions with respect to our or our licensors' patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our or our licensors' defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Patent reform legislation 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' issued patents.

In September 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. 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 and also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours 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. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications of those of our licensors.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. 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 PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our

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 issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, 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 and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our or our licensors' patents or in third-party patents. In addition, Congress or other ex-U.S. legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in ex-U.S. jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

We or our licensors may be subject to claims challenging the inventorship or ownership of our or our licensors' patents and other intellectual property.

We or our licensors may be subject to claims that former employees or other third parties have an ownership interest in our or our licensors' patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we or our licensors do not obtain patent term extension for azenosertib and any future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of azenosertib and any future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it for an FDA-approved indication or a method for manufacturing it may be extended. Patent term extension or equivalents thereof may also be available in certain ex-U.S. countries upon regulatory approval of our product candidates.

However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, failing to act with due diligence to develop product and seek regulatory approval, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration 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 revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we have issued patents and pending patent applications in the United States and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some ex-U.S. countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in ex-U.S. jurisdictions. The legal systems of many ex-U.S. countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our licensors' patent rights in ex-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly and our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our or our licensors' 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.

Many countries 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. In these countries, the patent owner may have limited remedies, 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various ex-U.S. patent offices at various points over the lifetime of our or our licensors' patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various ex-U.S. patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations 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. If such an event were to occur, it could have a material adverse effect on our business.

If we are unable to protect our trade secrets, our business and competitive position would be harmed.

In addition to patents, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information

and inventions agreements with employees, consultants, licensors and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we or our licensors do not apply for patent protection prior to public disclosure or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize azenosertib or any future product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, consultants and third-party CROs, to conduct certain aspects of our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors, including CROs, are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and ex-U.S. regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or ex-U.S. regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations and similar ex-U.S. requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal, state or ex-U.S. fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators, CROs and other third parties are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if

the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. 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 revenues could be delayed or precluded entirely.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. They may also suffer from high staff turnover which may leave them at least temporarily unable to sufficiently meet our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We contract with third parties for the manufacture of azenosertib for preclinical studies and ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of azenosertib or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of azenosertib or any future product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of azenosertib and any future product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements, and we purchase our required supply on a purchase order basis. Furthermore, the raw materials for azenosertib are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of azenosertib or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of azenosertib and any future product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturers to manufacture our product candidates according to our schedule, or at all, including if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party manufacturers at a time that is costly or inconvenient for us;
- the breach by the third-party manufacturers of our agreements with them;
- the failure of third-party manufacturers to comply with applicable regulatory requirements;
- the failure of the third-party manufacturers to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our third-party contract manufacturing partners for compliance with cGMP regulations or similar ex-U.S. requirements for manufacturing both

active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our third-party contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for the use of their manufacturing facilities for the manufacture of our product candidates. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or an ex-U.S. regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, stock recovery or spoilage. Any stock recovery of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, 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 harm our business. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

If we decide to establish collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our development programs and the potential commercialization of azenosertib and any future product candidates will require substantial additional cash to fund expenses. We have in the past and may in the future seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We may face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or ex-U.S. regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. Potential collaborators may view alternative product candidates or technologies as more attractive. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a

collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Ownership of Our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this “Risk Factors” section these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or product candidates or our competitors’ products or product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- speculative trading in and short sales of our common stock, as well as trading phenomena such as the "short squeeze";
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of U.S. and global economic conditions. The extent to which these events may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of azenosertib or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if azenosertib or any future product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant influence over matters subject to stockholder approval.

As of December 31, 2025, our executive officers and directors, combined with our stockholders who owned more than 5% of our common stock, together with their respective affiliates, owned a significant percentage of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as matters related to our management and affairs. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, 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. Outstanding shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act, or to the extent that such shares have already been registered under the Securities Act and are held by non-affiliates of ours. We also register 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.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and

the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified Board of Directors so that not all members of our Board of Directors are elected at one time;
- permit only the Board of Directors to establish the number of directors and fill vacancies on the Board of Directors;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our Board of Directors could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our Board of Directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our certificate of incorporation or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This exclusive-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. If a court were to find this exclusive-forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Nothing in our certificate of incorporation precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid any cash dividends on our equity securities. 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 for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose material changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and may continue to be volatile and, 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 against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity and availability of our critical systems and information. Our cybersecurity program is aligned with industry standards and reasonable security safeguards for comparable companies in our industry. We reference various security industry frameworks and controls, such as National Institute of Standards and Technology, or NIST, Cybersecurity Framework 2.0, ISO/IEC 27001:2022, the Sarbanes-Oxley Act, Title 21 Code of Federal Regulations Part 11, Network and Information Security Directive 2, and other guidance to help us assess, identify and manage cybersecurity risks. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the frameworks and controls as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business. We also actively engage with industry participants as part of our continuing efforts to evaluate and enhance the effectiveness of our information security policies and procedures. From time to time, we engage consultants and other third parties to assist us with assessing and improving our cybersecurity program.

Key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel and senior management;
- a cyber incident response team and cyber incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for key service providers based on our assessment of their criticality to our operations and respective risk profile.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see "Risk Factors—Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business—Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity."

Cybersecurity Governance

The Board considers cybersecurity risk as part of its overall risk oversight function and has delegated to the Audit Committee oversight of cybersecurity and information security risks, including oversight of management's implementation of our cybersecurity risk management program. The Audit Committee receives periodic reports from management regarding our cybersecurity program. These reports include updates on our cybersecurity program and the status of projects to strengthen our information security systems. In addition, management updates the Audit Committee, where it deems appropriate, regarding cybersecurity incidents it considers to be significant. The Audit Committee periodically reports to the full Board regarding its activities, including those related to cybersecurity.

Our management team, including our Chief Executive Officer, our Chief Legal Officer and our Vice President, Information Technology, is responsible for assessing and managing our risks from cybersecurity threats. Certain members of our management team are part of our Cyber Incident Response Team and are responsible for executing the processes set forth therein, including with respect to our key third party service providers. Our Vice President, Information Technology has over thirty years of experience in information security, and previously held a Certified Information Systems Auditor certification from the Information Systems Audit and Control Association from 2006 to 2022. Our Chief Executive Officer has thirty years of experience overseeing information technology, or IT, functions and has eight years of experience serving on the audit committees of companies that had oversight responsibility of the company's cybersecurity risk management program. Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties.

Our principal executive office is located at 10275 Science Center Drive, Suite 200, San Diego, California 92121, where we lease approximately 56,700 square feet and 17,900 square feet of office and laboratory space, respectively, under a lease that expires in September 2032. We believe that our facilities are sufficient to meet our current needs.

Item 3. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

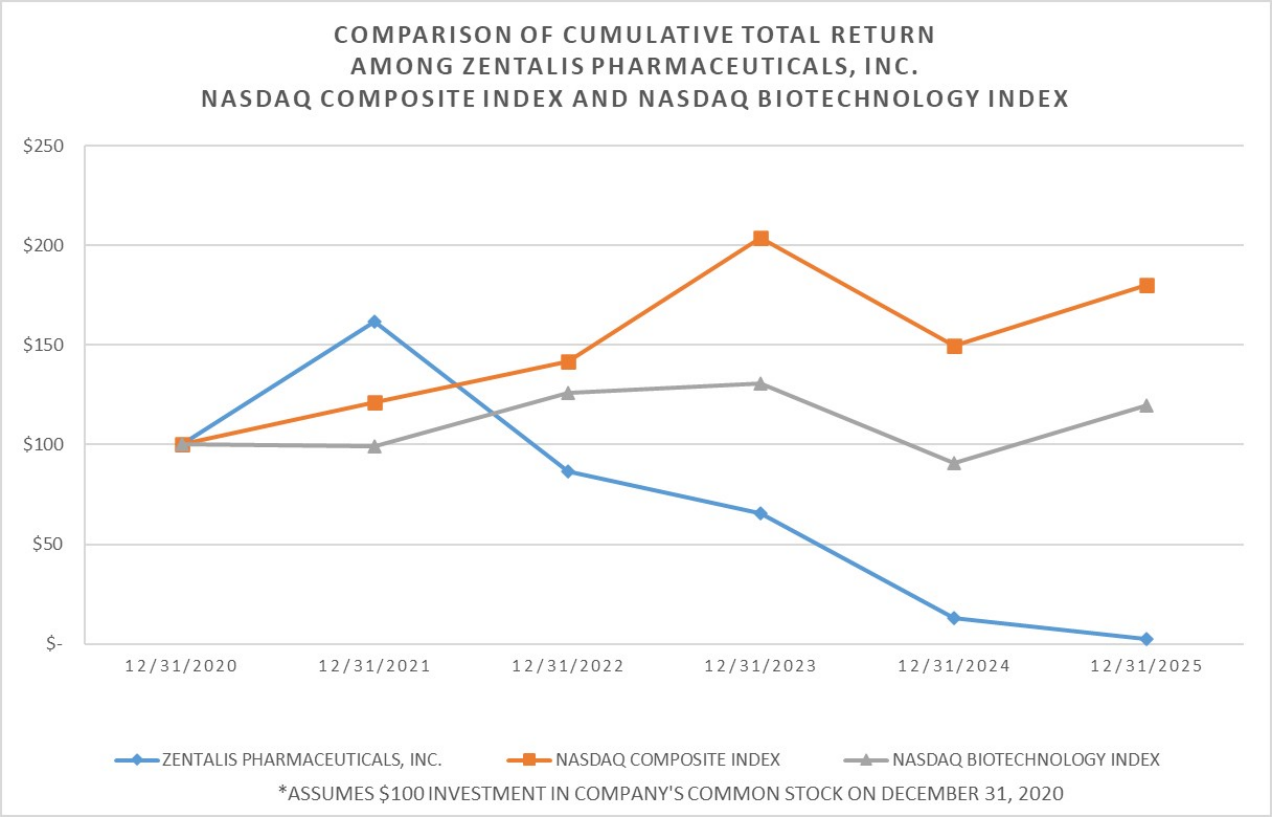
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

On April 3, 2020, our common stock began trading on The Nasdaq Global Market under the symbol "ZNTL." Prior to that time, there was no public market for our common stock.

Stock Performance Graph

The following graph and table illustrate the total return from December 31, 2020 through December 31, 2025, for (i) our common stock, (ii) the Nasdaq Composite Index, and (iii) the Nasdaq Biotechnology Index. The graph and the table assume that $100 was invested on December 31, 2020 in each of our common stock, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index, and that any dividends were reinvested. The comparisons reflected in the graph and table represent past performance and are not intended to forecast the future performance of our stock and may not be indicative of our future performance.



Holders

As of March 21, 2026, there were approximately 8 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors after

considering our financial condition, results of operations, capital requirements, business prospects and other factors the Board of Directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Recent Sales of Unregistered Securities

The Company did not sell any equity securities during the quarter ended December 31, 2025 that were not registered under the Securities Act.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12. "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Securities Authorized for Issuance Under Equity Compensation Plans" of this Annual Report on Form 10-K.

Issuer Repurchases of Equity Securities

During the fiscal quarter ended December 31, 2025, the Company made the following repurchases of shares of our common stock:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under The Plans or Programs
October 1, 2025 - October 31, 2025	—	—	—	—
November 1, 2025 - November 30, 2025	—	—	—	—
December 1, 2025 - December 31, 2025	7,500,000 (1)	$1.33	—	—
Total	7,500,000	$1.33	—	—

(1) On December 15, 2025, the Company repurchased 7,500,000 shares of common stock from Matrix Capital Master Fund, LP pursuant to a privately negotiated Stock Purchase Agreement at $1.33 per share. This repurchase was not made pursuant to a publicly announced repurchase plan or program.

Item 6. [Reserved].

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

You should read the following discussion and analysis of financial condition and operating results together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K contains forward-looking statements based upon current plans, expectations and beliefs involving significant risks and uncertainties. As a result of many important factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.

A discussion regarding our financial condition and results of operations for the years ended December 31, 2025 and 2024, including a year-to-year comparison between 2025 and 2024, is presented below. For a discussion regarding our financial condition and results of operations for the year ended December 31, 2023, including a year-to-year comparison between 2024 and 2023, refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2024 filed on March 26, 2025.

Overview

We are a clinical-stage biopharmaceutical company developing azenosertib (ZN-c3), an investigational, potentially first-in-class and best-in-class WEE1 inhibitor, for patients with ovarian cancer and other tumor types. In clinical trials, azenosertib has been well tolerated and has demonstrated anti-tumor activity as a single agent across multiple tumor types. We are currently focused on advancing the clinical development of azenosertib in Cyclin E1-positive platinum-resistant ovarian cancer, or PROC. We believe that our DENALI (ZN-c3-005) Part 2 clinical trial of azenosertib in patients with Cyclin E1-positive PROC, if successful, has the potential to support an accelerated approval, subject to U.S. Food and Drug Administration, or FDA, review. Azenosertib also has broad franchise potential beyond Cyclin E1-positive PROC. We exclusively in-license or solely own worldwide development and commercialization rights to azenosertib.

Azenosertib (WEE1 Inhibitor)

Mechanism of Action

Azenosertib is an investigational, potentially first-in-class and best-in-class oral, small molecule WEE1 inhibitor. The inhibition of WEE1, a DNA damage response kinase, drives cancer cells into mitosis without being able to repair damaged DNA, resulting in cell death and thereby preventing tumor growth and potentially causing tumor regression. We have designed azenosertib to have advantages over other investigational therapies targeting WEE1, including superior selectivity and pharmacokinetic, or PK, properties.

Cyclin E1 Expression as a Sensitive and Specific Predictive Biomarker

Cells with Cyclin E1 activation are exquisitely sensitive to WEE1 inhibition via azenosertib because Cyclin E1 activation further accelerates cancer cells into the DNA replication phase without adequate DNA repair. As a result, we have used retrospective analyses to establish Cyclin E1 as a sensitive and specific predictive biomarker that can be used to identify patients who might benefit from azenosertib. In addition, based on published retrospective analyses, Cyclin E1 alteration is a biomarker of poor prognosis and low benefit from standard-of-care single-agent chemotherapy in PROC patients.

We are working with a diagnostic partner to validate a companion diagnostic test that will identify patients with PROC that overexpress the Cyclin E1 protein using our proprietary immunohistochemistry, or IHC, cutoff. A prototype of this test is being used in DENALI Part 2 and is ready for use in our Phase 3 trial, ASPENOVA.

Market Opportunity

In 2022, the global ovarian cancer market was approximately $3 billion, with significant growth expected over the next several years. PROC is a subset of the ovarian cancer market. Based on our analysis utilizing our IHC cutoff, we estimate that approximately 50% of PROC patients overexpress Cyclin E1 protein, which accounts for approximately 21,500 patients on an annual basis in the United States, EU4 (France, Germany, Italy, Spain) and the United Kingdom, based on 2024 estimates. As a result, we believe there is a large market opportunity for azenosertib in Cyclin E1-positive PROC patients. Moreover, the successful launch of mirvetuximab in PROC patients with high folate receptor alpha, or FRα-high, expression underscores the demand for biomarker-directed therapies for PROC patients. The limited overlap between FRα-high PROC patients and those

that have Cyclin E1 overexpression is estimated to be less than 20%, which highlights the significant unmet need in patients with Cyclin E1-positive PROC.

