UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

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.)**
1359 Broadway, Suite 801 **New York,** **New York**	
(Address of principal executive offices)	**10018** **(Zip Code)**

(212) 433-3791
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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 Stock Market LLC (The Nasdaq Global Market)

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

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

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

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

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

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

As of August 7, 2023, the registrant had 70,609,407 shares of common stock, $0.001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, 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 Quarterly Report 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” 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 Quarterly Report include, but are not limited to, statements about:

- our competitive position and 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;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the global macroeconomic environment and increased inflation and interest rates;
- the timing and focus of our ongoing and future preclinical studies and clinical trials, 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;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our and our collaborators' strategy, plans and expectations with respect to the development, manufacturing, supply, approval and commercialization of our product candidates 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 and licensees, and the anticipated arrangements and benefits under our collaboration and license agreements, including with respect to milestones and royalties;
- our pipeline, including its potential, and our related research and development activities;
- our plans relating to our biomarker enrichment strategies targeting tumors of high genomic instability, such as Cyclin E1 positive tumors and homologous recombination deficient tumors;
- our plans relating to the further development of our product candidates, 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 our product candidates, if approved;
- our plans, including the costs thereof, of development of any diagnostic tools;
- our plans to evaluate additional strategic opportunities to maximize the value of our pipeline;
- our plans to advance our ongoing research on protein degrader programs;
- our plans to advance IND-enabling studies for our product candidates, including our BCL-xL protein degrader product candidate;
- our plans to develop our product candidates in combination with other therapies;
- our existing collaborations and 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 our product candidates;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- timing and likelihood of success of our research, development and commercialization efforts;
- timing of expected milestones and the announcement thereof;
- the size of the market opportunity for our product candidates;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;

- the timing or likelihood of regulatory filings and approvals, including our expectation to seek an accelerated approval pathway and special designations for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- existing regulations and regulatory developments in the United States, the European Union 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, lease commitments, and future availability of facilities;
- 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 our product candidates;
- insurance coverage;
- estimated periods of performance of key contracts;
- the need to hire additional personnel and our ability to attract and retain personnel, and our ability to provide competitive compensation and benefits; and
- the impact of COVID-19 on our business.

The forward-looking statements in this Quarterly Report 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 Quarterly Report 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 Quarterly Report entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report.

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.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q. 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 our lead product candidates, azenosertib (ZN-c3) and/or ZN-d5, which are currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize these product candidates in a timely manner, our business will be harmed.
- The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or FDA, or other comparable ex-U.S. regulatory authorities or otherwise produce positive results.
- If we are unable to successfully develop diagnostic tools for biomarkers that enable patient selection, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.
- We are developing our product candidates in combination with other therapies, which exposes us to additional risks.
- The regulatory approval processes of the FDA and other comparable ex-U.S. regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our 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 our 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 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 our product candidates and our business could be substantially harmed.
- 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.
- 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—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 266,558	$ 43,069
Marketable securities, available-for-sale	286,428	394,302
Prepaid expenses and other current assets	10,943	14,562
Total current assets	563,929	451,933
Property and equipment, net	6,650	7,705
Operating lease right-of-use assets	36,584	42,373
Prepaid expenses and other assets	7,918	9,723
Goodwill	3,736	3,736
Investment in Zentera Therapeutics	—	21,213
Restricted cash	2,627	2,627
Total assets	$ 621,444	$ 539,310
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 12,305	$ 11,247
Accrued expenses	39,454	45,400
Total current liabilities	51,759	56,647
Deferred tax liability	—	853
Long-term lease liability	44,027	45,166
Other long-term liabilities	2,376	2,620
Total liabilities	98,162	105,286
Commitments and contingencies		
EQUITY		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 250,000,000 shares authorized; 70,603,663 and 59,280,247 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	70	59
Additional paid-in capital	1,295,520	1,031,462
Accumulated other comprehensive loss	(338)	(1,353)
Accumulated deficit	(772,111)	(596,365)
Total stockholders' equity	523,141	433,803
Noncontrolling interests	141	221
Total equity	523,282	434,024
Total liabilities and stockholders' equity	$ 621,444	$ 539,310

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating Expenses				
Research and development	$ 42,684	$ 43,825	$ 91,268	$ 89,937
Zentera in-process research and development	45,568	—	45,568	—
General and administrative	15,664	19,636	32,033	31,403
Total operating expenses	103,916	63,461	168,869	121,340
Operating loss	(103,916)	(63,461)	(168,869)	(121,340)
Other Income (Expense)				
Investment and other income, net	4,451	424	8,560	850
Net loss before income taxes	(99,465)	(63,037)	(160,309)	(120,490)
Income tax (benefit) expense	(605)	17	(497)	50
Loss on equity method investment	13,704	5,338	16,014	7,089
Net loss	(112,564)	(68,392)	(175,826)	(127,629)
Net loss attributable to noncontrolling interests	(37)	(35)	(80)	(195)
Net loss attributable to Zentalis	$ (112,527)	$ (68,357)	$ (175,746)	$ (127,434)
Net loss per common share outstanding, basic and diluted	$ (1.85)	$ (1.34)	$ (2.93)	$ (2.64)
Common shares used in computing net loss per share, basic and diluted	60,790	51,117	60,038	48,197

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (112,564)	$ (68,392)	$ (175,826)	$ (127,629)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	218	(670)	1,015	(1,654)
Total comprehensive loss	(112,346)	(69,062)	(174,811)	(129,283)
Comprehensive loss attributable to noncontrolling interests	(37)	(35)	(80)	(195)
Comprehensive loss attributable to Zentalis	$ (112,309)	$ (69,027)	$ (174,731)	$ (129,088)

See notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2023	**2022**
Operating Activities:		
Consolidated net loss	$ (175,826)	$ (127,62
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	704	69
Operating lease right-of-use asset and fixed asset impairment	4,953	-
Noncash consideration portion of Zentera in-process research and development	15,045	-
Loss on equity method investment	16,014	7,08
Share-based compensation	27,075	26,91
(Loss)/gain on disposal of equipment	(4)	5
(Accretion of discounts)/amortization of premiums on marketable securities, net	(6,483)	1
Deferred income taxes	(853)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,922)	(6,66
Accounts payable and accrued liabilities	(5,805)	4,02
Operating lease right-of-use assets and liabilities, net	544	2,27
Net cash used in operating activities	(128,558)	(93,22
Investing Activities:		
Purchases of marketable securities	(189,085)	(277,57
Proceeds from maturities of marketable securities	304,457	156,00
Purchases of property and equipment	(319)	(72
Net cash provided by (used in) investing activities	115,053	(122,30
Financing Activities:		
Proceeds from issuance of common stock, net	235,680	209,29
Proceeds from issuance of common stock under equity incentive plans	1,314	1,41
Net cash provided by financing activities	236,994	210,71
Net increase (decrease) in cash, cash equivalents and restricted cash	223,489	(4,81
Cash, cash equivalents and restricted cash at beginning of period	45,696	62,58
Cash, cash equivalents and restricted cash at end of period	$ 269,185	$ 57,77
Supplemental disclosure of non-cash investing and financing activities:		
Accrued capital expenditures	$ —	$ 9

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:

	June 30,	
	2023	2022
Cash and cash equivalents	$ 266,558	$ 55,14
Restricted cash	2,627	2,62
Total cash, cash equivalents and restricted cash reported in the Condensed Consolidated Statement of Cash Flows	$ 269,185	$ 57,77

See notes to condensed consolidated financial statements.