We believe there is additional market opportunity for azenosertib in earlier lines of treatment for ovarian cancer, and across other solid tumor types.

Clinical Development Program

The following ongoing and planned studies constitute the current clinical development program for azenosertib:

- ***Monotherapy – Phase 2 Clinical Trial in PROC (DENALI - ZN-c3-005).***

    - **DENALI Part 1b** is a single-arm study that evaluated azenosertib monotherapy at our primary dose-of-interest, 400 mg QD 5:2, in 102 patients with PROC. Tissue collection for biomarker assessment was mandated in the study and upon a retrospective analysis, approximately 50% of the patients were Cyclin E1-positive per our IHC cutoff. In January and March of 2025, we announced clinical data from this study, which is described in Part I Item 1, "Business – Clinical Data – DENALI Part 1b" in this Annual Report on Form 10-K.

    - **DENALI Part 2** is designed to enroll approximately 100 patients with Cyclin E1-positive PROC at the selected dose who have received one to three prior lines of therapy, or for patients whose tumors are also FRα-high and who have received mirvetuximab soravtansine, one to four prior lines of therapy. We have aligned with the FDA on the design of our DENALI Part 2 study in patients with Cyclin E1-positive PROC, which allows for seamless enrollment across Parts 2a and 2b. DENALI Part 2a is designed to confirm 400 mg QD 5:2 as the recommended pivotal study dose by enrolling approximately 30 patients at each of two dose levels, 400 mg QD 5:2 and 300 mg QD 5:2. DENALI Part 2b is designed to enroll approximately 70 patients at a single dose, the selection of which will be informed by the Part 2a results and FDA interaction. In April 2025, we announced that the first patient was dosed in DENALI Part 2a. In January 2026, we announced that the enrollment for Part 2a was completed in 2025 and we plan to announce dose selection from Part 2a in the first half of 2026. We anticipate a topline readout for DENALI Part 2 by year end 2026. We believe that DENALI Part 2, if successful, has the potential to support an accelerated approval, subject to FDA review. The FDA has granted Fast Track Designation to azenosertib for the treatment of patients with PROC who are positive via IHC for Cyclin E1 protein levels.

- ***Monotherapy – Phase 3 Clinical Trial in Cyclin E1-positive PROC (ASPENOVA).*** We have aligned with the FDA on the trial design for ASPENOVA, a randomized Phase 3 confirmatory clinical trial of azenosertib versus standard-of-care chemotherapy for the treatment of patients with Cyclin E1-positive PROC designed to support a full approval of azenosertib in this setting. We plan to initiate ASPENOVA in the first half of 2026 and enroll concurrently with DENALI Part 2b.

- ***Combination – Phase 1b Clinical Trial of Azenosertib and Chemotherapy or Bevacizumab in Ovarian Cancer (MUIR - ZN-c3-002).*** We are currently enrolling patients in an arm of our ZN-c3-002 Phase 1b clinical trial that is evaluating azenosertib in combination with bevacizumab as maintenance therapy in ovarian cancer. The dose expansion portion will enroll second-line platinum-sensitive ovarian cancer (PSOC) patients for maintenance treatment, whose disease progressed while on a PARP inhibitor.

We also completed enrollment in a Phase 2 clinical trial evaluating azenosertib as a monotherapy in patients with uterine serous carcinoma, or USC (TETON - ZN-c3-004). We plan to publish results from this trial in the future. We do not plan further development of azenosertib in USC.

Liquidity Overview

Since our inception, our operations have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product pipeline. We do not have any products approved for commercial sale and have not generated any revenues from product sales. We will not generate revenue from product sales unless and until we successfully complete clinical development, obtain regulatory approval for, and commercialize one or more of our product candidates. We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy.

Since inception, we have incurred significant operating losses. Our net losses were $137.1 million for the year ended December 31, 2025. We had an accumulated deficit of $1.2 billion as of December 31, 2025. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We had cash, cash equivalents and marketable securities of $245.9 million as of December 31, 2025. We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund our operating expenses and capital expenditure requirements into late 2027. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

License Agreements and Strategic Collaborations

Recurium IP Holdings, LLC License Agreement

In December 2014, our wholly owned subsidiary, Zeno Pharmaceuticals, Inc., entered into the Recurium Agreement with Recurium IP Holdings, LLC, or Recurium IP, which was subsequently amended, under which Zeno Pharmaceuticals, Inc. was granted an exclusive worldwide license to certain intellectual property rights owned or controlled by Recurium IP to develop and commercialize pharmaceutical products for the treatment or prevention of disease, other than for providing pain relief. Following a corporate restructuring disclosed elsewhere in this Annual Report on Form 10-K, our wholly owned subsidiary, ZMI, became the Zentalis contracting party to the Recurium Agreement. The intellectual property rights exclusively licensed by ZMI under the Recurium Agreement include certain intellectual property covering azenosertib. ZMI has the right to sublicense its rights under the Recurium Agreement, subject to certain conditions. ZMI is required to use commercially reasonable efforts to develop and commercialize at least one product that comprises or contains a compound modulating one of ten specific biological targets and to execute certain development activities.

Under the terms of the Recurium Agreement, ZMI is obligated to make development and regulatory milestone payments, pay royalties on net sales, and make certain sublicensing payments with respect to products that comprise or contain a compound modulating one of ten specific biological targets, including azenosertib. ZMI is obligated to make development and regulatory milestone payments for each such licensed product of up to $44.5 million. In addition, ZMI is obligated to make milestone payments of up to $150,000 for certain licensed products used in animals. ZMI is also obligated to pay royalties on sales of such licensed products at a mid- to high-single digit percentage. In addition, if ZMI chooses to sublicense or assign to any third parties its rights under certain patents exclusively in-licensed under the Recurium Agreement, ZMI must pay to Recurium IP 20% of certain sublicensing income received in connection with such transaction.

The Recurium Agreement will expire on the later of December 21, 2032 and, on a country-by-country basis, on the date of expiration of the last-to-expire royalty term for all licensed products in such country, unless earlier terminated by either party for cause or a bankruptcy event.

Pfizer Development Agreement

In April 2022, we entered into a development agreement with Pfizer to collaborate to advance the clinical development of azenosertib. We did not grant Pfizer any economic ownership or control of azenosertib or the rest of our pipeline. In October 2022, we announced our first clinical development collaboration with Pfizer to initiate a Phase 1/2 dose escalation study of azenosertib, in combination with encorafenib and cetuximab (an FDA-approved standard of care known as the BEACON regimen) in patients with BRAF V600E-mutant mCRC. In January 2025, we announced that we would not advance to the dose expansion phase of the study due to resource prioritization and an evolving treatment landscape.

GSK Clinical Trial Collaboration and Supply Agreement

In April 2021, we entered into a clinical trial collaboration and supply agreement with GSK under which we have evaluated the combination of azenosertib and niraparib, GSK's poly (ADP-ribose) polymerase (PARP) inhibitor, in patients

with PROC. In January 2025, we announced that the trial was fully enrolled and that we were not proceeding further with the development of the combination of azenosertib with niraparib as efficacious exposures of azenosertib were not reached. Pursuant to this agreement, we were responsible for the conduct and cost of the study, under the supervision of a joint development committee made up of our representatives and representatives of GSK. GSK supplied niraparib for use in the collaboration, at no cost to us.

This agreement does not grant any right of first negotiation to participate in future clinical trials, and neither party granted the other any additional right or ability to evaluate their respective compounds in any other clinical studies, either as monotherapy or in combination with any other product or compound, in any therapeutic area.

The agreement with GSK will expire upon completion of all obligations of the parties thereunder or upon termination by either party. In addition, there are standard early termination provisions under this agreement.

Immunome Agreements

In January 2024, we entered into an exclusive, worldwide license agreement with Immunome, or the Immunome License Agreement, under which Immunome licensed from us ZPC-21 (now known as IM-1021), a preclinical ROR1 ADC with best-in-class potential, and our proprietary ADC platform technology, or the ADC Assets. Under the terms of the deal, we received an up-front payment of $35.0 million in cash and Immunome common stock (with the stock valued at the trailing 30-day volume-weighted average price). In October 2024, we entered into an asset purchase agreement with Immunome, pursuant to which Immunome purchased the ADC Assets, or the Immunome Purchase Agreement. We received $25.0 million worth of Immunome common stock, with the shares valued at the trailing 30-day volume-weighted average price of Immunome's common stock. On the date of execution of the transaction, the Immunome stock was valued at $21.9 million based on the closing price of Immunome's common stock on that date. We were also eligible to receive $5.0 million of contingent consideration upon the achievement of a developmental milestone, which was achieved in December 2024. The Immunome License Agreement terminated upon the parties' entry into the Immunome Purchase Agreement.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue, and we do not expect to generate any revenue in the foreseeable future from product sales. We have generated, and may in the future generate, revenue from payments received under our licensing, collaboration and asset sale agreements, which included payments of upfront fees, license fees, milestone-based payments and reimbursements for research and development efforts.

Research and Development Expenses

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

- salaries, benefits and other related costs, including non-cash stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including CROs and other third parties that conduct research, preclinical activities and clinical trials on our behalf as well as CMOs that manufacture drug material for use in our preclinical studies and clinical trials;
- costs of outside consultants, including their fees, non-cash stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- license payments made for intellectual property used in research and development activities; and
- allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Reimbursed research and development costs under certain collaborative arrangements are recorded as a reduction to research and development expenses and are recognized in the period in which the related costs are incurred.

We track external development costs by product candidate or development program, but we do not allocate personnel costs, general license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses and discontinued programs in the table below.

The following table summarizes our research and development expenses by product candidate or development program:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Azenosertib	$ 48,102	$ 75,837
Unallocated research and development expenses and discontinued programs	59,193	91,931
Total research and development expenses	$ 107,295	$ 167,768

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Following the strategic restructuring announced in January 2025, we incurred certain associated non-recurring expenses in the first quarter of 2025. As a result of the strategic restructuring, we realized a decrease in research and development expenses during the year ended December 31, 2025. If our azenosertib development program continues to advance successfully, we expect our research and development expenses to increase as we initiate and execute our planned Phase 3 ASPENOVA confirmatory study and prepare for potential commercialization.

The successful development of azenosertib, and any of our future product candidates is highly uncertain. At this time, we cannot determine with certainty the duration and costs of our existing and future clinical trials of azenosertib or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for azenosertib, or any future product candidate. The duration, costs and timing of clinical trials and development of our product candidates and any other product candidate we may develop in the future will depend on a variety of factors, including:

- per patient trial costs;
- the number of patients who enroll in each trial;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- any delays in clinical trials, including as a result of clinical holds or the global macroeconomic environment;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate.
- uncertainties in clinical trial design and patient enrollment rates;
- the actual probability of success for our product candidates, including the safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- our ability to attract and retain skilled personnel.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including non-cash stock-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Following the strategic restructuring announced in January 2025 for which we incurred certain associated non-recurring expenses in the first quarter of 2025, we have realized a decrease in general and administrative expenses during the year ended December 31, 2025; however, if our azenosertib development program continues to advance successfully, we expect our general and administrative expenses to increase as we initiate and execute our planned Phase 3 ASPENOVA confirmatory study and prepare for potential commercialization. We also expect to continue to incur expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Restructuring Expenses

Restructuring expenses consist of involuntary employee termination benefits pursuant to a one-time benefit arrangement.

Investment and Other Income, Net

Investment and other income, net consists of interest earned on cash, cash equivalents and available-for-sale marketable securities, sublease income and the change in value of equity securities during the period.

Income Taxes

Since our inception, we and our corporate subsidiaries have generated cumulative federal, state and foreign net operating loss in certain jurisdictions for which we have not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within their respective carryforward periods.

Results of Operations

Comparison of Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024, together with the changes in those items in dollars:

	Year Ended December 31,		
	2025	2024	Increase (Decrease)
	(in thousands)		
Revenues from Licensing and Sales of Intellectual Property	$ —	$ 67,425	$ (67,425)
Operating Expenses			
Research and development	107,295	167,768	(60,473)
General and administrative	37,717	87,115	(49,398)
Restructuring	7,796	—	7,796
Goodwill impairment	—	3,736	(3,736)
Total operating expenses	152,808	258,619	(105,811)
Loss from operations	(152,808)	(191,194)	38,386
Investment and other income, net	16,190	25,504	(9,314)
Net loss before income taxes	(136,618)	(165,690)	29,072
Income tax expense (benefit)	442	177	265
Net loss	(137,060)	(165,867)	28,807
Net loss attributable to noncontrolling interests	—	(28)	28
Net loss attributable to Zentalis	$ (137,060)	$ (165,839)	$ 28,779

Revenues from Licensing and Sales of Intellectual Property

Revenues from licensing and sales of intellectual property for the year ended December 31, 2025 were zero compared to $67.4 million for the year ended December 31, 2024. The decrease relates to the Immunome License Agreement and related stock issuance agreement with Immunome entered during the three months ended March 31, 2024 and the Immunome Purchase Agreement and the related stock issuance agreement with Immunome entered during the three months ended December 31, 2024.

Research and Development Expenses

Research and development, or R&D, expenses for the year ended December 31, 2025 were $107.3 million, compared to $167.8 million for the year ended December 31, 2024. The decrease of $60.5 million was primarily due to decreases of $22.3 million for clinical expenses, $12.9 million for lab services, $8.8 million for drug manufacturing, and $1.3 million for supplies and other expense. A decrease of $16.4 million from personnel expense, of which $6.5 million was non-cash stock-based compensation, also contributed to the overall reduction in research and development expenses. These decreases were partially offset by an increase of $1.2 million from a one-time impairment charge recorded on research and development equipment during the first quarter ended March 31, 2025.

Restructuring Expenses

On January 22, 2025, our Board of Directors approved a strategic restructuring of the Company to support execution of late-stage development for azenosertib, and extend its cash runway beyond a potentially registration-enabling azenosertib topline readout from the Company's DENALI Part 2 study, anticipated by the end of 2026. In connection with this strategic restructuring, the Company reduced its workforce by approximately 40%. Restructuring expenses for the year ended December 31, 2025 were $7.8 million, compared to zero during the year ended December 31, 2024.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2025 were $37.7 million, compared to $87.1 million during the year ended December 31, 2024. The decrease of $49.4 million was primarily due to a decrease of $47.1 million of personnel expense, of which $40.8 million was non-cash stock-based compensation. Decreases of $3.3 million related to consulting and outside services also contributed to the overall reduction in general and administrative expenses. These decreases were partially offset by an increase of $1.0 million related to allocated and other costs.

Goodwill Impairment

Goodwill impairment for 2024 of $3.7 million was the result of an impairment test performed in the fourth quarter of 2024.

Investment and Other Income, Net

Investment and other income, net was $16.2 million for the year ended December 31, 2025, compared to $25.5 million for the year ended December 31, 2024. The decrease of $9.3 million was primarily driven by a decrease of $8.4 million in returns on invested cash and marketable debt securities and decreases in the mark to market adjustment for the fair value of Immunome common stock of $4.1 million. The decreases were partially offset by a reduction of one-time miscellaneous expenses incurred in 2024.

Liquidity and Capital Resources

Since our inception, our operations have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product pipeline. We do not have any products approved for commercial sale and have not generated any revenues from product sales, and we have incurred significant operating losses.

As a result, we will need to raise substantial additional capital to support our continuing operations and pursue our strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all, particularly in light of the global macroeconomic environment and fluctuating inflation and interest rates. If we are unable to secure adequate additional funding as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of azenosertib or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with developing and commercializing 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 revenue from product sales, we may not become profitable. 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 do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the sale of equity securities. From inception through December 31, 2025, we raised a total of $1.2 billion in gross proceeds from the sale of shares of our common stock and convertible preferred units. As of December 31, 2025, we had $36.0 million in cash and cash equivalents, $209.9 million in marketable debt securities, and an accumulated deficit of $1.2 billion. We maintain the majority of our cash and cash equivalents in accounts with major financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. We had no indebtedness as of December 31, 2025.

ATM Program

In May 2021, the Company entered into a sales agreement, or the Sales Agreement, with SVB Leerink LLC, or SVB Leerink, as sales agent (the "Sales Agreement"), pursuant to which the Company may, from time to time, issue and sell common stock with an aggregate value of up to $75.0 million in “at-the-market” offerings, or the ATM, under the Company's Registration Statement on Form S-3 (File No. 333-286122) filed with the SEC on March 26, 2025. Sales of common stock pursuant to the Sales Agreement, may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Market or any other existing trading market for the Company's common stock. In December 2025, the Company sold 3,928,571 shares of common stock under the Sales Agreement at a price of $1.40 per share, raising aggregate gross proceeds of $5.5 million before fees and expenses of $0.1 million. As of December 31, 2025 there was $69.5 million of our common stock remaining available for sale under our ATM.

Stock Purchase Agreement

On December 15, 2025, the Company entered into a Stock Purchase Agreement (the “Stock Purchase Agreement”) with Matrix Capital Master Fund, LP ("Matrix"), one of our then-stockholders. Pursuant to the Stock Purchase Agreement, the

Company agreed to repurchase 7,500,000 shares of the Company's common stock from Matrix at a price of $1.33 per share, representing a discount from the Company's closing share price of $1.40 on December 12, 2025 (the "Repurchase"). The Repurchase closed on December 15, 2025.

Cash Flows

The following table summarizes our sources and uses of cash for the period presented:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (125,247)	$ (170,860)
Net cash provided by investing activities	131,623	176,561
Net cash (used in) provided by financing activities	(4,282)	108
Net increase in cash, cash equivalents and restricted cash	$ 2,094	$ 5,809

Operating Activities

We have incurred losses since inception. Net cash used in operating activities for the year ended December 31, 2025 was $125.2 million, consisting primarily of our net loss of $137.1 million as we incurred expenses associated with the restructuring event, research activities for our product candidate and incurred general and administrative expenses, as well as changes in operating assets and liabilities of $9.1 million, partially offset by non-cash adjustments of $20.9 million.

Net cash used in operating activities for the year ended December 31, 2024 was $170.9 million, consisting primarily of our net loss of $165.9 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses, as well as changes in operating assets and liabilities of $16.5 million, partially offset by non-cash adjustments of $11.5 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2025 of $131.6 million was attributable to proceeds from maturities of $250.0 million of marketable debt securities, the sale of marketable equity securities of $20.4 million and proceeds from the sale of property and equipment of $698 thousand offset by net investment of excess cash of $139.5 million.

Net cash provided by investing activities for the year ended December 31, 2024 of $176.6 million was attributable to proceeds from maturities of $271.2 million of marketable debt securities, the sale of marketable equity securities of $33.5 million and proceeds from the sale of property and equipment of $65 thousand offset by net investment of excess cash of $128.0 million and the purchases of property and equipment of $221 thousand.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2025 of $4.3 million was attributable to the Repurchase of $10.0 million offset by the $5.4 million net cash provided by shares sold through the SVB Leerink ATM agreement, and an additional $304 thousand provided from the issuance of common stock under equity incentive plans.

Net cash provided by financing activities in the year ended December 31, 2024 of $108 thousand consisted of $349 thousand provided from the issuance of common stock under equity incentive plans, offset by cash used in the net-settlement of restricted stock unit vesting of $241 thousand.

Funding Requirements

Our future capital requirements will depend on many factors, including:

- the clinical development of azenosertib for the treatment of oncology indications;
- the preclinical and clinical development of other programs, resources allowing;

- the development of a companion diagnostic with a partner in conjunction with our clinical development of azenosertib as a monotherapy for the treatment of Cyclin E1-positive PROC, if applicable, diagnostics tools for additional biomarkers for azenosertib and any future product candidates;
- the costs of in-licensing or acquiring the rights to other products, product candidates or technologies;
- the legal costs related to maintaining, expanding and protecting our intellectual property portfolio;
- hiring additional personnel, if needed;
- the costs to seek regulatory approval for azenosertib for the treatment of Cyclin E1-positive PROC and support our diagnostic partner's seeking regulatory approval of a companion diagnostic to identify patients with Cyclin E1-positive PROC, and resources allowing, seek regulatory approval of azenosertib for additional oncology indications, assuming supportive clinical data; and
- the costs to seek regulatory approval for any future product candidates and, if needed, diagnostics tools for biomarkers associated with such product candidates, that successfully complete clinical development, resources allowing.

As of December 31, 2025, we have $3.9 million and $35.7 million in current and long-term lease liabilities, respectively. We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund our operating expenses and capital expenditure requirements into late 2027. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our clinical trials for azenosertib for patients with Cyclin E1-positive PROC and, resources allowing, any additional indications, and any future product candidates;
- the progress, costs and results to develop a companion diagnostic to identify patients with Cyclin E1-positive PROC;
- the progress, costs and results of additional research and preclinical studies in other research programs we initiate in the future and, if needed, of diagnostics tools for additional biomarkers for azenosertib and any future product candidates;
- the costs and timing of process development and manufacturing scale-up activities associated with azenosertib and, resources allowing, our product candidates and other programs as we advance them through preclinical and clinical development;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims; and
- our ability to attract and retain skilled personnel.

Further, our operating results may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions.

We currently have no credit facility or committed sources of capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and 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, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures require us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Impairment of Long-Lived Assets

Methodology	*Judgment and Uncertainties*	*Effect if Actual Results Differ From Assumptions*
We evaluate long-lived assets, including property, equipment and operating lease right-of-use (ROU) assets, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset or asset group may not be recoverable. We group assets at the lowest level for which cash flows are separately identified in order to measure an impairment.	The determination of events or changes in circumstances that would result in an impairment review is subject to judgment. Additionally, the determination of impairment is subject to key assumptions including projected cash flows and discount rate.	We base our estimates on the best information available at the time. If actual results are not consistent with the assumptions used, the impairment expense may be overstated or understated.

Revenue Recognition

Methodology	*Judgment and Uncertainties*	*Effect if Actual Results Differ From Assumptions*
For revenue with customers, we are entitled to receive event-based payment subject to the customer's achievement of specific regulatory milestones. We recognize revenue when it is deemed probable that these milestones will be achieved, which could be in a period preceding its actual occurrence. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones, and if necessary, adjust our estimate of the overall transaction price.	Revenue is recognized when we determine it is probable a milestone will be achieved. This assessment is based on market insight and customer communications.	An adjustment of our estimate of the overall transaction price and reversal of revenue will be required in the event it is determined that achievement of a milestone, previously deemed probable, will not occur. This adjustment and reversal may be material.

Research and Development Expenses - Clinical Trial Accruals

Methodology	*Judgment and Uncertainties*	*Effect if Actual Results Differ From Assumptions*
All of our clinical trials have been executed with support from CROs and other vendors. We accrue costs for clinical trial activities performed by CROs and other vendors based upon the estimated amount of work completed on each trial.	For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the activities to be performed for each patient, the number of active clinical sites, and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms.	We base our estimates on the best information available at the time. However, additional information may become available to us, which may allow us to make a more accurate estimate in future periods. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. There were no such significant changes during the years ended December 31, 2025 or 2024.

Share-Based Payments

Methodology	*Judgment and Uncertainties*	*Effect if Actual Results Differ From Assumptions*
We maintain equity incentive plans, which provide for share-based awards, including stock options, restricted stock units, or RSUs, restricted stock and performance awards. We also maintain an employee stock purchase plan. We determine the fair value of our stock option awards and performance awards at the date of grant using a Black-Scholes model. We determine the fair value of our restricted stock awards at the date of grant using the closing market value of our common stock on the date of grant.	Option-pricing models and generally accepted valuation techniques require management to make assumptions and to apply judgment to determine the fair value of our awards. These assumptions and judgments include estimating the future volatility of our stock price, expected dividend yield and future employee stock option exercise behaviors. Changes in these assumptions can materially affect the fair value estimate.	We do not currently believe there is a reasonable likelihood that there will be a material change in estimates or assumptions we use to determine stock-based compensation expense. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to changes in share-based compensation expense that could be material. If actual results are not consistent with the assumptions used, the share-based compensation expense reported in our financial statements may not be representative of the actual economic cost of the share-based compensation. A 10% change in our share-based compensation expense for the year ended December 31, 2025, would have affected pre-tax earnings by approximately $2.1 million.

Recent Accounting Pronouncements

See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further information on certain accounting standards that have been adopted during 2025 or that have not yet been required to be implemented and may be applicable to our future operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Inherent Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation under this framework, our principal executive officer and our principal financial officer have concluded that our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

In accordance with applicable rules and regulations, this report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Arrangements and Policies

During the three months ended December 31, 2025, no director or officer 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders under the sections entitled "Proposal 1: Election of Directors," "Executive Officers," "Corporate Governance" and if required, "Delinquent Section 16(a) Reports" and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders under the sections entitled "Executive Compensation," "Director Compensation" and "Corporate Governance" and is incorporated herein by reference.

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

The information required by this item will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders under the sections entitled "Securities Authorized For Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

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

The information required by this item will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders under the sections entitled "Certain Relationships and Related Person Transactions" and "Corporate Governance" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders under the sections entitled "Proposal 2: Ratification of Appointment of Independent Registered Public Accounting Firm" and "Independent Registered Public Accounting Firm Fees and Other Matters" and is incorporated herein by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The following documents are included on pages F-1 through F-31 attached hereto and are filed as part of this Annual Report on Form 10-K.

Index to Consolidated Financial Statements

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	F-1
Consolidated Financial Statements	
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Comprehensive Loss	F-5
Consolidated Statements of Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-8
Notes to Consolidated Financial Statements	F-10

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Plan of Conversion Converting Zentalis Pharmaceuticals, LLC (a Delaware limited liability company) into Zentalis Pharmaceuticals, Inc. (a Delaware corporation)	10-Q	001-39263	2.1	05/15/2020	
2.2	Certificate of Conversion Converting Zentalis Pharmaceuticals, LLC (a Delaware limited liability company) into Zentalis Pharmaceuticals, Inc. (a Delaware corporation)	10-Q	001-39263	2.2	05/15/2020	
3.1	Certificate of Incorporation of Zentalis Pharmaceuticals, Inc.	S-8	333-237593	4.1	04/07/2020	
3.2	Certificate of Amendment to Certificate of Incorporation of Zentalis Pharmaceuticals, Inc., dated June 16, 2023	8-K	001-39263	3.1	06/16/2023	
3.3	Amended and Restated Bylaws of Zentalis Pharmaceuticals, Inc.	8-K	001-39263	3.1	02/15/2024	
3.4	Second Amended and Restated Limited Liability Company Agreement of Zentalis Pharmaceuticals, LLC	S-1	333-236959	3.3	03/06/2020	
4.1	Amended and Restated Investors' Rights Agreement, dated as of September 6, 2019, by and among Zeno Pharma, LLC and the investors party thereto	S-1	333-236959	4.1	03/06/2020	
4.2	Specimen of Common Stock Certificate evidencing the shares of common stock	S-1	333-236959	4.2	03/06/2020	
4.3	Description of Capital Stock	10-K	001-39263	4.3	03/25/2021	
10.1#	Zentalis Pharmaceuticals, LLC 2017 Profits Interest Plan, as amended, and form of profit interest award agreement thereunder	S-1	333-236959	10.1	03/06/2020	
10.2.1#	2020 Incentive Award Plan and form of option agreement and restricted stock unit agreement thereunder	S-1/A	333-236959	10.2	03/30/2020	
10.2.2#	Amendment No. 1 to the Zentalis Pharmaceuticals, Inc. 2020 Incentive Award Plan	10-Q	001-39263	10.3	05/17/2021	
10.3#	Non-Employee Director Compensation Program	10-K	001-39263	10.3	03/26/2025	

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.4#	2020 Employee Stock Purchase Plan, as amended and restated	S-8	333-254506	99.1	03/19/2021	
10.5.1#	Zentalis Pharmaceuticals, Inc. 2022 Employment Inducement Incentive Award Plan, as amended	10-K	001-39263	10.5.1	03/26/2025	
10.5.2#	Form of Option Agreement pursuant to the Zentalis Pharmaceuticals, Inc. 2022 Employment Inducement Incentive Award Plan	8-K	001-39263	10.2	07/22/2022	
10.5.3#	Form of RSU Agreement pursuant to the Zentalis Pharmaceuticals, Inc. 2022 Employment Inducement Incentive Award Plan	8-K	001-39263	10.3	07/22/2022	
10.6#	Form of Indemnification Agreement for Directors and Officers	10-Q	001-39263	10.1	05/10/2023	
10.7#†	Employment Agreement, dated November 13, 2024, between Zeno Management, Inc. and Ingmar Bruns, M.D.	10-K	001-39263	10.10	03/26/2025	
10.8#†	Employment Agreement, dated November 13, 2024, between Zeno Management, Inc. and Julie Eastland	10-K	001-39263	10.11	03/26/2025	
10.9#	Amended and Restated Employment Agreement, dated February 28, 2023, between Zeno Management, Inc. and Andrea Paul	10-K	001-39263	10.16	03/01/2023	
10.10#†	Release Agreement, dated October 1, 2025 between Zentalis Pharmaceuticals, Inc., Zeno Management, Inc., and Andrea Paul	10-Q	001-39263	10.1	11/10/2025	
10.11#	Amended and Restated Employment Agreement, dated December 31, 2023, between Zeno Management, Inc. and Mark Lackner, Ph.D.	10-K	001-39263	10.23	02/27/2024	
10.12#†	Release Agreement, dated April 25, 2025 between Zentalis Pharmaceuticals, Inc., Zeno Management, Inc. and Mark Lackner, Ph.D.	10-Q	001-39263	10.1	08/06/2025	
10.13#†	Consulting Agreement, dated April 25, 2025 between Zentalis Pharmaceuticals, Inc. and Mark Lackner, Ph.D.	10-Q	001-39263	10.2	08/06/2025	
10.14#†	Employment Agreement, dated September 15, 2025 between Zentalis Pharmaceuticals, Inc. and James B. Bucher					*
10.15†	Third Amended and Restated License Agreement, dated June 5, 2023, by and between Zeno Management, Inc. and Recurium IP Holdings, LLC	10-Q	001-39263	10.1	08/09/2023	
19.1	Insider Trading Compliance Policy	10-K	001-39263	19.1	03/26/2025	
21.1	List of Subsidiaries of Zentalis Pharmaceuticals, Inc.	10-K	001-39263	21.1	02/27/2024	
23.1	Consent of Independent Registered Public Accounting Firm.					*
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).					*
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a).					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.					**

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
97#	Zentalis Pharmaceuticals, Inc. Policy for Erroneously Awarded Compensation	10-K	001-39263	97	02/27/2024	
101.INS	Inline 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	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.
# Indicates management contract or compensatory plan.
† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZENTALIS PHARMACEUTICALS, INC.