Zentalis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands)

Three Months Ended June 30, 2023

	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Equity
	Shares	Amount					
Balance at March 31, 2023	59,442	$ 59	$ 1,045,568	$ (556)	$ (659,584)	$ 178	$ 385,665
Share-based compensation expense	—	—	13,342	—	—	—	13,342
Other comprehensive loss	—	—	—	218	—	—	218
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	79	—	—	—	—	—	—
Issuance of common stock upon exercise of options, net	51	—	941	—	—	—	941
Cancellation of restricted stock awards	(1)	—	—	—	—	—	—
Net loss attributable to non-controlling interest	—	—	—	—	—	(37)	(37)
Net loss attributable to Zentalis	—	—	—	—	(112,527)	—	(112,527)
Balance at June 30, 2023	70,604	$ 70	$ 1,295,520	$ (338)	$ (772,111)	$ 141	$ 523,282

Six Months Ended June 30, 2023

	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	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	—	—	27,075	—	—	—	27,075
Other comprehensive loss	—	—	—	1,015	—	—	1,015
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	218	—	—	—	—	—	—
Issuance of common stock upon exercise of options, net	51	—	941	—	—	—	941
Shares issued under employee stock purchase plan	25	—	373	—	—	—	373
Cancellation of restricted stock awards	(3)	—	—	—	—	—	—
Net loss attributable to non-controlling interest	—	—	—	—	—	(80)	(80)
Net loss attributable to Zentalis	—	—	—	—	(175,746)	—	(175,746)
Balance at June 30, 2023	70,604	$ 70	1,295,520	$ (338)	$ (772,111)	$ 141	$ 523,282

Three Months Ended June 30, 2022

	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Equity
	Shares	Amount					
Balance at March 31, 2022	45,584	$ 46	$ 734,997	$ (1,109)	$ (418,636)	$ 368	$ 315,666
Share-based compensation expense	—	—	16,764	—	—	—	16,764
Other comprehensive loss	—	—	—	(670)	—	—	(670)
Issuance of common stock in connection with an equity offering, net of underwriting discounts, commissions and offering costs	11,284	11	209,286	—	—	—	209,297
Issuance of common stock in connection with restricted stock unit vesting	104	—	—	—	—	—	—
Issuance of common stock upon exercise of options, net	9	—	158	—	—	—	158
Cancellation of restricted stock awards	(14)	—	—	—	—	—	—
Net loss attributable to non-controlling interest	—	—	—	—	—	(35)	(35)
Net loss attributable to Zentalis	—	—	—	—	(68,357)	—	(68,357)
Balance at June 30, 2022	56,967	$ 57	$ 961,205	$ (1,779)	$ (486,993)	$ 333	$ 472,823

Six Months Ended June 30, 2022

	Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Equity
	Shares	Amount					
Balance at December 31, 2021	45,491	45	723,593	(125)	(359,559)	528	364,482
Share-based compensation expense	—	—	26,911	—	—	—	26,911
Other comprehensive loss	—	—	—	(1,654)	—	—	(1,654)
Issuance of common stock in connection with an equity offering, net of underwriting discounts, commissions and offering costs	11,284	11	209,286	—	—	—	209,297
Issuance of common stock in connection with restricted stock unit vesting	149	1	—	—	—	—	1
Issuance of common stock upon exercise of options, net	42	—	803	—	—	—	803
Shares issued under employee stock purchase plan	16	—	612	—	—	—	612
Cancellation of restricted stock awards	(15)	—	—	—	—	—	—
Net loss attributable to non-controlling interest	—	—	—	—	—	(195)	(195)
Net loss attributable to Zentalis	—	—	—	—	(127,434)	—	(127,434)
Balance at June 30, 2022	56,967	57	961,205	(1,779)	(486,993)	333	472,823

See notes to condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Organization

Zentalis Pharmaceuticals, Inc. ("Zentalis," "We" or the "Company") is a clinical-stage biopharmaceutical company discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. Utilizing its Integrated Discovery Engine, the Company is developing a focused pipeline of potentially best-in-class oncology candidates, which include azenosertib (ZN-c3), a WEE1 inhibitor for advanced solid tumors, ZN-d5, a BCL-2 inhibitor for hematologic malignancies and related disorders, and a heterobifunctional degrader of BCL-xL for solid and hematological malignancies. 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 statement 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 interim unaudited condensed consolidated financial statements for the quarter ended June 30, 2023 are issued.

2. Interim Unaudited Financial Statements

Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. The year-end condensed consolidated balance sheet data was derived from the Company's audited financial statements but do not include all disclosures required by U.S. GAAP. These interim unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 1, 2023. The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operation for the periods presented, with such adjustments consisting only of normal recurring adjustments. Certain reclassifications have been made to the prior period condensed consolidated balance sheet to conform to the current period presentation.

The accompanying interim unaudited condensed consolidated financial statements include our wholly-owned subsidiaries and a variable interest entity ("VIE"), for which we are the primary beneficiary. All intercompany transactions and balances have been eliminated in consolidation.

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.

The equity method is used to account for investments in which we have the ability to exercise significant influence, but not control, over the investee. Such investments are recorded on the balance sheet, and the share of net income or losses of equity investments is recognized on a one quarter lag in investment and other income (expense), net.

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.

Significant Accounting Policies

During the six months ended June 30, 2023, we adopted the following significant accounting policies not previously reported in the Company's significant accounting policies as described in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

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 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 in-process research and development ("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.

3. Significant Transactions

Zentera Therapeutics

On June 15, 2023, we announced that we and certain of our wholly owned subsidiaries had entered into an agreement to terminate our Collaboration and License Agreements (the "Termination Agreement") with Zentera Therapeutics, a Shanghai-based clinical-stage biopharmaceutical company focused on developing cancer therapeutics ("Zentera"), pursuant to which such wholly owned subsidiaries had granted to Zentera certain development and commercialization rights to our product candidates, azenosertib, ZN-d5 and ZN-c5 (the "Zentera Collaboration Products") in the People's Republic of China, Macau, Hong Kong and Taiwan (collectively, "Greater China"). As a result of the termination of these agreements, we have regained the rights from Zentera for azenosertib, ZN-d5 and ZN-c5 in Greater China, and now hold worldwide development and commercialization rights to these assets. Concurrent with the agreement to terminate the Collaboration and License Agreements, we executed a share purchase agreement (the "Share Purchase Agreement") with Zentera to return our 40.3% equity stake in Zentera for de minimis consideration.

We assessed the Termination Agreement and Share Purchase Agreement together and determined that the transaction to reacquire the licensed intellectual property without an acquired workforce, inputs or any substantive processes capable of contributing to the ability to produce outputs, represents asset acquisitions for accounting purposes.

The total consideration transferred of $45.6 million was comprised of the following components: Fixed consideration of $30 million, representing an up-front payment. Fixed consideration of forgiveness of $9.4 million of outstanding receivables under the Collaboration and License Agreements. Fixed consideration of the return of our 40.3% equity stake in Zentera for de minimis cash consideration. Using the adjusted balance sheet method under the cost approach, the difference between the carrying value of the equity method investment at the time of the transaction and the fair value of the equity method investment after the return of the intellectual property was $13.7 million, which was recognized as a loss on the equity method investment line item in the statement of operations during the second quarter of 2023. Variable consideration of a change in control milestone payment as contingent consideration can be either zero or $15.0 million. The value of the contingent consideration of approximately $0.5 million was calculated using estimates of future discounted cash flows, and other significant estimates including estimates for probability of milestone achievement and discount rates. The value of the

contingent consideration for this milestone will be remeasured at fair value at each reporting period with gains and losses reported in the statement of operations. We also incurred $0.5 million of acquisition-related costs that were included in the total consideration for the acquired assets. Additional consideration to be paid to Zentera includes a low single digit royalty on net sales of azenosertib, ZN-d5 and ZN-c5 in the Greater China region. These additional payments are payable only after regulatory approval and commercials sales in the Greater China region and are excluded from the transaction price.

The fair value of in-process research and development assets acquired was based on the market approach, which includes significant estimates. These estimates included calibration adjustments for comparable companies, cost estimates, control and marketability discounts, as well as estimates for the probability of success and applicable discount rates. The excess of the fair value of the consideration given in exchange for the Zentera in-process research and development received was accounted for as a contract termination cost. The Company determined to recognize the full amount of $45.6 million in the condensed consolidated statement of operations and comprehensive loss during the three months ended June 30, 2023.

4. Business Combinations

Kalyra Pharmaceuticals, Inc.

On December 21, 2017, we acquired $4.5 million of Kalyra Pharmaceuticals, Inc.'s ("Kalyra") Series B Preferred Stock representing a 25% equity interest in Kalyra for purposes of entering the analgesics therapeutic research space. The acquisition price was paid entirely in cash.

In accordance with the authoritative guidance, we concluded that Kalyra is a business consisting of inputs, employees, intellectual property and processes capable of producing outputs. Additionally, we have concluded that Kalyra is a VIE, we are the primary beneficiary and have the power to direct the activities that most significantly affect Kalyra's economic performance through common management and our board representation. Prior to December 21, 2017, the Company and Kalyra transacted for the delivery of research and development services and support. The financial position and results of operations of Kalyra have been included in our consolidated financial statements from the date of the initial investment.

Pursuant with authoritative guidance, we have recorded the identifiable assets, liabilities and noncontrolling interests in the VIE at their fair value upon initial consolidation. The identified goodwill is comprised of the workforce and expected synergies from combining the entities. Total assets and liabilities of Kalyra as of June 30, 2023 and December 31, 2022 are immaterial. The liabilities recognized as a result of consolidating Kalyra do not represent additional claims on our general assets. Pursuant to the authoritative guidance, the equity interest in Kalyra not owned by Zentalis is reported as a noncontrolling interest on our condensed consolidated balance sheets.

The following is a reconciliation of equity (net assets) attributable to the noncontrolling interest (in thousands):

	June 30, 2023	December 31, 2022
Noncontrolling interest at beginning of period	$ 221	$ 52
Net loss attributable to noncontrolling interest	(80)	(30
Noncontrolling interest at end of period	$ 141	$ 22

5. Fair Value Measurement

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

	June 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 171,816	$ 12	$ (200)	$ 171,62
Corporate Debt Securities	—	—	—	-
US Government Agencies	85,248	28	(112)	85,16
US Treasury	29,702	—	(66)	29,63
	$ 286,766	$ 40	$ (378)	$ 286,42

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 296,309	$ 71	$ (587)	$ 295,79
Corporate Debt securities	7,472	—	(26)	7,44
US Government Agencies	23,970	—	(182)	23,78
US Treasury securities	67,904	—	(629)	67,27
	$ 395,655	$ 71	$ (1,424)	$ 394,30

As of June 30, 2023, forty-two of our available-for-sale debt securities with a fair market value of $193.7 million were in a gross unrealized loss position of $0.4 million. Of those, thirty-eight have been in a gross unrealized loss position of $0.4 million for less than one year and four have been in a gross unrealized loss position of $25.9 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 June 30, 2023, 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):

	June 30, 2023	December 31, 2022
	Estimated Fair Value	
Due within one year	$ 264,470	$ 394,302
After one but within five years	21,958	—
	$ 286,428	$ 394,302

The Company had $0.5 million in contingent consideration liabilities as of June 30, 2023 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 (See *Note 3 - Significant Transactions* for additional information). 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 did not exist as of December 31, 2022.

The following table summarizes the financial assets and liabilities that are measured on a recurring basis at fair value as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023			
	Level 1	Level 2	Level 3	Total estimated fair value
Financial assets:				
Cash equivalents:				
Money market funds	$ 261,994	$ —	$ —	$ 261,994
Commercial paper	—	—	—	—
Total cash equivalents:	261,994	—	—	261,994
Available-for-sale marketable securities:				
Commercial paper	—	171,628	—	171,628
Corporate Debt Securities	—	—	—	—
US Government Agencies	—	85,164	—	85,164
US Treasury securities	29,636	—	—	29,636
Total available-for-sale marketable securities:	29,636	256,792	—	286,428
Total assets measured at fair value	$ 291,630	$ 256,792	$ —	$ 548,422
Financial Liabilities:				
Contingent consideration	$ —	$ —	$ 500	$ 500
Total financial liabilities	$ —	$ —	$ 500	$ 500

	December 31, 2022			
	Level 1	Level 2	Level 3	Total estimated fair valu
Financial assets:				
Cash equivalents:				
Money market funds	$ 26,811	$ —	$ —	$ 26,8
Commercial paper	1,998	—	—	1,9
Total cash equivalents:	28,809	—	—	28,8
Available-for-sale marketable securities:				
Commercial paper	—	295,793	—	295,7
Corporate Debt Securities	—	7,446	—	7,4
US Government Agencies	—	23,788	—	23,7
US Treasury securities	67,275	—	—	67,2
Total available-for-sale marketable securities:	67,275	327,027	—	394,3
Total assets measured at fair value	$ 96,084	$ 327,027	$ —	$ 423,1
Financial Liabilities:				
Contingent consideration	$ —	$ —	$ —	$ -
Total financial liabilities	$ —	$ —	$ —	$ -

The following significant unobservable inputs were used in the valuation of the contingent consideration payable to Zentera pursuant to the Termination Agreement at June 30, 2023.

Contingent Consideration Liability	Fair Value as of June 30, 2023 (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, 2022	$ —
Issuance of contingent consideration to Zentera	500
Changes in the fair value of contingent consideration	—
Contingent consideration at June 30, 2023	$ 500

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the six months ended June 30, 2023. We had one instrument that was classified within Level 3 as of June 30, 2023. No instruments were classified as Level 3 as of December 31, 2022. As of June 30, 2023 and December 31, 2022, 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):

	June 30, 2023	December 31, 2022
Prepaid insurance	$ 1,322	$ 1,01
Prepaid software licenses and maintenance	574	95
Foreign R&D credit refund	911	65
Prepaid research and development expenses	13,872	15,00
Interest receivable	878	50
Sublease assets	932	-
Zentera receivable	—	5,87
Other prepaid expenses	372	26
Total prepaid expenses and other assets	18,861	24,28
Less long-term portion	7,918	9,72
Total prepaid expenses and other assets, current	$ 10,943	$ 14,56

7. Property and Equipment, net

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

	June 30, 2023	December 31, 2022
Lab equipment	$ 2,754	$ 2,62
Leasehold improvements	4,432	4,89
Office equipment and furniture	1,854	2,06
Computer equipment	150	15
Construction in progress	224	3
Subtotal	9,414	9,76
Accumulated depreciation and amortization	(2,764)	(2,06
Property and equipment, net	$ 6,650	$ 7,70

Depreciation and amortization expense for the three months ended June 30, 2023 and 2022 was approximately $344 thousand and $348 thousand, respectively. Depreciation and amortization expense for the six months ended June 30, 2023 and 2022 was $704 thousand and $692 thousand, respectively.

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued research and development expenses	$ 28,783	$ 32,31
Accrued employee expenses	7,992	11,24
Accrued legal expenses	602	1,25
Accrued general and administrative expenses	996	66
Lease liability	2,335	2,16
Contingent consideration	500	-
Taxes payable	622	38
Total accrued expenses	41,830	48,02
Less long-term portion	2,376	2,62
Total accrued expenses	$ 39,454	$ 45,40

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.

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"), as amended in January 2021, 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 (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.

At June 30, 2023, 10,223,133 shares were subject to outstanding awards under the 2020 Plan and 973,778 shares were available for future grants of share-based awards under the 2020 Plan.

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. The Board of Directors has initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards granted under the 2022 Inducement Plan.

At June 30, 2023, 1,360,975 shares were subject to outstanding awards under the 2022 Inducement Plan and 139,025 shares were available for future grants of share-based awards under the 2022 Inducement Plan.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development expense	$ 5,985	$ 5,155	$ 11,858	$ 10,19
General and administrative expense	7,357	11,609	15,217	16,71
Total share-based compensation expense	$ 13,342	$ 16,764	$ 27,075	$ 26,91

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Stock Options	$ 10,205	$ 12,524	$ 20,814	$ 20,30
Employee Stock Purchase Plan	111	110	216	21
RSAs and RSUs	3,026	4,130	6,045	6,39
	$ 13,342	$ 16,764	$ 27,075	$ 26,91

Stock Options and Restricted Stock Units

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 six months ended June 30, 2023 and June 30, 2022 was determined with the following assumptions:

	June 30, 2023	June 30, 2022
Expected volatility	77.5% - 80.8%	73.6% - 80.5%
Average expected term (in years)	5.5 - 6.1	6.0 - 6.5
Risk-free interest rate	3.4% - 4.2%	1.5% - 3.2%
Expected dividend yield	— %	— %

Employee Stock Purchase Plan

Effective April 2020, the Company's Board of Directors adopted, and the Company's stockholders approved the Zentalis Pharmaceuticals, Inc. 2020 Employee Stock Purchase Plan (the "ESPP"), which was subsequently amended and restated effective March 15, 2021. The maximum aggregate number of shares of the Company's common stock available for issuance under the ESPP at June 30, 2023 was 1,929,891. Under the terms of the ESPP, the Company's employees may elect to have up to 20% of their compensation, up to a maximum value of $25,000 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. The weighted average assumptions used to estimate the fair value of stock purchase rights under the ESPP during the period ended are as follows:

	Ended June 30, 2023
ESPP	
Volatility	94.2 %
Expected term (years)	0.5
Risk free rate	4.9 %
Expected dividend yield	—

Compensation Expense Summary

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):

	June 30, 2023	
	Unrecognized Expense	Remaining Weighted-Average Recognition Period (years)
Stock options	$ 113,266	3.02
RSAs	101	0.28
RSUs	31,227	2.88
ESPP	$ 110	0.25

During the six months ended June 30, 2023, we issued 51.5 thousand shares of common stock in connection with the exercises of stock options. For the six months ended June 30, 2023, 73.5 thousand shares of common stock issued in conjunction with certain restricted stock awards (“RSAs”), vested. Outstanding stock options, unvested RSAs, and unvested RSUs totaling approximately 10.1 million shares, 47.7 thousand shares and 1.5 million shares of our common stock, respectively, were outstanding as of June 30, 2023.