Date: March 26, 2026

By: /s/ Julie Eastland
Julie Eastland
President and Chief Executive Officer

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

Name	Title	Date
/s/ Julie Eastland **Julie Eastland**	President, Chief Executive Officer and Director *(principal executive officer)*	March 26, 2026
/s/ Vincent A. Vultaggio **Vincent A. Vultaggio**	Senior Vice President, Finance and Principal Accounting Officer *(principal financial and accounting officer)*	March 26, 2026
/s/ Scott Myers **Scott Myers**	Chairperson of the Board of Directors	March 26, 2026
/s/ David Johnson **David Johnson**	Director	March 26, 2026
/s/ Enoch Kariuki **Enoch Kariuki**	Director	March 26, 2026
/s/ Jan Skvarka **Jan Skvarka**	Director	March 26, 2026
/s/Luke Walker, M.D. **Luke Walker, M.D.**	Director	March 26, 2026

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Zentalis Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Zentalis Pharmaceuticals, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matter

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

	Accrued clinical trial expenses
Description of the Matter	During the year ended December 31, 2025, the Company incurred $107.3 million for research and development expenses and as of December 31, 2025, the Company accrued $14.7 million for research and development expenses, which includes clinical trial expenses and accruals. As described in Note 2 of the consolidated financial statements, the Company records accruals for estimated costs of research and development activities that include costs for clinical trials. The Company records costs based on estimates and/or representations from contract research organizations ("CROs") and other vendors regarding work performed, level of patient enrollment, completion of patient studies, and progress of the clinical trials. The Company monitors patient enrollment levels and related activities through internal reviews, correspondence with CROs, and reviews of contractual terms.

Auditing management's accounting for accrued clinical trial expenses was especially challenging as the evaluation is dependent upon a high volume of data received from third-party service providers and internal clinical personnel, which is tracked in spreadsheets. The accrued amounts are determined based on an evaluation of the unique terms and conditions set forth in each respective agreement.

How We Addressed the Matter in Our Audit	To test the adequacy of the Company's accrued clinical trial expenses, our substantive audit procedures included, among others, testing the completeness and accuracy of data and assumptions used in management's clinical trial accrual models by inspecting a sample of invoices paid to date, agreeing terms and conditions to a sample of contracts, and performing inquiries with clinical staff to corroborate progress and level of expended effort incurred by the Company's CROs and other third-party vendors. We further obtained the clinical trial agreements for a sample of active clinical sites and compared the costs and number of patient visits to the Company's clinical trial accrual models. We also tested a sample of expenses against the related invoices and contracts and examined a sample of subsequent payments to evaluate the completeness of the accrued clinical trial expenses. Further, for a sample of active clinical sites, we obtained direct confirmation of current year invoices billed, the dollar value of the clinical agreement based upon the most recent executed contract, the current status of activities, and the completeness of change orders or amendments with the CRO.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

San Diego, California
March 26, 2026

Zentalis Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except share amounts and par value)

	December 31,	
	2025	2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 35,995	$ 33,901
Marketable debt securities, available for sale	209,898	318,009
Marketable equity securities	—	19,174
Contracts receivable	—	5,000
Prepaid expenses and other current assets	7,298	9,982
Total current assets	253,191	386,066
Property and equipment, net	2,770	4,699
Operating lease right-of-use assets	26,271	32,528
Prepaid expenses and other assets	4,108	4,417
Restricted cash	2,627	2,627
Total assets	$ 288,967	$ 430,337
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 7,208	$ 7,438
Accrued expenses	29,351	45,287
Total current liabilities	36,559	52,725
Long-term lease liability	35,704	39,577
Other long-term liabilities	500	849
Total liabilities	72,763	93,151
Commitments and contingencies (see Note 10)		
EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.001 par value; 250,000,000 shares authorized; 69,085,980 and 71,282,400 shares issued and outstanding at December 31, 2025 and 2024, respectively	69	71
Additional paid-in capital	1,407,394	1,390,952
Accumulated other comprehensive income	196	558
Accumulated deficit	(1,191,455)	(1,054,395)
Total stockholders' equity	216,204	337,186
Total liabilities and stockholders' equity	$ 288,967	$ 430,337

See accompanying notes to consolidated financial statements.

Zentalis Pharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Year ended December 31,		
	2025	**2024**	**2023**
Revenues from Licensing and Sales of Intellectual Property	$ —	$ 67,425	$ —
Operating Expenses			
Research and development	107,295	167,768	189,590
Zentera in-process research and development	—	—	45,568
General and administrative	37,717	87,115	64,351
Restructuring	7,796	—	—
Goodwill impairment	—	3,736	—
Total operating expenses	152,808	258,619	299,509
Loss from operations	(152,808)	(191,194)	(299,509)
Other Income (Expense)			
Investment and other income, net	16,190	25,504	22,617
Net loss before income taxes	(136,618)	(165,690)	(276,892)
Income tax expense (benefit)	442	177	(601)
Loss on equity method investment	—	—	16,014
Net loss	(137,060)	(165,867)	(292,305)
Net loss attributable to noncontrolling interests	—	(28)	(114)
Net loss attributable to Zentalis	$ (137,060)	$ (165,839)	$ (292,191)
Net loss per common share outstanding, basic and diluted	$ (1.91)	$ (2.33)	$ (4.47)
Common shares used in computing net loss per share, basic and diluted	71,869	71,080	65,409

See accompanying notes to consolidated financial statements.

Zentalis Pharmaceuticals, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year ended December 31,		
	2025	2024	2023
Net loss	$ (137,060)	$ (165,867)	$ (292,305)
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable debt securities, net	(362)	(1,636)	3,547
Total comprehensive loss	(137,422)	(167,503)	(288,758)
Comprehensive loss attributable to noncontrolling interests	—	(28)	(114)
Comprehensive loss attributable to Zentalis	$ (137,422)	$ (167,475)	$ (288,644)

See accompanying notes to consolidated financial statements.

Zentalis Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except per unit amounts)

	Year Ended December 31, 2023						
	Zentalis Stockholders						
	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total Equity
	Shares	Amount					
Balance at December 31, 2022	59,280	$ 59	$1,031,462	$ (1,353)	$ (596,365)	$ 221	$ 434,024
Share-based compensation expense	—	—	54,822	—	—	—	54,822
Issuance of common stock in connection with an equity offering, net of underwriting discounts, commissions and offering costs	11,033	11	235,669	—	—	—	235,680
Issuance of common stock in connection with restricted stock unit vesting	361	—	—	—	—	—	—
Issuance of common stock upon exercise of options	54	—	995	—	—	—	995
Shares issued under employee stock purchase plan	42	—	628	—	—	—	628
Cancellation of restricted stock awards	(3)	—	—	—	—	—	—
Other comprehensive income	—	—	—	3,547	—	—	3,547
Net loss attributable to non-controlling interest	—	—	—	—	—	(114)	(114)
Net loss attributable to Zentalis	—	—	—	—	(292,191)	—	(292,191)
Balance at December 31, 2023	70,767	$ 70	$1,323,576	$ 2,194	$ (888,556)	$ 107	$ 437,391

	Year Ended December 31, 2024						
	Zentalis Stockholders						
	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Equity
	Shares	Amount					
Balance at December 31, 2023	70,767	$ 70	$ 1,323,576	$ 2,194	$ (888,556)	$ 107	$ 437,391
Share-based compensation expense	—	—	67,269	—	—	—	67,269
Issuance of common stock in connection with restricted stock unit vesting, net	466	1	(241)	—	—	—	(240)
Deconsolidation of Kalyra	—	—	—	—	—	(79)	(79)
Issuance of common stock upon exercise of options	1	—	8	—	—	—	8
Shares issued under employee stock purchase plan	48	—	340	—	—	—	340
Other comprehensive loss	—	—	—	(1,636)	—	—	(1,636)
Net loss attributable to non-controlling interest	—	—	—	—	—	(28)	(28)
Net loss attributable to Zentalis	—	—	—	—	(165,839)	—	(165,839)
Balance at December 31, 2024	71,282	$ 71	$ 1,390,952	$ 558	$ (1,054,395)	$ —	$ 337,186

	Year Ended December 31, 2025					
	Zentalis Stockholders					
	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Equity
	Shares	Amount				
Balance at December 31, 2024	71,282	$ 71	$ 1,390,952	$ 558	$ (1,054,395)	$ 337,186
Issuance of common stock in ATM Offering, net of commissions	3,929	4	5,386	—	—	5,390
Repurchase of common stock	(7,500)	(7)	(9,969)	—	—	(9,976)
Share-based compensation expense	—	—	20,722	—	—	20,722
Other comprehensive loss	—	—	—	(362)	—	(362)
Issuance and withholding of common stock in connection with restricted stock unit vesting, net	1,138	1	(1)	—	—	—
Shares issued under employee stock purchase plan	237	—	304	—	—	304
Net loss attributable to Zentalis	—	—	—	—	(137,060)	(137,060)
Balance at December 31, 2025	69,086	$ 69	$ 1,407,394	$ 196	$ (1,191,455)	$ 216,204

See accompanying notes to consolidated financial statements.

Zentalis Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Operating activities:			
Net loss	$ (137,060)	$ (165,867)	$ (292,305)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	739	1,289	1,389
Operating lease right-of-use and fixed asset impairment	4,136	—	4,953
Noncash consideration portion of Zentera in-process research and development	—	—	15,045
Share-based compensation	20,722	67,269	54,822
Goodwill impairment	—	3,736	—
(Gain)/loss on disposal of equipment	(660)	(13)	406
Non-cash impact of revenues from licensing and sales of intellectual property	—	(47,425)	—
Non-cash recognized mark-to-market of equity securities	(1,239)	(5,228)	—
Accretion of discounts on marketable securities, net	(2,763)	(8,002)	(13,157)
Loss on equity method investment	—	—	16,014
Deferred income taxes	—	—	(853)
Deconsolidation of Kalyra	—	(79)	—
Changes in operating assets and liabilities:			
Accounts receivable	5,000	(5,000)	—
Prepaid expenses and other assets	2,993	6,218	(5,678)
Accounts payable and accrued liabilities	(17,316)	(18,022)	10,919
Operating lease right-of-use assets and liabilities, net	201	264	623
Net cash used in operating activities	(125,247)	(170,860)	(207,822)
Investing activities:			
Purchases of marketable debt securities	(139,488)	(127,962)	(549,182)
Proceeds from maturities of marketable debt securities	250,000	271,200	505,307
Proceeds from sale of marketable equity securities	20,413	33,479	—
Proceeds from sale of property and equipment	698	65	—
Purchases of property and equipment	—	(221)	(583)
Net cash provided by (used in) investing activities	131,623	176,561	(44,458)
Financing activities:			
Proceeds from issuance of common stock, net	5,390	—	235,680
Proceeds from issuance of common stock under equity incentive plans	304	349	1,623
Repurchase of common stock	(9,976)	—	—
Net-settlement of restricted stock unit vesting	—	(241)	—
Net cash (used in) provided by financing activities	(4,282)	108	237,303
Net increase (decrease) in cash, cash equivalents and restricted cash	2,094	5,809	(14,977)
Cash, cash equivalents and restricted cash at beginning of year	36,528	30,719	45,696
Cash, cash equivalents and restricted cash at end of year	$ 38,622	$ 36,528	$ 30,719
Supplemental disclosure of cash flow information:			
Income taxes paid	$ 85	$ 359	$ 140
Supplemental disclosure of non-cash investing and financing activities:			
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ —	$ 602

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the Consolidated Statements of Cash Flows for the periods presented:

	Year Ended December 31,		
	2025	2024	2023
Cash and cash equivalents	$ 35,995	$ 33,901	$ 28,038
Restricted cash, non-current	2,627	2,627	2,681
Total cash, cash equivalents and restricted cash reported in the Consolidated Statement of Cash Flows	$ 38,622	$ 36,528	$ 30,719

See accompanying notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Organization

Zentalis Pharmaceuticals, Inc. (“Zentalis,” “We” or the “Company”) is a clinical-stage biopharmaceutical company developing azenosertib (ZN-c3), an investigational potentially first-in-class and best-in-class WEE1 inhibitor for patients with Cyclin E1-positive platinum-resistant ovarian cancer ("Cyclin E1-positive PROC"). The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. All of the Company’s tangible assets are held in the United States.

Liquidity

Substantial doubt about an entity’s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statements issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that the audited consolidated financial statements for the year ended December 31, 2025 are issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) and include our wholly-owned subsidiaries and Kalyra Pharmaceuticals, Inc. ("Kalyra"), a variable interest entity (“VIE”) for which we were the primary beneficiary until Kalyra was dissolved in January 2024. All intercompany transactions and balances have been eliminated in consolidation. Certain prior year amounts have been reclassified to conform to the current year's presentation. Following the dissolution of Kalyra, we no longer have an interest in any VIEs.

We evaluate our ownership, contractual and other interests in entities that are not wholly-owned to determine if these entities are VIEs, and, if so, whether we are the primary beneficiary of the VIE. In determining whether we are the primary beneficiary of a VIE and therefore required to consolidate the VIE, we apply a qualitative approach that determines whether we have both (1) the power to direct the activities of the VIE that most significantly impact the VIE’s economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE.

We will continuously assess whether we are the primary beneficiary of a VIE, as changes to existing relationships or future transactions may result in the consolidation or deconsolidation of such VIE. During the periods presented, we have not provided any other material financial or other support to our VIE that we were not contractually required to provide.

Noncontrolling Interests

Noncontrolling interests represent interests held by third parties in our consolidated subsidiaries. We reflect noncontrolling interest attributable to the other owners in a separate line in our consolidated statements of operations and a separate line within stockholders' equity in our consolidated balance sheets.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management’s estimates.

Cash and Cash Equivalents

Cash equivalents are comprised of short-term, highly-liquid investments with maturities of ninety days or less at the date of purchase. As of December 31, 2025 and 2024, our cash equivalents consisted of money market funds.

Marketable Debt Securities

Marketable debt securities are investments with original maturities of more than ninety days from the date of purchase that we have the ability to liquidate to fund current operations. Accordingly, those investments with contractual maturities of greater than one year from the date of purchase are classified as short-term investments on the accompanying consolidated balance sheets. Marketable debt securities are considered available-for-sale and are carried at fair value with unrealized gains and losses recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity. The cost of marketable debt securities is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in investment and other income, net through an allowance account. We use the specific identification method for calculating realized gains and losses on marketable securities sold. Realized gains and losses on marketable securities, if any, are included in investment and other income, net in the consolidated statements of operations.

Investments in Equity Securities

We carry investments of less than twenty percent ownership in equity securities at fair value and record the changes in fair value in the consolidated statement of operations as a component of Investment and other income, net. We account for our equity investments in publicly traded companies at their listed stock price. As of December 31, 2025, we no longer hold any equity investments.