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.

Leases

Our commitments include payments related to operating leases. Approximate annual future minimum operating lease payments as of June 30, 2023 are as follows (in thousands):

Year	Operating Leases
2023 (remaining)	$ 3,257
2024	6,486
2025	6,799
2026	7,278
2027	7,451
Thereafter	38,778
Total minimum lease payments:	70,049
Less: imputed interest	(23,687)
Total operating lease liabilities	46,362
Less: current portion	(2,335)
Lease liability, net of current portion	$ 44,027

The weighted-average remaining lease term of our operating leases is approximately 9.3 years.

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 our New York lease during the six months ended June 30, 2023. For the six months ended June 30, 2023, we recorded lease income of $0.2 million relating to this sublease.

11. Net Loss Per Common Share

Basic and diluted net loss per common share were calculated as follows (in thousands except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss attributable to Zentalis	$ (112,527)	$ (68,357)	$ (175,746)	$ (127,434)
Denominator:				
Weighted average number of common shares outstanding, basic and diluted	60,790	51,117	60,038	48,197
Net loss per common share	$ (1.85)	$ (1.34)	$ (2.93)	$ (2.64)

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).

	June 30,	
	2023	2022
Outstanding stock options	10,085	7,828
Unvested RSAs	42	222
Unvested RSUs	1,499	472
	11,626	8,522

12. Related Party Disclosures

Tempus

Kimberly Blackwell, M.D., our Chief Executive Officer and a member of our Board of Directors, was previously employed by Tempus Labs, Inc. ("Tempus") and served as an advisor of Tempus until June 2023. The Company entered into a Master Services Agreement with Tempus in December 2020 to provide data licensing and research services. There were $0.5 million and immaterial fees incurred for services performed by Tempus for the six months ended June 30, 2023 and 2022, respectively.

Zentera

Kevin D. Bunker, Ph.D., our Chief Scientific Officer, served as a member of the Board of Directors of Zentera until June 2023, when Dr. Bunker resigned in connection with the termination of our Collaboration and License Agreements with Zentera and the sale of our 40.3% equity stake in Zentera back to Zentera. For additional information, please see Note 3. Accordingly, the Company identified Zentera as a related party.

In May 2020, each of our wholly owned subsidiaries, Zeno Alpha, Inc., K-Group Alpha, Inc. and K-Group Beta, Inc., entered into Collaboration and License Agreements, pursuant to which we collaborated with Zentera on

the development and commercialization of the Zentera Collaboration Products, in Greater China. Under the terms of the Collaboration and License Agreements with Zentera, Zentera was responsible for the costs of developing the Zentera Collaboration Products in Greater China, and we were responsible for the costs of developing the Zentera Collaboration Products outside Greater China, provided that Zentera was obligated to reimburse us for a portion of its costs for global data management, pharmacovigilance, safety database management, and chemistry, manufacturing and controls activities with respect to each Zentera Collaboration Product. For the six months ended June 30, 2023 and 2022, the amounts incurred under this arrangement totaled $3.5 million and $5.1 million, respectively, and are presented as contra-research and development expense in the consolidated statement of operations. As disclosed above, these Collaboration and License Agreements were terminated in June 2023.

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

The following discussion and analysis of financial condition and operating results should be read together with our interim unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q contains forward-looking statements that involve significant risks and uncertainties. As a result of many important factors, such as those set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, 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.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. We are developing a focused pipeline of potentially best-in-class oncology candidates, including the following:

- Azenosertib (ZN-c3), a potentially first-in-class WEE1 inhibitor for advanced solid tumors and hematological malignancies;
- ZN-d5, a B-cell lymphoma 2, or BCL-2, inhibitor for hematological malignancies and related disorders; and
- A heterobifunctional degrader of BCL-xL, a member of the anti-apoptotic BCL-2 proteins, for solid tumors and hematological malignancies.

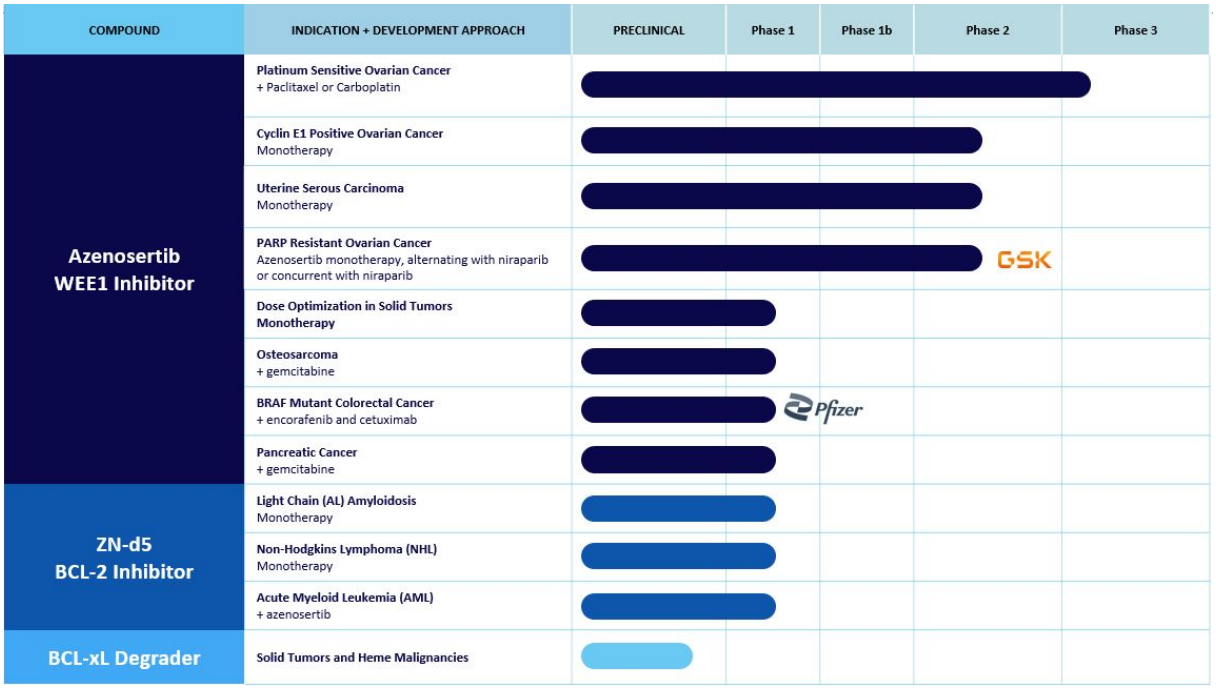
We are currently evaluating azenosertib and ZN-d5 in multiple ongoing clinical trials and conducting studies to enable an Investigational New Drug, or IND, application for our BCL-xL product candidate. We also continue to use our extensive drug discovery experience and capabilities across cancer biology and medicinal chemistry, which we refer to as our Integrated Discovery Engine, to advance our ongoing research on protein degraders of undisclosed targets. We believe our product candidates are differentiated from current programs targeting similar pathways and, if approved, have the potential to significantly impact clinical outcomes of patients with cancer.

Our Pipeline

We are developing a focused pipeline of oncology product candidates with the potential to address significant unmet medical need for cancer patients. Two of our product candidates are currently in multiple ongoing clinical trials: azenosertib, an inhibitor of WEE1, a protein tyrosine kinase, and ZN-d5, a selective inhibitor of BCL-2. To date, azenosertib has been well tolerated and has demonstrated monotherapy anti-tumor activity across multiple tumor types in clinical trials. In addition, ZN-d5 has been well tolerated in clinical trials to date. We have also declared a development candidate for our BCL-xL degrader program, for which we are conducting IND-enabling studies.

We currently exclusively in-license or solely own worldwide development and commercialization rights to azenosertib, ZN-d5, and our BCL-xL product candidate.