Contracts Receivable

Our contracts receivable balance represents the amounts we are contractually allowed to bill our customers and that are due to us unconditionally for goods we have delivered, services we have performed or milestones achieved. When we bill our customers with payment terms based on the passage of time, we consider the contracts receivable to be unconditional.

Restricted Cash

Under the terms of our office leases, we are required to maintain a letter of credit as a security deposit during the term of such leases. At December 31, 2025 and 2024, restricted cash of $2.6 million was pledged as collateral for the letters of credit.

Fair Value of Financial Instruments

The authoritative guidance defines fair value and requires us to establish a framework for measuring fair value and disclosure about fair value measurements using a three-tier approach. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Our financial instruments include cash equivalents, marketable securities, prepaid expenses and other assets, accounts payable and accrued expenses. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision.

The fair value of marketable securities is determined using proprietary valuation models and analytical tools, which utilize market pricing or prices for similar instruments that are both objective and publicly available, such as matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities and bids and offers.

The carrying amount of cash equivalents, prepaid expenses and other assets, accounts payable and accrued expenses are generally considered to be representative of their respective values because of the short-term nature of those instruments.

Concentrations of Credit Risk and Sources of Supply

We are subject to credit risk from our portfolios of cash equivalents and marketable securities. We maintain our cash and cash equivalent and marketable securities balances with major commercial banks. Deposits held with the financial institutions exceed the amount of insurance provided on such deposits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents and marketable securities to the extent recorded on the consolidated balance sheets. We have also established guidelines to limit our exposure to credit risk by diversifying our marketable securities portfolio and placing them in investments with maturities that maintain safety and liquidity.

We rely on third-party manufacturers for the supply of raw materials, active drug substance and finished drug product.

Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Equipment is depreciated using the straight-line method over its estimated useful life ranging from three to five years and leasehold improvements are amortized using the straight-line method over the estimated useful life of the asset or the lease term, whichever is shorter. Repair and maintenance costs are expensed as incurred.

Leases

We have entered into operating leases for real estate. We determine if an arrangement is a lease at inception and evaluate each lease agreement to determine whether the lease is an operating or finance lease. For leases where we are the lessee, right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Liabilities from operating leases are included in accrued expenses and long-term lease liabilities on our consolidated balance sheet. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As our leases do not provide an implicit interest rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The operating lease ROU asset also includes any prepaid lease payments, lease incentives received, and costs which will be incurred in exiting a lease. Our leases often include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that we will exercise that option. As of December 31, 2025, it is not reasonably certain that these options will be exercised and they are not included within the lease term. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. We have lease agreements with lease and non-lease components which are accounted for as a single lease component for all of our leases.

Impairment of Long-Lived Assets

We account for long-lived assets in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. See Note 10 regarding impairment test performed for our operating lease right-of-use asset associated with our San Diego lease.

Goodwill

Our goodwill, which has an indefinite useful life, represents the excess of the cost over the fair value of net assets acquired from its business combination. The determination of the value of goodwill and intangible assets arising from business combinations and asset acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including capitalized in-process research and development ("IPR&D").

Goodwill is reviewed for impairment at least annually, or more frequently if an event occurs indicating the potential for impairment. During the impairment review process, we consider qualitative factors to determine whether it is more-likely-than-not that the fair value of the reporting unit is less than the carrying amount, including goodwill. If we determine that it is not more-likely-than-not that the fair value of our reporting unit is less than the carrying amount, then no additional assessment is deemed necessary. Otherwise, we proceed to compare the estimated fair values of the reporting units with the carrying values, including goodwill. If the carrying amounts of the reporting units exceed the fair values, we record an impairment loss based on the difference.

During the fourth quarter ended December 31, 2024, we concluded the sustained decrease in the Company's stock price and overall market capitalization during the quarter was an indication that the fair value of a reporting unit might be less than its carrying amount and that a goodwill test was required. As a result, the Company performed a quantitative test over the reporting unit, noting that the fair value of the reporting unit was less than the carrying value, which resulted in an impairment of goodwill of $3.7 million.

In performing a quantitative test for impairment of goodwill, we primarily use the market approach method of valuation that includes the guideline public company method to determine the fair value of the reporting unit. In order to further validate the reasonableness of the fair value concluded for our reporting unit, a reconciliation to market capitalization was performed by estimating a reasonable implied control premium and other market factors.

Equity Method Accounting

We held significant influence, but not a controlling interest, in our former affiliate Zentera Therapeutics, Inc. ("Zentera"). From the deconsolidation of Zentera during July 2021 until the termination of our collaboration with and divestiture of our ownership position in Zentera during the six-months ended June 30, 2023, this investment was accounted for using the equity method. Our share of earnings or losses of the investment entity were reported on the consolidated statement of operations, with a corresponding increase or decrease to the equity investment carried on the statement of financial position. This information was generally not received sufficiently timely for us to record our portion of earnings or loss in the current financial statements, and therefore we reported our portion of earnings or loss on a one quarter lag. The maximum exposure to loss as a result of our investment in Zentera was directly associated with the carrying amount of the equity method investment on our consolidated balance sheet.

Revenue Recognition and Collaborative Arrangements

The Company generates revenues from payments received under collaborative, intellectual property licensing and sale agreements.

At contract execution, we analyze our collaborative arrangements and license agreements to assess whether both parties are active participants in the activities and are exposed to significant risks and rewards and therefore are within the scope of ASC 808, Collaborative arrangements (“ASC 808”). ASC 808 does not address the recognition and measurement of payments from collaborative arrangements and instead refers companies to use other authoritative accounting literature. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration reflect a vendor-customer relationship and therefore are within the scope of ASC 606, Revenue from Contracts with Customers. When we determine elements of a collaboration agreement do not reflect a vendor-customer relationship, we consistently apply a reasonable and rational policy election we made by analogizing to authoritative accounting literature. We evaluate the income statement classification for presentation of amounts due from or owed to other participants in a collaboration arrangement based on the nature of each separate activity.

To determine revenue recognition for contracts with customers, we perform the following five steps: (i) identify the contract(s) with the customer; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations.

From time to time we amend our agreements. When this occurs, we are required to assess (1) if the additional goods or services are distinct from the other performance obligations in the previous agreement(s) and (2) if the goods or services are transferred at a stand-alone selling price. If we conclude the goods and/or services in the amendment are distinct from the performance obligations in the original agreement and at a stand-alone selling price, we account for the amendment as a separate agreement. If we conclude the goods and/or services are not distinct and are sold at a stand-alone selling price, we then assess whether the remaining goods or services are distinct from those already provided. If the goods and/or services are distinct from what we have already provided, then we treat the amendment as a termination of the existing contract and allocate the total remaining transaction price from the original agreement and the additional transaction price from the amendment to the remaining goods and/or services. If the goods and/or services are not distinct from what we have already provided, we update the transaction price and allocate it to the remaining performance obligations and adjust revenue previously recognized based on an updated measure of progress for the partially satisfied performance obligations.

Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, external clinical trial expenses, research-related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operating expenses as incurred when these expenditures relate to our research and development efforts and have no alternative future uses.

We are obligated to make upfront payments upon execution of certain research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred. Such amounts are recognized as expense as the related goods are delivered or the related services are performed, or such time when we do not expect the goods to be delivered or services to be performed.

Clinical Trial Expenses

We make payments in connection with our clinical trials under contracts with CROs that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of our obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts we are obligated to pay under our clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we adjust our accruals accordingly. Revisions to our contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Restructuring Expense

The Company recognizes and measures a liability for one-time employee termination benefits for which no future service is required once the plan of termination meets all of the following criteria and has been communicated to employees: (i) management commits to a plan of termination; (ii) the plan identifies the number of employees to be terminated and their job classifications or functions, locations and the expected completion date; (iii) the plan establishes the terms of the benefit arrangement; and (iv) it is unlikely that significant changes to the plan will be made or the plan will be withdrawn. For one-time termination benefits for which future service is required, a liability is measured at the communication date based on its fair value as of the termination date and recognized ratably over the future service period. The Company recognizes and measures a liability for other related costs in the period in which the liability is incurred.

Share-Based Compensation

We record share-based compensation expense associated with equity instruments in accordance with the authoritative guidance for stock-based compensation. The cost of employee services received in exchange for an award of an equity instrument is measured at the grant date based on the estimated fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award. Share-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized, and any previously recognized compensation expense is reversed. Forfeitures are recognized as a reduction of share-based compensation expense as they occur.

Income Taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A provision has been made for income taxes due on taxable income and for the deferred taxes on temporary differences. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment. Realization of the deferred income tax asset is dependent on gathering sufficient taxable income in future years.

Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the period and the change during the period in deferred tax assets and liabilities. We follow the accounting guidance on accounting for uncertainty in income taxes. The guidance prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities based on the technical merits of the position.

Accumulated Other Comprehensive Income

Accumulated other comprehensive income is the result of unrealized gains and losses on marketable securities.

Net Loss per Common Share Outstanding

Basic net loss per common share outstanding is computed by dividing net loss, after adjusting for dividends, if declared, by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share outstanding is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential common shares. Potential common shares consist of unvested restricted stock units and common shares issuable upon the exercise of stock options.

Acquisitions and Contingent Consideration

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business.

If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting as indicated in Accounting Standards Update (ASU) 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquired entity and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities, and non-controlling interest in the acquired entity based on the fair value estimates as of the date of acquisition. In accordance with Accounting Standards Codification (ASC) 805, Business Combinations, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

The consideration for the Company's business acquisitions may include future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration, other than changes due to payments, are recognized as a gain or loss and recorded within change in the fair value of deferred and contingent consideration liabilities in the consolidated statements of comprehensive loss. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities. Contingent consideration liabilities expected to be settled 12 months after the balance sheet date are presented in long-term liabilities.

If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50, which requires the acquiring entity to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. No gain or loss is recognized as of the date of acquisition unless the fair value of non-cash assets given as consideration differs from the assets' carrying amounts on the acquiring entity's books. Consideration transferred that is non-cash will be measured based on either the cost (which shall be measured based on the fair value of the consideration given) or the fair value of the assets acquired and liabilities assumed, whichever is more reliably measurable. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and therefore have no alternative future use, the Company expenses payments made under such license agreements as acquired IPR&D expense in its consolidated statement of comprehensive loss. Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration is paid or becomes payable (unless the contingent consideration meets the definition of a derivative, in which case the amount becomes part of the basis in the asset

acquired). Upon recognition of the contingent consideration payment, the amount is included in the cost of the acquired asset or group of assets.

Adoption and Pending Adoption of Recent Accounting Pronouncements

The following table provides a brief description of recently issued accounting standards, those adopted in the current period and those not yet adopted:

Standard	Description	Effective Date	Effect on the Financial Statements or Other Significant Matters
In December 2023, the FASB issued ASU 2023-09, Income Taxes — Improvements to Income Tax Disclosures (Topic 740)	This standard requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction.	January 1, 2025	We adopted the new standard on a prospective basis for the annual period ended December 31, 2025, with no material impact on our consolidated financial statements. The required disclosures have been included in the notes to the financial statements.
In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses	This standard is intended to improve transparency by requiring entities to disclose, in the notes to the financial statements, a disaggregation of certain expense categories that are included within the line items presented on the face of the income statement.	January 1, 2027	We are currently evaluating the impact that adoption of ASU 2024-03 will have on our financial statement disclosures.

3. Significant Transactions

Immunome License Agreement

In January 2024, the Company and Immunome, Inc. (“Immunome”) entered into an exclusive, worldwide license agreement under which Immunome licensed from Zentalis ZPC-21 (now known as IM-1021), a preclinical ROR1 antibody-drug conjugate (“ADC”) and proprietary ADC technology platform (the “Immunome License Agreement”). Simultaneously, the Company and Immunome entered into a stock issuance agreement (together with the Immunome License Agreement, the “Immunome License Agreements”). The upfront consideration from Immunome amounted to $40.6 million, which consisted of $15.0 million in cash and approximately 2.3 million shares (quantified using a 30-day volume average price) of Immunome common stock valued at approximately $25.6 million on the date of acquisition and accounted for as marketable equity securities on the consolidated balance sheet. Changes to the fair value of the Immunome stock were recorded as a component of investment and other income, net within the condensed consolidated statement of operations. The Company was eligible to receive up to $275.0 million in development, regulatory and sales milestones as well as tiered royalties on net sales of licensed products. The Immunome License Agreement terminated upon the parties’ entry into the Immunome Purchase Agreement in October 2024, as described below under "Immunome Asset Sale", and the Company was no longer eligible to receive development, regulatory and sales milestones or royalties under this Immunome License Agreement. The Company divested the 2.3 million shares of Immunome common stock acquired through the Immunome License Agreement during the year ended December 31, 2024, resulting in net proceeds of $33.5 million.

The Company determined that the Immunome License Agreements fall within the scope of ASC 606, Revenue from Contracts with Customers (ASC 606) as Immunome has contracted to obtain goods and services that are an output of ordinary activities and is a customer. Furthermore, subsequent to the execution of the Immunome License Agreements, the Company is no longer an active participant in the research and is no longer exposed to the significant risks and rewards of the research. Management of the Company determined there was one combined performance obligation for the Immunome License Agreements and know-how given the deliverables are not distinct. The Company evaluated the performance obligation within the Immunome License Agreements and determined the combined performance obligation was satisfied at a point in time with Immunome as the Immunome License Agreements represents a right to use the functional intellectual property as it exists at the time of the Immunome License Agreements, the customer has significant risk and rewards of ownership of the asset and the

customer has accepted the asset with the transfer of know-how within the quarter ended March 31, 2024. In addition, variable consideration consisting of milestone payments was evaluated based on the Company's analysis that the possibility of achieving any of the milestone payments was remote, and therefore determined to be constrained and excluded from the transaction price.

Immunome Asset Sale

In October 2024, the Company and Immunome entered into an asset purchase agreement, pursuant to which Immunome purchased from the Company ZPC-21 (now known as IM-1021), a preclinical ROR1 ADC, and the Company's proprietary ADC platform technology (the "Immunome Purchase Agreement"). The assets subject to the Immunome Asset Sale Agreement were previously licensed to Immunome under the Immunome License Agreement. Simultaneously, the Company and Immunome entered into a stock issuance agreement (together with the Immunome Purchase Agreement, the "Immunome Asset Purchase Agreements"). The upfront consideration from Immunome amounted to $30 million, which consisted of 1.8 million shares of Immunome common stock based on the trailing 30-day volume weighted average price of Immunome common stock (valued at approximately $21.9 million based on the closing price of Immunome's common stock on the date of acquisition), and $5.0 million of contingent consideration due upon the achievement of a developmental milestone. The developmental milestone was achieved in December 2024. Pursuant to the terms of the Immunome Stock Agreement, Zentalis was obligated to hold and not sell greater than 50% of the shares until the six-month anniversary in April 2025 of the closing date, subject to certain exceptions. The Immunome License Agreement terminated upon the parties' entry into the Immunome Purchase Agreement. The Company divested the 1.8 million shares of Immunome common stock acquired through the Immunome Purchase Agreement during the year ended December 31, 2025, resulting in net proceeds of $20.4 million. As of December 31, 2025, the Company no longer holds shares of Immunome common stock.

The Company determined that the Immunome Asset Purchase Agreements fall within the scope of ASC 606, Revenue from Contracts with Customers (ASC 606) as Immunome has contracted to obtain goods and services that are an output of ordinary activities and is a customer. Furthermore, the Immunome Asset Purchase Agreements changes existing enforceable rights and obligations of the Immunome License Agreement and is accounted for as a contract modification. Management of the Company determined there was one combined performance obligation for the Immunome Asset Purchase Agreements. The Company evaluated the performance obligation within the Immunome Purchase Agreements and determined the performance obligation was satisfied at a point in time with Immunome as the Immunome Asset Purchase Agreements represent the transfer of ownership of functional intellectual property as it existed at the time of the Immunome Asset Purchase Agreements within the quarter ended December 31, 2024. In addition, variable consideration consisting of milestone payments was evaluated based on the Company's analysis that the possibility of achieving the milestone payment was probable. During the twelve months ended December 31, 2024, the Company recognized revenue from milestone payments of $5.0 million.

4. Segment Reporting and Disaggregation of Relevant Expense Captions

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The determination of a single business segment is consistent with the consolidated financial information periodically reviewed by the Chief Executive Officer as chief operation decision maker ("CODM") in assessing segment performance and deciding how to allocate resources.

The CODM uses net income or loss to monitor budgets, forecasts and expected cash flows in assessing segment performance and in deciding how to allocate resources. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The following table presents information about reported significant segment expenses and net loss (in thousands):

	Year ended December 31,		
	2025	2024	2023
Revenues	$ —	$ 67,425	$ —
Less:			
Research and development [1]:			
Azenosertib external development costs	48,102	75,837	67,019
Unallocated research and development expenses and discontinued programs	59,193	91,931	122,571
Total Research and development	107,295	167,768	189,590
General and administrative	37,717	87,115	64,351
Other [2]	(7,952)	$ (21,591)	38,364
Net loss	(137,060)	(165,867)	(292,305)
Adjustments for cash used in operations:			
Non-Cash expenses	20,935	11,547	78,619
Changes in working capital	(9,122)	(16,540)	5,864
Cash used in operations:	$ (125,247)	$ (170,860)	$ (207,822)

[1] The Company tracks external development costs by product candidate or development program, but does not allocate personnel costs, general license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses and discontinued programs.

[2] Other consists of investment and other income, net, restructuring, goodwill impairment charges, Zentera in-process research and development, Income tax expense (benefit), and loss on equity method investment.

5. Fair Value Measurement

Available-for-sale marketable debt securities consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 159,767	$ 167	$ (11)	$ 159,923
US Treasury securities	49,935	40	—	49,975
	$ 209,702	$ 207	$ (11)	$ 209,898

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	233,291	731	(81)	233,941
US Treasury securities	84,160	43	(135)	84,068
	$ 317,451	$ 774	$ (216)	$ 318,009

As of December 31, 2025, six of our available-for-sale debt securities with a fair market value of $54.9 million were in a gross unrealized loss position of $11 thousand. Five have been in a gross unrealized loss position of $7 thousand for less than one year, and one has been in a gross unrealized loss position of $4 thousand for more than one year. When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, our intent to sell or the likelihood that we would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. Based on our review of these marketable securities, we believe none of the unrealized loss is as a result of a credit loss as of December 31, 2025,

because we do not intend to sell these securities, and it is not more-likely-than-not that we will be required to sell these securities before the recovery of their amortized cost basis.

Contractual maturities of available-for-sale debt securities are as follows (in thousands):

	December 31, 2025	December 31, 2024
	Estimated Fair Value	
Due within one year	$ 209,898	$ 249,308
After one but within five years	—	68,701
	$ 209,898	$ 318,009

Equity investment gains (losses) for the years ended December 31, 2025 and December 31, 2024 are summarized as follows (in thousands):

	December 31, 2025	December 31, 2024
Change in unrealized investment losses during the year on securities held at the end of the year	$ —	$ (2,690)
Investment gains losses during the year on securities sold	1,239	7,918
Net gains recognized on equity securities	$ 1,239	$ 5,228

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. The Company determines the fair value of financial assets and liabilities using three levels of inputs as follows:

Level 1—Inputs which include quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) that are either directly or indirectly observable, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life.

Level 3—Unobservable inputs for assets or liabilities and include little or no market activity.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company had $0.5 million in contingent consideration liabilities as of December 31, 2025 and 2024 related to the agreement to terminate its Collaboration and License Agreements with Zentera. The contingent consideration balance is limited to one potential milestone payment measured at fair value. The fair value of the contingent consideration is estimated based on the monetary value of the milestone discounted for the probability of achieving the milestone and a present value factor based on the timing of when the milestone is expected to be achieved. The value for the contingent consideration balance is based on significant inputs not observable in the market which represents Level 3 measurement within the fair value hierarchy. This liability existed as of December 31, 2025 and 2024.

The following table summarizes, by major security type, our cash equivalents and available-for-sale marketable securities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total estimated fair value
Cash equivalents:				
Money market funds	$ 18,637	$ —	$ —	$ 18,637
Total cash equivalents:	18,637	—	—	18,637
Available-for-sale marketable securities:				
Corporate debt securities	—	159,923	—	159,923
US Treasury securities	49,975	—	—	49,975
Total available-for-sale marketable securities:	49,975	159,923	—	209,898
Total assets measured at fair value	$ 68,612	$ 159,923	$ —	$ 228,535
Financial liabilities:				
Contingent consideration	—	—	500	500
Total financial liabilities	$ —	$ —	$ 500	$ 500

	December 31, 2024			
	Level 1	Level 2	Level 3	Total estimated fair value
Cash equivalents:				
Money market funds	$ 13,723	$ —	$ —	$ 13,723
Total cash equivalents:	13,723	—	—	13,723
Available-for-sale marketable securities:				
Corporate debt securities	—	233,941	—	233,941
US Treasury securities	84,068	—	—	84,068
Total available-for-sale marketable securities:	84,068	233,941	—	318,009
Immunome marketable equity securities	19,174	—	$ —	19,174
Total assets measured at fair value	$ 116,965	$ 233,941	$ —	$ 350,906
Financial liabilities:				
Contingent consideration	—	—	500	500
Total financial liabilities	$ —	$ —	$ 500	$ 500

The following significant unobservable inputs were used in the valuation of the contingent consideration payable to Zentera as variable consideration for a change in control milestone payment of either zero or $15.0 million pursuant to the termination of our Collaboration and License Agreement at December 31, 2025 and December 31, 2024:

Contingent Consideration Liability	Fair Value as of December 31, 2025 (in thousands)	Valuation Technique	Unobservable Input	Range
Milestone payment	$ 500	Discounted cash flow	Likelihood of occurrence	1.0%- 2.4%
			Discount rate	40%
			Expected term	Perpetuity

The following table reflects the activity for the Company's contingent consideration, measured at fair value using Level 3 inputs (in thousands):

Contingent consideration at December 31, 2024	$ 500
Changes in the fair value of contingent consideration	—
Contingent consideration at December 31, 2025	$ 500

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the years ended December 31, 2025 and December 31, 2024. We had one instrument that was classified within Level 3 as of December 31, 2025 and December 31, 2024. As of December 31, 2025 and December 31, 2024, no material fair value adjustments were required for non-financial assets and liabilities.

6. Prepaid Expenses and Other Assets

Prepaid expenses and other assets consisted of the following (in thousands):

	December 31,	
	2025	2024
Prepaid insurance	$ 300	$ 249
Prepaid software licenses and maintenance	394	509
Foreign R&D credit refund	142	—
Prepaid research and development expenses	6,682	8,788
Interest receivable	1,928	2,943
Deferred tax asset	51	101
Sublease assets	496	626
Other prepaid expenses	1,413	1,183
Total prepaid expenses and other current assets	11,406	14,399
Less long-term portion	4,108	4,417
Total prepaid expenses and other assets, current	$ 7,298	$ 9,982

7. Property and Equipment, net

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

	December 31,	
	2025	2024
Lab equipment	$ —	$ 3,382
Leasehold improvements	4,168	4,168
Office equipment and furniture	1,277	1,280
Computer equipment	99	143
Subtotal	5,544	8,973
Accumulated depreciation and amortization	(2,774)	(4,274)
Property and equipment, net	$ 2,770	$ 4,699

Depreciation and amortization expense was approximately $0.7 million, $1.3 million and $1.4 million for the years ended December 31, 2025, 2024 and 2023 respectively.

During the year ended December 31, 2025, management determined that changes in circumstances indicated the carrying value of certain research and development equipment may not be recoverable and recorded an impairment charge of $1.2 million, which is reported in the research and development expense line item of the consolidated statement of operations.

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2025	2024
Accrued research and development expenses	$ 14,699	$ 28,715
Accrued employee expenses	9,777	12,799
Accrued general and administrative expenses	466	642
Lease liability	3,873	3,072
Contingent consideration	500	500
Income taxes payable	194	—
Accrued legal expenses	342	408
Total accrued expenses	29,851	46,136
Less long-term portion	500	849
Total accrued expenses, current	$ 29,351	$ 45,287

9. Stockholders' Equity

Follow-on Offering of Common Stock

On June 15, 2023, we completed a follow-on offering in which we issued and sold 11,032,656 shares of common stock at a public offering price of $22.66 per share. The total gross proceeds for the offering were approximately $250.0 million, before deducting offering expenses of $14.3 million payable by us.

ATM Offering

In May 2021, the Company entered into a sales agreement, or the Sales Agreement, with SVB Leerink LLC, or SVB Leerink, as sales agent, pursuant to which the Company may, from time to time, issue and sell common stock with an aggregate value of up to $75.0 million in “at-the-market” offerings, or the ATM, under the Company's Registration Statement on Form S-3 (File No. 333-286122) filed with the SEC on March 26, 2025. Sales of common stock pursuant to the Sales Agreement may be made in sales deemed to be an “at the market offering” as defined in Rule 415(a) of the Securities Act, including sales made directly through the Nasdaq Global Market or any other existing trading market for the Company's common stock. In December 2025, the Company sold 3,928,571 shares of common stock under the Sales Agreement at a price of $1.40 per share, raising

aggregate gross proceeds of $5.5 million before fees and expenses of $0.1 million. As of December 31, 2025 there was $69.5 million of our common stock remaining available for sale under our ATM.

Stock Purchase Agreement

See Note 13 regarding the stock purchase agreement entered into between the Company and Matrix Capital Master Fund, LP (“Matrix”), one of our stockholders during the year ended December 31, 2025.

Share-based Compensation

Effective April 2020, the Company’s Board of Directors adopted, and the Company’s stockholders approved the 2020 Incentive Award Plan (the "2020 Plan"), which allows for grants to selected employees, consultants and non-employee members of the Board of Directors. We currently grant stock options and restricted stock units (“RSUs”), under the 2020 Plan. Awards may be made under the 2020 Plan covering up to the sum of (1) 5,600,000 shares of common stock; plus (2) any shares forfeited from the unvested restricted shares of our common stock issued upon conversion of unvested Class B common units during the corporate conversion in conjunction with our initial public offering (up to 1,250,000 shares); plus (3) an annual increase on the first day of each fiscal year beginning with the fiscal year ending December 31, 2021 and continuing to, and including, the fiscal year ending December 31, 2030, equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by our Board of Directors.

In July 2022, the Company’s Board of Directors approved the Zentalis Pharmaceuticals, Inc. 2022 Employment Inducement Incentive Award Plan (the “2022 Inducement Plan”), which is used exclusively for the grant of equity awards to new employees as an inducement material to the employees’ entering into employment with the Company. As of December 31, 2025, the Board of Directors reserved 8,775,000 shares of the Company’s common stock for issuance pursuant to awards granted under the 2022 Inducement Plan.

As of December 31, 2025, 10,687,087 shares were subject to outstanding awards under the 2020 Plan and 6,062,486 shares were available for future grants of share-based awards under the 2020 Plan. As of December 31, 2025, 6,931,460 shares were subject to outstanding awards under the 2022 Inducement Plan and 1,641,290 shares were available for future grants of share-based awards under the 2022 Inducement Plan.

During 2025, we did not issue any shares of common stock in connection with the exercises of stock options for cash. We did not issue any shares of common stock in connection with grants of restricted stock awards ("RSAs"). We issued 1,137,960 shares of common stock, upon vesting of RSU's.

Total share-based compensation expense related to share-based awards was comprised of the following (in thousands):

	Year ended December 31,		
	2025	2024	2023
Research and development expense	$ 8,996	$ 14,932	$ 24,519
General and administrative expense	11,726	52,337	30,303
Total share-based compensation expense	$ 20,722	$ 67,269	$ 54,822

Share-based compensation expense by type of share-based award (in thousands):

	Year ended December 31,		
	2025	2024	2023
Stock options	$ 12,659	$ 49,307	$ 41,642
RSAs and RSUs	7,873	17,721	12,816
Employee Stock Purchase Plan	190	241	364
	$ 20,722	$ 67,269	$ 54,822

Total unrecognized estimated compensation cost by type of award and the weighted average requisite service period over which such expense is expected to be recognized (in thousands, unless otherwise noted):

	December 31, 2025	
	Unrecognized Expense	Remaining Weighted-Average Recognition Period (Years)
Stock options	$ 15,638	2.5
RSUs	$ 4,952	1.4

Stock Options: The following table summarizes option activity for the year ended December 31, 2025. The amounts include stock options granted to both employees and non-employees:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	13,369,301	$ 15.50		
Granted	2,484,654	$ 1.64		
Exercised	—	$ —		
Cancelled	(3,593,430)	$ 21.17		
Outstanding at December 31, 2025	12,260,525	$ 11.02	7.0	$16
Vested and expected to vest at December 31, 2025	12,260,525	$ 11.02	7.0	$16
Exercisable at December 31, 2025	5,871,868	$ 17.52	5.4	$—

The weighted average grant date fair value of stock options granted during the years ended December 31, 2025, 2024 and 2023 was $0.94 per share, $4.51 per share and $15.48, respectively. The total intrinsic value of options exercised during the years ended December 31, 2025, 2024 and 2023 was immaterial.

The exercise price of stock options granted is equal to the closing price of the Company's common stock on the date of grant. The fair value of each option award is estimated on the date of grant using the Black-Scholes model. Due to the Company’s limited operating history and a lack of company specific historical and implied volatility data, the Company estimates expected volatility based on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the stock-based awards. The Company uses the “simplified method” for estimating the expected term of employee options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years). The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not issued any dividends and does not expect to issue dividends over the life of the options. As a result, the Company has estimated the dividend yield to be zero. The fair value of the stock options granted during the years ended December 31, 2025, 2024 and 2023 was determined with the following assumptions:

	Year ended December 31,		
	2025	2024	2023
Expected volatility	55.9% - 67.2%	75.3% - 83.2%	73.5% - 80.8%
Average expected term (in years)	6.0 - 6.1	2.7 - 6.1	5.5 - 6.1
Risk-free interest rate	3.7% - 4.4%	3.7% - 4.6%	3.4% - 4.7%
Expected dividend yield	—%	—%	—%

Restricted Stock Awards: RSAs are shares of our common stock subject to forfeiture restrictions that lapse based on the awardee's continued employment or service. The shares covered by a RSA cannot be sold, pledged or otherwise disposed of until the awards vest, and any unvested shares will be forfeited following the awardee's termination of service.