The following table summarizes our product candidate pipeline:



Our Development Programs

Azenosertib (WEE1 Inhibitor)

Azenosertib is a potentially best-in-class and first-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. Currently, there are no WEE1 inhibitors approved by the U.S. Food and Drug Administration, or FDA. We have designed azenosertib to have advantages over other investigational therapies targeting WEE1, including superior selectivity and pharmacokinetic, or PK, properties. Azenosertib is currently being evaluated in the clinic for advanced solid tumors and hematological malignancies:

- as a monotherapy,
- in combination with traditional chemotherapy and DNA damaging agents, and
- in combination with molecularly targeted agents.

Two key components of our azenosertib clinical development strategy are our dose optimization activities and our exploration of biomarker enrichment strategies targeting tumors of high genomic instability, such as Cyclin E1 positive tumors and homologous recombination deficient tumors. On June 6, 2023, we announced that, based on the data generated from our dose optimization work, we identified the following monotherapy recommended Phase 2 dose, or RP2D, for azenosertib: 400 mg daily on a five days on, two days off weekly administration schedule, or 400 mg QD 5:2.

Azenosertib is being evaluated in multiple current or planned clinical trials, including the following:

- ***Monotherapy - Phase 2 Clinical Trial in Cyclin E1 Driven High-Grade Serous Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer (HGSOC) (ZN-c3-005).*** We are evaluating azenosertib as a monotherapy in a Phase 2 clinical trial in patients with Cyclin E1 positive platinum-resistant HGSOC, or PROC. Our Cyclin E1 positive enrichment strategy is supported by preclinical data that showed that high Cyclin E1 protein expression sensitized cancer cells to the anti-tumor effects of azenosertib as well as preliminary retrospective clinical data that Cyclin E1 protein levels may be associated with clinical benefit from WEE1 inhibition. In addition, in April 2023, we announced preclinical data at the 2023 American Association for Cancer Research, or AACR, Annual Meeting that demonstrated that azenosertib drove cancer cell death in Cyclin E1-high tumor cells in vitro and substantially inhibited growth of Cyclin E1-high, patient derived, in vivo tumor models.

- ***Monotherapy - Phase 2 Clinical Trial in Recurrent or Persistent Uterine Serous Carcinoma (USC) (ZN-c3-004).*** Azenosertib is currently being evaluated as a monotherapy in a Phase 2 clinical trial in adult women with USC. As of a September 14, 2022 data cutoff, a total of 43 patients were enrolled and dosed. Azenosertib was well tolerated. The most common treatment related adverse events, or AEs, were nausea (60.5% all grades/9.3% grade 3 or higher), fatigue (46.5% all grades/9.3% grade 3 or higher), diarrhea (37.2% all grades/7.0% grade 3 or higher) and vomiting (32.6% all grades/7.0% grade 3 or higher). The FDA granted Fast Track designation in November 2021 to azenosertib in patients with advanced or metastatic USC who have received at least one prior platinum-based chemotherapy regimen for management of advanced or metastatic disease. We believe that the study design in this patient population has the potential to support registration in the United States.

- ***Combination - Phase 1/2 Clinical Trial of Azenosertib and PARP Inhibitor (PARPi) in PROC (ZN-c3-006).*** We are evaluating azenosertib in combination with GSK's PARP inhibitor, niraparib (ZEJULA®), in a Phase 1/2 clinical trial in PROC patients who have failed PARPi, treatment as part of a clinical collaboration with GSK. This study is currently evaluating three cohorts: one with concurrent dosing of the two drugs, one with alternating dosing of the two drugs, and a third with monotherapy azenosertib at the monotherapy RP2D announced on June 6, 2023. This clinical study is supported by preclinical data that showed that combining azenosertib and niraparib resulted in synergistic cell killing in ovarian cancer *in vivo* models.

- ***Combination - Phase 1b Clinical Trial of Azenosertib and Chemotherapy in PROC (ZN-c3-002).*** Azenosertib is currently being evaluated in combination with each of paclitaxel, carboplatin, PLD, and gemcitabine in four separate cohorts in a Phase 1b clinical trial in patients with PROC. On May 25, 2023, we announced positive data from this Phase 1b clinical trial. Azenosertib was well tolerated in combination with multiple types of chemotherapy and demonstrated encouraging clinical activity, with noteworthy objective response rates, or ORRs, and median progression free survival, or mPFS, in all patients, but especially in those patients with Cyclin E1 positive tumors, a subgroup recognized to have a poor prognosis and to show relatively poor outcomes following treatment with chemotherapy. A total of 115 patients were enrolled in the study across all chemotherapy combination groups. At April 10, 2023, 94 were response evaluable. Across all dosing schedules, azenosertib plus paclitaxel demonstrated the highest ORR of 50.0% (mPFS of 7.4m; mDOR of 5.6m), followed by an ORR of 38.5% (mPFS of 8.3m; mDOR of 6.2m) for azenosertib plus gemcitabine. Azenosertib plus carboplatin demonstrated an ORR of 35.7% (mPFS of 10.4m; mDOR of 11.4m), and azenosertib plus PLD demonstrated an ORR of 19.4% (mPFS of 6.3m; mDOR of 8.3m). Of patients who had available tissue for immunohistochemistry, or IHC, 87% were Cyclin E1+ (H-score >50). Cyclin E1+ status was associated with a superior ORR and a longer mPFS across the response-evaluable patient population with IHC data (ORR of 40.0% vs 8.3%; mPFS of 9.86 vs 3.25 months; HR = 0.37; P = 0.0078), showcasing the potential synergy of WEE1 inhibition with chemotherapy in this patient population. Frequent Grade ≥3 treatment-related adverse events (%) across all azenosertib intermittent dosing groups were thrombocytopenia (27.5%), neutropenia (25.5%), anemia (15.7%), and fatigue (9.8%). Based on these results, the Company is planning to initiate a Phase 3 study comparing

azenosertib dosed intermittently in combination with either carboplatin or paclitaxel in patients with Cyclin E1 positive platinum-sensitive ovarian cancer.

- ***Monotherapy - Phase 1 Dose Finding Clinical Trial in Solid Tumors (ZN-c3-001).*** We are currently evaluating azenosertib as a monotherapy in a Phase 1 dose finding clinical trial for the treatment of solid tumors. On June 6, 2023, we announced positive data from this clinical trial. We also announced on June 6, 2023 that, based on the encouraging data from this trial, we identified the monotherapy RP2D for azenosertib as 400 mg QD 5:2. As of April 24, 2023, a total of 127 heavily pretreated patients with advanced solid tumors were enrolled and received monotherapy azenosertib at doses ≥ 300 mg on either continuous daily dosing or intermittent weekly administration schedules. Across all tumor types, 74 patients received azenosertib on a continuous dosing schedule and 53 patients received azenosertib on an intermittent dosing schedule. When evaluating continuous versus intermittent at comparable clinically meaningful dose levels, the data are the following: intermittent dosing maintained safety and improved tolerability of azenosertib as compared to continuous dosing. Gastrointestinal, fatigue, and hematologic Grade 3 and 4 treatment-related adverse events, or TRAEs, were comparable or favorable versus continuous dosing. No discontinuations due to TRAEs were observed in the intermittent cohorts. Steady state exposure, as measured by $AUC_{0\text{-}24}$, more than doubled at the new intermittent RP2D, compared to AUC observed at 300 mg QD with continuous administration, and intermittent dosing achieved higher maximal concentration levels as compared to continuous administration. As of June 2, 2023, the confirmed ORR in patients treated with intermittent dosing was 36.8% (7/19), versus 19.2% (5/26) in those who received a continuous dosing. In the response evaluable patients who received intermittent dosing azenosertib, the confirmed ORR was 50% in USC and 30.8% in ovarian cancer. 89% of ovarian cancer and USC patients who received an intermittent dosing schedule had target lesion reductions from their baseline scans. Patients in this subgroup who received an intermittent dosing schedule had a median follow up of 4.4 months, and 63% (12/19) patients remained on therapy as of June 2, 2023.