There were no RSAs that vested during the year ended December 31, 2025. As of December 31, 2025, there were no RSAs outstanding.

The total grant date fair value of RSAs vested during the years ended December 31, 2024 and 2023 was $4 thousand and $0.7 million, respectively. The fair value of RSAs vested during the years ended December 31, 2024 and 2023 was $14 thousand and $2.7 million, respectively.

Restricted Stock Units: An RSU is a promise by us to issue a share of our common stock upon vesting of the unit.

The following table summarizes RSU activity for the year ended December 31, 2025. The amounts include RSUs granted to both employees and non-employees:

	Number of Shares		Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	2,074,114	$	11.38
Granted	5,716,319	$	1.63
Vested	(1,137,960)	$	10.35
Forfeited	(1,294,451)	$	1.74
Outstanding at December 31, 2025	5,358,022	$	3.07

The estimated fair value of the RSUs was based on the closing market value of our common stock on the date of grant. The total grant date fair value of RSUs vested during the years ended December 31, 2025, 2024 and 2023 was approximately $11.8 million, $11.8 million and $9.7 million, respectively. The fair value of RSUs vested during the years ended December 31, 2025, 2024 and 2023 was approximately $2.0 million, $4.4 million and $7.7 million, respectively.

Employee Stock Purchase Plan

Effective April 2020, the Company's Board of Directors adopted, and the Company's stockholders approved the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which was subsequently amended and restated effective March 15, 2021 to provide for a share reserve of 2,000,000 shares. As of December 31, 2025, 1,628,130 shares were available for issuance under the 2020 ESPP.

The weighted average assumptions used to estimate the fair value of stock purchase rights under the 2020 ESPP are as follows:

	Year ended December 31,		
	2025	2024	2023
ESPP			
Volatility	66.5 %	83.3 %	85.8 %
Expected term (years)	0.5	0.5	0.5
Risk free rate	4.2 %	3.8 %	4.8 %
Expected dividend yield	— %	— %	— %

Under the terms of the 2020 ESPP, the Company's employees may elect to have up to 20% of their compensation, up to a maximum of $21,250 per calendar year, withheld to purchase shares of the Company's common stock for a purchase price equal to 85% of the lower of the fair market value per share (at closing) of the Company's common stock on (i) the first trading day of a six-month offering period, or (ii) the applicable purchase date, defined as the last trading day of the six-month offering period.

10. Commitments and Contingencies

Legal Contingencies

From time to time, we may be involved in various disputes, including lawsuits and claims arising in the ordinary course of business, including actions with respect to intellectual property, employment, and contractual matters. Any of these claims could subject us to costly legal expenses. The Company records a liability in its consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary to make the consolidated financial statements not misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in our consolidated financial statements. While we do generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, or our policy limits may be inadequate to fully satisfy any damage awards or settlement. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. We are currently not a party to any legal proceedings that require a loss liability to be recorded.

Operating Leases

In September 2020, we entered into a lease of laboratory and office space in San Diego. This lease was partially terminated and amended during September 2021. This amendment reduced the rentable square feet. The lease commenced in December 2021 and continues through September 2032. The lease also included access to a temporary space of laboratory and office space in San Diego. This lease component commenced in November 2020 and continued through January 2022. The lease is subject to approximately 3.0% annual increases throughout the lease term. We also pay for various operating costs, including utilities and real property taxes. The agreement includes two options to extend the lease for a period of five years each. When we determined our lease term for our operating lease right-of-use assets and lease liabilities for these leases, we did not include the extension options for this lease.

As a result of certain triggering events associated with the lease of our facility in San Diego, we performed an interim impairment test by comparing the carrying value of the long-lived asset group to its estimated fair value, which was determined based on the income approach using a discounted cash flow model. Estimates and assumptions used in the model included projected cash flows and a discount rate. As a result, we recorded an impairment expense of $3.0 million within our operating expenses against our operating lease right-of-use asset associated with our San Diego lease during the year ended December 31, 2025.

In March 2021, we entered into a lease of office space at 1359 Broadway, Suites 1710 and 1800 in New York, New York. The lease commenced in December 2021 and continues through November 2032. The lease is subject to one increase in per annum rent of approximately 8.1% commencing on the sixth anniversary of the commencement date. We received lease incentives under the agreement, including tenant allowances and free rent periods. We also pay for various operating costs, including utilities and real property taxes. The agreement contains one option to extend the lease for a period of five years. When we determined our lease term for our operating lease right-of-use assets and lease liabilities, we did not include the extension options for the lease.

On March 6, 2023, we entered into a sublease agreement pursuant to which we sublet the office space located at 1359 Broadway, Suites 1710 and 1800 in New York, New York to a subtenant. As a result of certain triggering events, we performed an interim impairment test by comparing the carrying value of the long-lived asset group to its estimated fair value, which was determined based on the income approach using a discounted cash flow model. Estimates and assumptions used in the model included projected cash flows and a discount rate. As a result, we recorded an impairment expense of $5.0 million within our operating expenses against our operating lease right-of-use asset and fixed assets associated with this New York lease during the year ended December 31, 2023. For the years ended December 31, 2025 and 2024, we recorded lease income of $1.4 million relating to this sublease, presented as other income in the statement of operations.

In December 2023, we entered into a lease office space in New York, New York. In June 2024, we entered into an agreement to terminate this lease in exchange for consideration of $0.5 million.

Rent expense recorded by the Company under the leases was approximately $6.8 million, $6.9 million and $6.9 million for the years ended December 31, 2025, 2024 and 2023 respectively. We paid approximately $6.8 million, $6.5 million and $6.4 million of lease payments, respectively, during the years ended December 31, 2025, 2024 and 2023.

The following table presents the weighted average remaining lease term and weighted average discount rates related to our operating leases as of December 31, 2025:

Weighted average remaining lease term (in years)	6.8
Weighted average discount rate	9.0%

Approximate annual future minimum operating lease payments as of December 31, 2025 are as follows (in thousands):

Year	Amount
2026	$ 7,278
2027	7,451
2028	7,760
2029	7,930
2030	8,105
Thereafter	14,984
Total minimum lease payments:	53,508
Less: imputed interest	13,931
Total operating lease liabilities	39,577
Less: current portion	3,873
Lease liability, net of current portion	$ 35,704

11. Income Taxes

Zentalis Pharmaceuticals, Inc. is a corporation for tax purposes and is subject to income taxes which have been included in the consolidated financial statements.

The amount of net loss before income taxes and loss on equity method investment for the years ended December 31, 2025, 2024 and 2023 is as follows (in thousands):

	Year ended December 31,		
	2025	2024	2023
U.S. net loss before income taxes	$ (136,986)	$ (165,490)	$ (293,284)
Foreign net income (loss) before income taxes	368	(200)	378
Net loss before income taxes, including loss on equity method investment	$ (136,618)	$ (165,690)	$ (292,906)

The following table presents the current and deferred income tax provision (benefit) for federal, state and foreign income taxes (in thousands):

	Year ended December 31,		
	2025	2024	2023
Current tax provision:			
Federal	$ —	$ —	$ —
State	328	228	41
Foreign	63	12	249
Total current tax provision	391	240	290
Deferred tax provision:			
Federal	—	—	(891)
State	—	—	—
Foreign	51	(63)	—
Total deferred tax provision	51	(63)	(891)
Total provision (benefit) for income taxes:	$ 442	$ 177	$ (601)

The following table is a reconciliation of the expected tax computed at the U.S. statutory federal income tax rate to the total provision for income taxes (in thousands):

	Year ended December 31,	
	2025	
U.S. Federal Statutory Tax Rate	$ (28,690)	21.0 %
State and Local Income Tax, net of Federal Income Tax Effect [1]	261	(0.2)%
Foreign Tax Effects	(1)	— %
Effect of Cross-Border Tax Laws	(44)	— %
Tax Credits		
Research & Development Credit, Net	(3,644)	2.7 %
Change in Valuation Allowance	26,369	(19.3)%
Nontaxable or Nondeductible Items		
Stock Options	5,053	(3.7)%
Other Adjustments	1,138	(0.8)%
Effective Tax Rate	$ 442	(0.3)%

[1] State taxes in New York made up the majority (greater than 50%) of the tax effect in this category.

	Year ended December 31,			
	2024		2023	
Expected tax at 21%	$ (34,796)	21.0 %	$ (61,509)	21.0 %
State income tax, net of federal tax	(2,565)	1.5 %	(2,384)	0.8 %
Research credits	(7,393)	4.5 %	(2,031)	0.7 %
Share-based compensation	11,295	(6.8)%	3,008	(1.0)%
Deemed royalty	—	— %	8,263	(2.8)%
Kalyra deconsolidation and impairment	2,461	(1.5)%	—	— %
Other	320	(0.2)%	586	(0.2)%
Section 162(m) limitations	2,985	(1.8)%	5,028	(1.7)%
Effective Tax Rate Change	—	— %	(10,420)	3.6 %
Change in valuation allowance	27,870	(16.8)%	58,858	(20.1)%
Provision for income taxes	$ 177	(0.1)%	$ (601)	0.2 %

The following table presents the Company's income taxes paid, net of refunds (in thousands):

	Year ended December 31,
	2025
Federal	$ —
States	
California	11
New York	72
Other U.S. States	2
Foreign	—
Total Income Taxes Paid	$ 85

Deferred income taxes as of each of the following periods reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of our net deferred tax asset or liability are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets		
Net operating loss	$ 145,810	$ 98,506
Compensation	1,903	2,411
Share-based compensation	9,068	11,375
ASC 842 lease liability	9,720	10,474
Intangibles	9,445	10,079
Capitalized research and experimental expenditures	72,117	85,872
Research credits	41,552	36,849
Other	28	422
Total gross deferred tax assets	289,643	255,988
Valuation allowance	(281,978)	(247,025)
Net deferred tax assets	7,665	8,963
Deferred tax liabilities		
Depreciable assets	(487)	(874)
ASC 842 right of use asset	(6,452)	(7,988)
Other	(675)	—
Deferred tax liabilities	(7,614)	(8,862)
Net deferred tax assets	$ 51	$ 101

Realization of a portion of the Company's deferred tax assets is dependent upon the Company generating sufficient taxable income in future years to obtain benefit from the reversal of temporary differences. Management considered all available evidence under existing tax law and anticipated expiration of tax statutes and determined that a valuation allowance of $282.0 million and $247.0 million was required as of December 31, 2025 and 2024, for those deferred tax assets that are not expected to provide future tax benefits. The increase in valuation allowance of $35.0 million was primarily related to net operating loss during the period ended December 31, 2025 offset in part by a decrease in capitalized research and experimental expenditures due to the deduction of current year domestic incurred costs.

At December 31, 2025, we have gross federal and state net operating loss ("NOL") carryforwards of approximately $591.3 million and $336.0 million, respectively. The federal NOL carryforwards generated prior to January 1, 2018 begin to expire in 2035. The federal NOL generated after 2017 of $577.1 million can be carried forward indefinitely and be available to offset up to 80% of future taxable income each year. The state NOL carryforwards begin to expire in 2035.

At December 31, 2025, we have federal research and orphan drug tax credit carryforwards and state research tax credit carryforwards, net of reserves, of approximately $34.0 million and $10.0 million, respectively. The federal credit carryovers begin to expire in 2034, and the state credit carryforwards do not expire and generally can be carried forward indefinitely until utilized, except for $0.4 million which expire in 2032.

Pursuant to Internal Revenue Code ("Code") Sections 382 and 383, annual use of the Company’s federal and California net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has completed a Code Section 382 analysis through June 30, 2023 regarding the limitation of NOL carryforwards and other tax attributes. The Company experienced ownership changes in 2015, 2019 and 2022. Additionally, several of the subsidiaries experienced an ownership change in 2020 based on the Section 382 rules for the time period prior to when the Company was a consolidated group for tax purposes. The Company’s attributes are subject to annual limitations, and the Company estimates that all tax attributes can be utilized prior to expiration. There is a risk that additional ownership changes may occur in the future. If a future change in ownership occurs, the NOL carryforwards and other tax attributes could be limited or restricted. Additionally, the Company’s NOLs prior to the tax consolidation are also subject to the separate return loss year (“SRLY”) rules. The SRLY rules may limit one member from offsetting taxable income with losses generated from another member prior to joining the consolidated group.

Uncertain Tax Positions

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The following table reconciles the beginning and ending amount of unrecognized tax benefits for the fiscal years ended December 31, 2025, 2024 and 2023 (in thousands):

	December 31,		
	2025	2024	2023
Gross unrecognized tax benefits at the beginning of the year	$ 14,810	$ 4,214	$ 4,297
Increase related to current year tax positions	827	1,151	857
Increase related to prior year tax positions	392	9,445	—
Decrease related to prior year tax positions	—	—	(940)
Gross unrecognized tax benefits at end of the year	$ 16,029	$ 14,810	$ 4,214

Included in the balance of unrecognized tax benefits at December 31, 2025 is $15.3 million that, if recognized, would not impact the Company's income tax benefit or effective tax rate as long as our deferred tax asset remains subject to a valuation allowance.

The Company recognizes interest and penalties related to unrecognized tax positions within the income tax expense line in the accompanying consolidated statements of operations. There were no accrued interest and penalties associated with uncertain tax positions as of December 31, 2025 or December 31, 2024.

The Company files federal and state income tax returns in the United States as well as income tax returns in Australia. Due to the Company's unutilized NOLs and credits, all years remain subject to income tax examination by authorities. The Company is not currently under examination by federal, state or foreign jurisdictions.

12. Net Loss Per Common Share

Basic and diluted net loss per common share were calculated as follows (in thousands except per share amounts):

	Year ended December 31,		
	2025	2024	2023
Numerator:			
Net loss attributable to Zentalis	$ (137,060)	$ (165,839)	$ (292,191)
Denominator:			
Weighted average number of common shares outstanding, basic and diluted	71,869	71,080	65,409
Net loss per common share	$ (1.91)	$ (2.33)	$ (4.47)

Our potential and dilutive securities, which include outstanding stock options, unvested RSAs and unvested RSUs have been excluded from the computation of diluted net loss per common share as the effect would be anti-dilutive.

The following common stock equivalents have been excluded from the calculations of diluted net loss per common share because their inclusion would be antidilutive (in thousands):

	Year ended December 31,		
	2025	2024	2023
Outstanding stock options	12,261	13,369	10,017
Unvested RSAs	—	—	1
Unvested RSUs	5,358	2,074	1,219
	17,619	15,443	11,237

13. Related Party Transaction

On December 15, 2025, the Company entered into a Stock Purchase Agreement (the "Agreement") with Matrix. Pursuant to the Agreement, the Company agreed to repurchase 7,500,000 shares of the Company's common stock from Matrix at a price of $1.33 per share, representing a discount from the Company's closing share price of $1.40 on December 12, 2025 (the "Repurchase"). The Repurchase closed on December 15, 2025. As a result of the purchase of our common shares, we reduced our common stock for the par value of the shares purchased, with the excess purchase price over par value recorded as a reduction of additional paid-in capital.

14. Employee Savings Plan

We have an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. All employees are eligible to participate provided that they meet the requirements of the plan. The Company began making matching contributions under the plan during 2021. The Company has recorded as expense $1.4 million, $1.7 million and $1.5 million in matching contributions for the years ended December 31, 2025, 2024 and 2023 respectively.

15. Restructuring

On January 28, 2025, the Company announced a corporate restructuring, (the "Restructuring") to support execution of late-stage development for azenosertib and extend its cash runway beyond a potentially registration-enabling azenosertib data readout from the Company's DENALI Part 2 study. The Restructuring reduced the Company's work force by approximately 40%. The Company has completed all of the activities included in the restructuring plan and all of the costs associated with the restructuring were incurred during the quarter ended March 31, 2025.

In connection with the Restructuring, the Company recorded restructuring charges of $7.8 million which are reported as a separate line item in the accompanying consolidated statement of operations for the year ended December 31, 2025. The following table summarizes the components of the restructuring charges (in thousands):

	Year Ended December 31, 2025		
	Accruals	Non-cash items	Total
Employee separation costs	$ 6,947	$ 806	$ 7,753
Other restructuring charges	43	—	43
	$ 6,990	$ 806	$ 7,796

Employee separation costs consist primarily of salaries and benefits earned during the minimum notification period proscribed by law and severance costs associated with the reduction in the Company's workforce. Other restructuring charges consist of incremental direct costs associated with the Restructuring.

The following table sets forth activity in the restructuring liability (in thousands):

	Employee separation costs	Other restructuring charges	Total
Balance at December 31, 2024	$ —	$ —	$ —
Accruals	6,947	43	6,990
Payments	(6,947)	(43)	(6,990)
Balance at December 31, 2025	$ —	$ —	$ —

The Company records restructuring activities in accordance with ASC 420, Exit or Disposal Cost Obligations.

Director Biographical Information

Scott Myers

Scott Myers has served as a member of our Board and as the Chairperson of our Board since November 2024. Previously, Mr. Myers served as President, Chief Executive Officer and a member of the Board of Directors of Viridian Therapeutics, Inc. (Nasdaq: VRDN) from February 2023 to November 2023. Prior to Viridian, Mr. Myers served as Chief Executive Officer and a member of the Board of Directors of AMAG Pharmaceuticals, Inc. from April 2020 until it was acquired by Covis Group S.à.r.l. in November 2020. Mr. Myers served as Chief Executive Officer and Chairman of the Board of Directors of Rainier Therapeutics, Inc., a private oncology-focused biotechnology company, from 2018 to 2020 when its lead asset was purchased by Fusion Pharmaceuticals Inc., and as President, Chief Executive Officer and a member of the Board of Directors of Cascadian, from 2016 until it was acquired by Seagen, Inc. (fka Seattle Genetics, Inc.), in 2018. Mr. Myers has served as Chairperson of the Board of Directors of Convergent Therapeutics, Inc. since March 2024, and as a member of the Board of Directors of Umoja Biopharma, Inc. since November 2024. Mr. Myers also served as Chairperson of the Board of Directors of Dynavax Technologies Corporation until Dynavax was acquired by Sanofi (Nasdaq: SNY) in February 2026 and as a member of the Board of Directors of Harpoon Therapeutics, Inc., or Harpoon, from August 2018, and as Chairman of Harpoon from October 2021, until Harpoon was acquired by Merck (NYSE: MRK), in March 2024. Mr. Myers previously served as a member of the Boards of Directors of Selecta Biosciences, Inc. from June 2019 until its merger with Cartesian Therapeutics, Inc. (Nasdaq: RNAC) in November 2023, and Trillium Therapeutics Inc., or Trillium, from April 2021 until its acquisition by Pfizer Inc., or Pfizer (NYSE: PFE), in November 2021, and as Chairperson of the Board of Directors of Ironshore Therapeutics Inc. from April 2022 until its acquisition by Collegium Pharmaceutical Inc. (Nasdaq: COLL) in September 2024, and Sensorion S.A. (EPA: ALSEN) from December 2021 to March 2023. Mr. Myers received a B.A. in Biology from Northwestern University and an M.B.A. from the Graduate School of Business (Booth) at the University of Chicago. We believe Mr. Myers' experience in the biotechnology industry and his extensive experience in the leadership of both commercial and development stage biopharmaceutical companies qualify him to serve on our Board.

Julie Eastland

Julie Eastland has served as our President and Chief Executive Officer, and as a member of our Board, since November 2024. Previously she served as the President and Chief Executive Officer of Harpoon from November 2021, and a member of its Board of Directors from October 2018, in each case until Harpoon's acquisition by Merck (NYSE: MRK) in March 2024. From October 2020 to November 2021, Ms. Eastland served as Chief Operating Officer and Chief Financial Officer of ReCode Therapeutics, Inc., or ReCode, a privately held genetics medicine company. Prior to ReCode, from October 2018 to February 2020, she served as Chief Financial Officer and Chief Business Officer of Rainier Therapeutics, Inc., or Rainier, a privately held biopharmaceutical company focused on bladder cancer. Before Rainier, she was Chief Financial Officer and Chief Business Officer of Cascadian Therapeutics, or Cascadian, a publicly traded biopharmaceutical company, from August 2010 to March 2018, when it was acquired by Seagen. Prior to Cascadian, Ms. Eastland served as Chief Financial Officer and Vice President of Finance and Operations of VLST Corporation, a privately held biotechnology company, and held various financial and strategic management positions at privately held and publicly traded biotechnology companies including Dendreon Pharmaceuticals LLC and Amgen Inc. (Nasdaq: AMGN). Ms. Eastland served as a member of the Board of Directors of Dynavax Technologies Corporation (Nasdaq: DVAX) from July 2020 until May 2025, and serves as a member of the Boards of Directors of Lantheus Holdings, Inc. (Nasdaq: LNTH) and Seismic Therapeutic, Inc. Ms. Eastland received an M.B.A. from Edinburgh University Management School and a B.S. in finance from Colorado State University. We believe Ms. Eastland's extensive operational, strategic, and financial experience in the biopharmaceutical industry qualifies her to serve on our Board.

David Johnson

David Johnson has served as a member of our Board since January 2020. Mr. Johnson also served as the Chairperson of our Board from May 2022 to November 2024, and as the Lead Independent Director of our Board from April 2020 to May 2022. Mr. Johnson is Chief Executive Officer and a member of the Board of Directors of Solve Therapeutics, Inc., a venture backed start-up focused on developing next generation mAb based oncology therapeutics, a position he has held since July 2021. In addition, Mr. Johnson is a general partner at Velosity Capital, a position he has held since January 2022. Previously, Mr. Johnson served as Chief Executive Officer of VelosBio Inc., or VelosBio, an oncology-focused biopharmaceutical company that he founded in 2017, which was acquired by

Merck & Co., Inc., or Merck, (NYSE: MRK) in December 2020. From 2013 to 2016, Mr. Johnson served as Chief Executive Officer of Acerta Pharma, LLC, an oncology-focused pharmaceutical company, which is now a member of the AstraZeneca Group (Nasdaq: AZN). Mr. Johnson has served as a member of the Board of Directors of Aura (Nasdaq: AURA), a biopharmaceutical company, since January 2021, and as Chairman of the Board of Directors of Aura since March 2021, as a member of the Board of Directors of Incisive Genetics Inc., a biotechnology company, since June 2022, and as a member of the Board of Directors of Sudo Biosciences, Inc., a biopharmaceutical company, since January 2021. Mr. Johnson has also served as the Chairman of the Board of Directors of Lengo Therapeutics, Inc., or Lengo, a precision oncology company, from March 2021 until it was acquired by Blueprint Medicines Corporation, or Blueprint (Nasdaq: BPMC), in December 2021, and as a member of the Board of Directors of Palleon Pharmaceuticals Inc., a biopharmaceutical company, from August 2021 to July 2025. Mr. Johnson received a bachelor's degree from Indiana University. We believe Mr. Johnson's extensive and diverse expertise in the life sciences industry, including as an experienced executive of clinical-stage companies, qualifies him to serve on our Board.

Enoch Kariuki, Pharm.D.

Enoch Kariuki, Pharm.D., has served as a member of our Board since February 2021. Dr. Kariuki has served as President of Endeavor BioMedicines, a clinical-stage biotechnology company developing novel therapies for fibrosis and oncology, since March 2024. In addition, Dr. Kariuki is a general partner at Velosity Capital, a position he has held since March 2021. Previously, from June 2021 to January 2022, Dr. Kariuki served as Chief Executive Officer of Lengo until its acquisition by Blueprint (Nasdaq: BPMC). Prior to Lengo, Dr. Kariuki served as Chief Financial Officer of VelosBio, an oncology-focused biopharmaceutical company, from July 2020 until its acquisition by Merck (NYSE: MRK) in December 2020. From June 2018 to February 2020, Dr. Kariuki served as Senior Vice President, Corporate Development at Synthorx, Inc., a clinical stage biotechnology company that was acquired by Sanofi SA (Nasdaq: SNY). From 2014 to April 2018, Dr. Kariuki served as Vice President at H.I.G. Capital, a private equity and alternative assets investment firm. Dr. Kariuki has been a member of the Board of Directors of Pheon Therapeutics, an oncology-focused biotechnology company, since September 2024. Dr. Kariuki also served as a member of the Board of Directors of ProfoundBio, Inc., a clinical-stage oncology company, from February 2024 until it was acquired by Genmab A/S (Nasdaq: GMAB) in May 2024, as a member of the Board of Directors of Endeavor from December 2023 until March 2024, when he transitioned to the role of President, and as a member of the Board of Directors and Chairperson of the Audit Committee of Imago Biosciences, Inc., a biopharmaceutical company, from February 2021 until it was acquired by Merck (NYSE: MRK) in January 2023. Dr. Kariuki received an M.B.A. from the Tuck School of Business at Dartmouth and a Pharm.D. from Texas Southern University. We believe Dr. Kariuki's experience as a senior executive at large and small commercial and clinical-stage life sciences companies qualifies him to serve on our Board.

Jan Skvarka, Ph.D.

Jan Skvarka, Ph.D., has served as a member of our Board since September 2022. From September 2019 to November 2021, Dr. Skvarka was the President, Chief Executive Officer, and a member of the Board of Directors of Trillium, a publicly traded, clinical-stage immuno-oncology company, which was acquired by Pfizer (NYSE: PFE) in November 2021. From 2014 to January 2019, Dr. Skvarka served as the President, Chief Executive Officer, and a member of the Board of Directors of Tal Medical Inc., a clinical-stage neuroscience company. Previously, Dr. Skvarka was a partner in the life sciences practice at Bain & Company in Boston, Massachusetts, and a manager at Price Waterhouse, Corporate Finance in London, United Kingdom, and Vienna, Austria. Dr. Skvarka has served as Chairman of DEM Biopharma, Inc. since March 2024, having previously served as Executive Chairman from March 2022 to March 2024, as a member of the Board of Directors of Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE) since March 2023, and as a Senior Advisor to Sensible Biotechnologies, Inc. since March 2025. Dr. Skvarka is currently serving as a program advisor for the MS/MBA Biotechnology Life Sciences program at Harvard Business School. Dr. Skvarka holds an MBA from Harvard Business School and a Ph.D. in Economics from the University of Economics in Slovakia. We believe Dr. Skvarka is qualified to serve on our Board due to his operational, strategic, and financial experience in the biopharmaceutical industry.

Luke Walker, M.D.

Luke Walker, M.D., has served as a member of our Board since May 2024. Dr. Walker has served as the Chief Medical Officer of Umoja Biopharma, Inc., a company focused on the development of in vivo CAR T cell therapeutics, since January 2025. He previously was the Chief Medical Officer of Harpoon, an oncology-focused

biopharmaceutical company focused on the development of T-cell engagers in oncology, from October 2022 until Harpoon was acquired by Merck (NYSE: MRK) in March 2024. From March 2018 to September 2022, Dr. Walker served as Vice President, Clinical Development for Seagen, where he initially led the development of TUKYSA (tucatinib) and later, a portfolio of early stage programs. Prior to that, from 2011 to 2018, Dr. Walker held various roles in clinical development at Cascadian, a publicly traded biopharmaceutical company that was acquired by Seagen, culminating in his role as Senior Vice President, Clinical Development. Dr. Walker served as a medical oncologist and hematologist at Providence Regional Medical Center, Everett, WA, from 2007 to 2011 and at The Everett Clinic, Center for Cancer Care, from 2005 to 2007. Dr. Walker has served as a member of the Board of Directors of Context Therapeutics Inc. (Nasdaq: CNTX), an oncology-focused biopharmaceutical company, since September 2024. Dr. Walker is a current Diplomate of the American Board of Internal Medicine in Medical Oncology, with prior board certifications in Hematology and Internal Medicine. He completed fellowships in bone marrow and stem cell transplantation, and hematology and medical oncology at Oregon Health Sciences University. Dr. Walker received his M.D. from the University of Oklahoma Health Sciences Center and his B.A. in letters and French from the University of Oklahoma. Dr. Walker also completed the Stanford Graduate School of Business LGBTQ Executive Leadership Program in 2017. We believe Dr. Walker's extensive experience in the biopharmaceutical industry, particularly in oncology, makes him qualified to serve on our Board.

Information About Our Executive Officers

Julie Eastland

See biography under "Director Biographical Information"

Ingmar Bruns, M.D.

Ingmar Bruns, M.D., has served as our Chief Medical Officer since November 2024. From November 2021 to July 2024, Dr. Bruns served as the Development Head, Hematologic Malignancies, Pfizer Global Product Development at Pfizer (NYSE: PFE). Prior to Pfizer, Dr. Bruns served as Chief Medical Officer of Trillium, a publicly traded, clinical-stage immuno-oncology company, from November 2020 until its acquisition by Pfizer in November 2021. From October 2017 to November 2020, Dr. Bruns served as Senior Vice President, Head of Clinical Development of Pieris Pharmaceuticals, Inc., a publicly traded clinical stage biotechnology company that merged with Palvella Therapeutics, Inc. (Nasdaq: PVLA) in December 2024. From 2013 through 2017, Dr. Bruns served as Deputy Head of Early Development Oncology at Bayer Healthcare Pharmaceuticals Inc. Dr. Bruns received an M.D. and a Ph.D. from the University of Lubeck in Germany.

James Bucher

James Bucher has served as our Chief Legal Officer and Corporate Secretary since September 2025. Previously he served as the Chief Legal Officer of Harpoon Therapeutics, Inc. from December 2023 until its acquisition by Merck (NYSE: MRK) in March 2024. From October 2020 to March 2023, Mr. Bucher served as Executive Vice President and General Counsel and Head of Human Resources at Eliem Therapeutics, Inc.. Prior to Eliem Therapeutics, Inc., Mr. Bucher served as Executive Vice President and General Counsel at Alder Biopharmaceuticals, Inc., and in a senior legal position at Exelixis, Inc.. Earlier in his career, Mr. Bucher was a Partner at Shearman & Sterling LLP (now known as A&O Shearman). He earned his J.D. with distinction from Emory University School of Law and holds a B.A. in Biology and a minor in Political Science from Colgate University.