- ***Combination - Phase 1/2 Clinical Trial of Azenosertib and Chemotherapy in Relapsed or Refractory Osteosarcoma (ZN-c3-003).*** Azenosertib is currently being evaluated in combination with gemcitabine, in a Phase 1/2 clinical trial in adult and pediatric patients with R/R osteosarcoma. We reported initial results from this trial at the 2022 Connective Tissue Oncology Society, or CTOS, Annual Meeting in November 2022. As of a October 24, 2022 data cutoff, there were 12 patients evaluable for efficacy, with approximately 33% of patients demonstrating event-free survival, or EFS, at 18 weeks (compared to approximately 12% at 18 weeks for this indication historically). As of the October 24, 2022 data cutoff, there were 17 patients evaluable for safety. Azenosertib demonstrated a manageable safety profile with 82.4% experiencing treatment related AEs of which 52.9% were grade 3 or higher. The most common treatment related AEs were platelet count decreased/thrombocytopenia (47.1% all grades/35.3% grade 3 or higher), fatigue (29.4% all grades/5.9% grade 3 or higher), nausea (29.4% all grades/0% grade 3 or higher) and rash (29.4% all grades/5.9% grade 3 or higher). We received orphan drug designation and rare pediatric disease designation from the FDA for azenosertib in osteosarcoma.

- ***Combination - Phase 1/2 Clinical Trial of Azenosertib with Encorafenib and Cetuximab (BEACON Regimen) in BRAF V600E Mutant Metastatic Colorectal Cancer (mCRC) (ZN-c3-016).*** We are collaborating with Pfizer to evaluate 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 a Phase 1/2 clinical trial. In preclinical studies, WEE1 inhibition has shown synergy with many targeted agents in mutationally driven cancers, and the addition of azenosertib to the BEACON regimen enhanced anti-tumor activity in a cell-line-derived xenograft model. We initiated enrollment in this clinical trial in the first quarter of 2023.

- ***Combination - Phase 1/2 Clinical Trial of Azenosertib and Chemotherapy in Pancreatic Cancer.*** We have also agreed to support the Dana Farber-sponsored Phase 1/2 clinical trial evaluating azenosertib and chemotherapy, gemcitabine, in platinum-resistant pancreatic cancer patients.

ZN-d5 (BCL-2 Inhibitor)

ZN-d5 is a potentially best-in-class, selective, oral small molecule inhibitor of BCL-2. BCL-2 is a protein that plays a critical role in the regulation of cell death, known as apoptosis. The overexpression of BCL-2 is frequently detected in numerous cancer types, which prevents apoptosis of cancer cells. Utilizing our medicinal chemistry expertise, we have designed ZN-d5 to have best-in-class potency, selectivity and PK properties. ZN-d5 is currently being evaluated in the clinic in patients with hematological malignancies in both the monotherapy and combination settings.

ZN-d5 is being evaluated in the following monotherapy and combination clinical trials:

- ***Monotherapy - Phase 1/2 Clinical Trial in Relapsed or Refractory Light Chain Amyloidosis (R/R AL Amyloidosis) (ZN-d5-003).*** ZN-d5 is being evaluated as a monotherapy in a Phase 1/2 clinical trial in R/R AL amyloidosis. BCL-2 inhibition has demonstrated clinical activity in R/R AL amyloidosis; however, there are currently no FDA-approved BCL-2 inhibitors for the treatment of R/R AL amyloidosis. This Phase 1/2 study in patients with R/R AL amyloidosis consists of a dose escalation phase to establish the monotherapy dose in this setting, and an expansion phase to further assess the safety and efficacy of ZN-d5 in this population. The study is expected to enroll up to approximately 140 patients.

- ***Monotherapy - Phase 1 Clinical Trial in Non-Hodgkin Lymphoma (NHL) (ZN-d5-001).*** We are evaluating ZN-d5 as a monotherapy in a Phase 1 dose escalation clinical trial in patients with NHL. As of the database cutoff date of November 3, 2021, 23 patients with NHL were evaluable for safety. At our R&D Day in December 2021, we reported preliminary interim data from the NHL patients in this study. As of the November 3, 2021 database cutoff date, ZN-d5 was well tolerated, with 73.9% of the NHL patients having experienced AEs (30.4% grade 3 or higher), not all of which were related ZN-d5. Anemia (21.7% all grades/8.7% grade 3 or higher), diarrhea (13.0% all grades/4.3% grade 3 or higher), and nausea and vomiting (8.7% each all grades/0% grade 3 or higher) comprise the most commonly experienced AEs. Investigator-reported responses using the Lugano 2014 classification among 11 patients with diffuse large B-cell lymphoma included a complete response, an unconfirmed PR, and two subjects with stable disease, as of the database cutoff date of November 3, 2021.

- ***Combination - Phase 1/2 Clinical Trial of ZN-d5 and Azenosertib in Relapsed or Refractory Acute Myeloid Leukemia (R/R AML) (ZN-d5-004C).*** ZN-d5 is being evaluated in combination with azenosertib in a Phase 1/2 dose escalation clinical trial in patients with R/R AML. The Phase 1 portion of this trial will escalate the doses of both drugs to identify the dose for the combination, which will be assessed in Phase 2 expansion cohort(s). This study is expected to enroll up to approximately 100 patients. This clinical trial is supported by preclinical models that showed that the combination of ZN-d5 with azenosertib yielded a significant enhancement of activity in several indications, including R/R AML, as compared to activity shown with either of these product candidates as a single agent. Preclinical models also showed that the combination of ZN-d5 with azenosertib was well tolerated in mice. We believe we are the only company to have both a WEE1 inhibitor and a BCL-2 inhibitor in clinical development.

BCL-xL Heterobifunctional Degrader

In November 2022, we announced that we identified a BCL-xL protein degrader candidate and initiated IND-enabling studies. We are developing a BCL-xL heterobifunctional degrader based on non-functional or dysfunctional E3 ubiquitin ligase complex in platelets, allowing for the potential mitigation of dose-limiting thrombocytopenia historically associated with BCL-xL inhibitors.

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 $237.1 million for the year ended December 31, 2022, and $175.8 million and $127.6 million for the six months ended June 30, 2023 and June 30, 2022, respectively. We had an accumulated deficit of $772.1 million as of June 30, 2023. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We had cash, cash equivalents and marketable securities of $553.0 million as of June 30, 2023. We believe that our existing cash, cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements into 2026. 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, 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 certain corporate restructuring disclosed elsewhere in this Annual Report on 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, ZN-d5 and our BCL-xL product candidate. 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, ZN-d5 and our BCL-xL product candidate. 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.

GlaxoSmithKline Clinical Trial Collaboration and Supply Agreement

In April 2021, we entered into a clinical trial collaboration and supply agreement with GSK under which we are evaluating the combination of azenosertib and niraparib, GSK's poly (ADP-ribose) polymerase (PARP) inhibitor, in patients with platinum-resistant ovarian cancer. Pursuant to this agreement, we are responsible for the conduct and cost of the relevant studies, under the supervision of a joint development committee made up of our representatives and representatives of GSK that meets quarterly. GSK is supplying niraparib for use in the collaboration, at no cost to us. We are required to provide to GSK clinical data and other reports upon completion of the study.

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. We and GSK each have the right to terminate the agreement for material breach by the other party. In addition, the agreement may be terminated by either party due to safety considerations or if either party decides to discontinue development of its own compound for medical, scientific, legal or other reasons or if a regulatory authority takes any action preventing that party from supplying its compound for the study or in the event the other party is subject to specified bankruptcy, insolvency or similar circumstances. GSK also has the right to terminate this agreement if it notifies us in writing that it reasonably and in good faith believes that niraparib is being used in an unsafe manner, and we fail to incorporate changes to address such issue, and the issue is unable to be resolved following elevation to appropriate parties.

Zentera Therapeutics

On June 15, 2023, we announced that we and certain of our wholly owned subsidiaries had entered into an agreement to terminate our Collaboration and License Agreements with Zentera Therapeutics, or Zentera, pursuant to which such wholly owned subsidiaries had granted to Zentera certain development and commercialization rights to its product candidates, azenosertib, ZN-d5 and ZN-c5 in the People's Republic of China, Macau, Hong Kong and Taiwan, or Greater China. As a result of the termination of these agreements, we have regained the rights from Zentera for azenosertib, ZN-d5 and ZN-c5 in Greater China, and now hold worldwide development and commercialization rights to these assets.

In connection with the foregoing, we agreed to pay Zentera certain consideration, including a $30 million upfront payment, a milestone payment, and a low single digit royalty on net sales of azenosertib, ZN-d5 and ZN-c5 in Greater China. In addition, we sold our 40.3% equity stake in Zentera back to Zentera for de minimis consideration.

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 collaboration agreements, which includes 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 stock-based compensation expense, for personnel engaged in research and development functions;

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, and other third parties that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture drug material for use in our preclinical studies and clinical trials;
- costs of outside consultants, including their fees, 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 in the table below.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Azenosertib	$ 13,883	$ 11,542	$ 26,787	$ 24,147
ZN-d5	5,118	3,475	10,498	8,518
Unallocated research and development expenses	23,683	28,808	53,983	57,272
Total research and development expenses	$ 42,684	$ 43,825	$ 91,268	$ 89,937

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have a higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we complete our ongoing clinical trials, initiate new clinical trials, continue to discover and develop additional product candidates and prepare regulatory filings for any product candidates that successfully complete clinical development.

The successful development of our 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 our product candidates 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 any 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 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 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.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support research and development activities relating to our clinical stage programs, and any other

product candidates we may develop. We also expect to incur increased expenses associated with being a public company, particularly now that we are no longer an emerging growth 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.

Interest Income

Interest income consists of interest earned on cash, cash equivalents and available-for-sale marketable securities.

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 Three Months Ended June 30, 2023 to Three Months Ended June 30, 2022

The following table summarizes our results of operations for the periods indicated, together with the changes in those items in dollars:

	Three Months Ended June 30,		Increase (Decrease)
	2023	2022	
	(in thousands)		
Operating expenses			
Research and development	$ 42,684	$ $ 43,825	$ (1,14
Zentera in-process research and development	45,568	—	45,56
General and administrative	15,664	19,636	(3,97
Total operating expenses	103,916	63,461	40,45
Loss from operations	(103,916)	(63,461)	(40,45
Other Income (Expense)			
Investment and other income, net	4,451	424	4,02
Net loss before income taxes	(99,465)	(63,037)	(36,42
Income tax (benefit) expense	(605)	17	(62
Loss on equity method investment	13,704	5,338	8,36
Net loss	(112,564)	(68,392)	(44,17
Net loss attributable to noncontrolling interest	(37)	(35)	(
Net loss attributable to Zentalis	$ (112,527)	$ (68,357)	$ (44,17

Research and Development Expenses

Research and development, or R&D, expenses for the three months ended June 30, 2023 were $42.7 million, compared to $43.8 million for the three months ended June 30, 2022. The decrease of $1.1 million was primarily due to $1.7 million in decreased collaboration costs, a $1.1 million decrease related to clinical trials and R&D supplies, and a $0.6 million reduction in personnel and related expense. These decreases were partially offset by a $1.5 million increase in Zentera cost sharing and a $0.8 million increase in consulting and other expense.

Zentera In-process Research and Development

Zentera In-process Research and Development expenses for the three months ended June 30, 2023 were $45.6 million, compared to zero for the three months ended June 30, 2022. The increase was due to $45.6 million of total cash and non-cash consideration transferred to Zentera for in-process research and development during the three months ended June 30, 2023 relating to the termination of our collaboration with Zentera.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2023 were $15.7 million, compared to $19.6 million during the three months ended June 30, 2022. This decrease of $3.9 million was primarily attributable to a $4.2 million decrease in non-cash stock-based compensation expense and a $0.8 million decrease related to other personnel expenses. These decreases were partially offset by an increase of $0.8 million in allocated overhead expenditures and a $0.3 million increase in outside services and other costs.

Investment and Other Income, Net

Investment and other income, net was $4.5 million for the three months ended June 30, 2023, compared to $0.4 million for the three months ended June 30, 2022. The increase of $4.1 million was primarily driven by returns on an increase of invested cash and marketable securities.

Income Tax (Benefit) Expense

For the three months ended June 30, 2023 and June 30, 2022, we recorded an income tax benefit of $0.6 million and an income tax expense of $17 thousand, respectively. Due to the termination of our relationship with Zentera, we wrote off our deferred tax liability related to the equity method investment which resulted in a net tax benefit for the three months ended June 30, 2023.

Loss on Equity Method Investment

The loss on equity method investment for the three months ended June 30, 2023 was $13.7 million compared to $5.3 million for the six months ended June 30, 2022. The increase of $8.4 million was driven by a one time charge recorded to reflect the fair value of the equity returned to Zentera valued after the return of the intellectual property to Zentalis, which related to the termination of our collaboration with Zentera.

Comparison of Six Months Ended June 30, 2023 to Six Months Ended June 30, 2022

	Six Months Ended June 30,		Increase (Decrease)
	2023	2022	
	(in thousands)		
Operating expenses			
Research and development	$ 91,268	$ 89,937	$ 1,33
Zentera in-process research and development	45,568	—	45,56
General and administrative	32,033	31,403	63
Total operating expenses	168,869	121,340	47,52
Loss from operations	(168,869)	(121,340)	(47,52
Other Income (Expense)			
Investment and other income, net	8,560	850	7,71
Net loss before income taxes	(160,309)	(120,490)	(39,81
Income tax (benefit) expense	(497)	50	(54
Loss on equity method investment	16,014	7,089	8,92
Net loss	(175,826)	(127,629)	(48,19
Net loss attributable to noncontrolling interest	(80)	(195)	11
Net loss attributable to Zentalis	$ (175,746)	$ (127,434)	$ (48,31

Research and Development Expenses

R&D expenses for the six months ended June 30, 2023 were $91.3 million, compared to $89.9 million for the six months ended June 30, 2022. The increase of $1.3 million was primarily due to a $3.2 million increase in overhead expenses, a $1.6 million increase in Zentera cost sharing, a $1.4 million increase in personnel and other expenses, a $0.8 million increase in consulting expense and a $0.7 million increase in R&D supplies expense. These increases were partially offset by $4.0 million in decreased clinical trials expense and a $2.4 million decrease in collaborations expenses.

Zentera In-process Research and Development Expenses

Zentera In-process Research and Development expenses for the six months ended June 30, 2023 were $45.6 million, compared to zero for the six months ended June 30, 2022. The increase was due to $45.6 million of total cash and non-cash consideration transferred to Zentera for in-process research and development during the six months ended June 30, 2023 relating to the termination of our collaboration with Zentera.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2023 were $32.0 million, compared to $31.4 million during the six months ended June 30, 2022. This increase of $0.6 million was primarily attributable to a $5.0 million operating lease impairment charge. This was offset by a $2.2 million decrease in facilities and overhead

expense, a $2.0 million decrease in personnel expenses, driven by $1.5 million in decreased non-cash stock-based compensation, and a $0.2 million decrease in outside services and supplies expense.

Investment and Other Income, Net

Investment and other income, net was $8.6 million for the six months ended June 30, 2023, compared to $0.9 million for the six months ended June 30, 2022. The increase of $7.7 million was primarily driven by returns on an increase of invested cash and marketable securities.

Income Tax (Benefit) Expense

For the six months ended June 30, 2023 and June 30, 2022 , we recorded an income tax benefit of $0.5 million and income tax expense of $50 thousand. Due to the termination of our relationship with Zentera, we wrote off our deferred tax liability related to the equity method investment which resulted in a net tax benefit for the six months ended June 30, 2023.

Loss on Equity Method Investment

The loss on equity method investment for the six months ended June 30, 2023 was $16.0 million compared to $7.1 million for the six months ended June 30, 2022. The increase of $8.9 million was driven by a one time charge recorded to reflect the fair value of the equity returned to Zentera valued after the return of the intellectual property to Zentalis, which related to the termination of our collaboration with Zentera.

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. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our research programs and product candidates. We expect that our research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials for our current and future research programs and product candidates, contracting with CMOs to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations.

As a result, we will need to raise substantial additional capital to support our continuing operations and pursue our growth 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 increased 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 one or more product candidates 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 June 30, 2023, we raised a total of $1.2 billion in gross proceeds from the sale of our common stock and Series A, B and C

convertible preferred units, including a total of $250.0 million in gross proceeds from our follow-on offering in June 2023. As of June 30, 2023, we had cash, cash equivalents, and marketable securities of $553.0 million, and an accumulated deficit of $772.1 million. 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 June 30, 2023.

ATM Program

In May 2021, we entered into a sales agreement, or the Sales Agreement, with SVB Leerink LLC, or SVB Leerink, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $200.0 million in "at-the-market" offerings, or the ATM, under our Registration Statement on Form S-3 (File No. 333-255769) filed with the U.S. Securities and Exchange Commission, or the SEC, on May 4, 2021. Sales of common stock, if any, 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 of 1933, as amended, or the Securities Act, including sales made directly through The Nasdaq Global Market or any other existing trading market for our common stock. During the quarter ended June 30, 2023, we did not sell any shares of common stock under the Sales Agreement. As of June 30, 2023, there was $140.3 million of common stock remaining available for sale under the Sales Agreement.

Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (128,558)	$ (93,22
Net cash provided by (used in) investing activities	115,053	(122,30
Net cash provided by financing activities	236,994	210,71
Net increase (decrease) in cash and cash equivalents	$ 223,489	$ (4,81

Operating Activities

We have incurred losses since inception. Net cash used in operating activities for the six months ended June 30, 2023 was $128.6 million, consisting primarily of our net loss of $175.8 million as we incurred expenses associated with research and development activities for our product candidates and incurred general and administrative expenses, as well as changes in operating assets and liabilities of $9.2 million, partially offset by non-cash adjustments of $56.4 million.

Net cash used in operating activities for the six months ended June 30, 2022 was $93.2 million, consisting primarily of our net loss of $127.6 million as we incurred expenses associated with research and development activities for our product candidates and incurred general and administrative expenses, as well as changes in operating assets and liabilities of $0.4 million, partially offset by non-cash adjustments of $34.8 million.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2023 of $115.1 million was attributable to the proceeds from maturities of marketable securities of $304.5 million, offset by net investment of excess cash of $189.1 million and the purchases of property and equipment of $0.3 million.

Net cash used in investing activities for the six months ended June 30, 2022 of $122.3 million was attributable to the proceeds from maturities of marketable securities of $156.0 million, offset by net investment of excess cash of $277.6 million and the purchases of property and equipment of $0.7 million.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2023 of $237.0 million primarily relates to the June 2023 follow-on offering, which provided net cash of $235.7 million. An additional $1.3 million was provided from the issuance of common stock under equity incentive plans during the six months ended June 30, 2023.

Net cash provided by financing activities for the six months ended June 30, 2022 of $210.7 million primarily relates to the May 2022 follow-on offering, which provided net cash of $188.8 million, and the April 2022 direct offering to Pfizer, which provided net cash of $20.5 million. Of the $25.0 million gross proceeds received from Pfizer, $4.2 million of the proceeds represented a premium in excess of the fair value of our common stock on the date of the investment. This amount has been recorded as accrued research and development expense on the unaudited condensed consolidated balance sheet and will be recognized as a reduction of research and development expense over the term of the collaboration. An additional $1.4 million was provided from the issuance of common stock under equity incentive plans during the six months ended June 30, 2022.

Funding Requirements

Our operating expenses increased in 2022 and are expected to increase substantially in the future in connection with our ongoing activities.

Specifically, our expenses will increase as we:

- advance the clinical development of azenosertib and ZN-d5 for the treatment of oncology indications;
- pursue the preclinical and clinical development of other current and future research programs and product candidates and, if applicable, diagnostics tools for biomarkers associated with our product candidates and future product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel, including in research, manufacturing and regulatory and clinical development, as well as management personnel;
- seek regulatory approval for any product candidates and, if needed, diagnostic tools for biomarkers associated with such product candidates, that successfully complete clinical development; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our operations as a public company.

We believe that our existing cash, cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements into 2026. 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 our programs for azenosertib and ZN-d5;
- the progress, costs and results of additional research and preclinical studies in other research programs we initiate in the future and, if needed, of diagnostic tools for biomarkers associated with our product candidates and future product candidates;
- the costs and timing of process development and manufacturing scale-up activities associated with 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

The following represent updates to our critical accounting estimates from our disclosure reported in "Critical Accounting Estimates" in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Asset Acquisitions

Methodology	*Judgment and Uncertainties*	*Effect if Actual Results Differ From Assumptions*
We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. In an asset acquisition, the cost allocated to acquire in-process research and development with no alternative future use is recognized as expense on the acquisition date.	Consideration exchanged for in-process research and development can include assets without readily determinable fair values. We estimate the fair value of consideration without a readily determinable fair value using various accepted valuation models and techniques.	We perform our valuations using supportable estimates in accepted valuation models. If our estimates are not accurate, we may understate or overstate the value of our asset acquisitions.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. 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 Quarterly Report on Form 10-Q, 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 June 30, 2023.

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 June 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below and the other information in this Quarterly Report on Form 10-Q, including our interim unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. 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 and ZN-d5. We have not yet demonstrated our ability to obtain marketing approvals, manufacture 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 each 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 $237.1 million for the year ended December 31, 2022, and $175.8 million and $127.6 million for the six months ended June 30, 2023 and June 30, 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $772.1 million. 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 our 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 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 our 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 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 preclinical and clinical development of our product candidates, including azenosertib and ZN-d5 and any other future product candidates, as well as the associated costs, including any unforeseen costs we have incurred and may continue to incur as a result of preclinical study or clinical trial delays due to public health emergencies, U.S. and global economic issues, including rising inflation and interest rates, or the ongoing military conflict between Russia and Ukraine, among other causes;
- if applicable, the availability or successful development of diagnostic tools for biomarkers associated with our product candidates or any other future product candidates;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development, both in the United States and internationally, of our product candidates, including azenosertib and ZN-d5, and any other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- maintaining marketing approvals, including 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.

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, and we expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, azenosertib, ZN-d5 and our other product candidates. Even if one or more of the product candidates 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 may also incur costs related to collaborating with certain diagnostic companies for the development, manufacturing and supply of diagnostic tools for biomarkers associated with our product candidates 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 and ZN-d5, 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, additional costs associated with operating as a public company, particularly now that we are no longer an emerging growth company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of June 30, 2023, we had cash and cash equivalents and marketable securities of $553.0 million. Based on current business plans, we believe that our existing cash, cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements into 2026, but will not be sufficient to fund all of the activities that are necessary to complete the development of our 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 such as COVID-19, U.S. and global economic issues, global supply chain disruptions, international political instability, rising inflation and interest rates 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 research-stage programs, 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 our lead product candidates, azenosertib and/or ZN-d5, which are currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize these product candidates 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 lead product candidates. We are investing significant efforts and financial resources in the research and development of our product candidates, which will require additional clinical development, evaluation of 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 other product candidate before we receive marketing approval from the FDA and/or comparable ex-U.S. regulatory authorities, and we may never receive such marketing approvals.

The success of our lead product candidates 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 our product candidates 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 comparable 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;
- if applicable, the availability or successful development of diagnostic tools for biomarkers associated with our product candidates or any other future product candidates;
- 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 our product candidates;
- 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 our product candidates if approved, including for supplies of drugs that we are testing in combination with our product candidates;
- 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 our product candidates, which would materially harm our business. If we do not receive marketing approvals for our 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 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 are collaborating with Pfizer on development of azenosertib, GSK on development of azenosertib and Dana Farber on development of azenosertib. Our likely collaborators in any future collaboration arrangements we may enter into 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 our research programs, our product candidates and any future research programs or product candidates we may develop pose the following risks to us:

- 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 good laboratory practice, or GLP, good clinical practice, or GCP, and current good manufacturing practice, or cGMP, or to secure approval for clinical development plans from the FDA or comparable 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 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.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond those we currently have in clinical development. 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 other comparable ex-U.S. regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our 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 other comparable 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 other comparable 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 none of our existing product candidates or 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 other comparable ex-U.S. regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or other comparable 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 other comparable 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 other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or other comparable ex-U.S. regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or other comparable 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 comparable ex-U.S. regulatory authority requires approval or clearance of a companion diagnostic for a particular product candidate, 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 other comparable 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 other comparable 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 draft guidance and launched programs aiming to reform and modernize the dose optimization procedures used by clinical trial sponsors during the development of oncology drugs. Although these efforts have not yet resulted in any formal changes to the FDA's regulations or policies, 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. The FDA has also issued a draft guidance regarding diversity in clinical trials. The purpose of this guidance is to provide recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan to enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States. If implemented, the FDA will evaluate the Race and Ethnicity Diversity Plan as an important part of the sponsor's development program. This could require us to change the way we enroll our planned clinical trials, 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 European Union, or EU, recently evolved. 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 Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, 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 to all member states concerned. 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 foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials, including those that are ongoing, will become 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, 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 our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA or other comparable ex-U.S. regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from the FDA or other comparable 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, may not be functionally validated in 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 comparable 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. 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, 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 comparable 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 clinical trial protocol;
- clinical sites deviating from 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 we are developing our product candidates, 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 comparable 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;
- 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.

In addition, disruptions caused by COVID-19 have caused and may continue to cause difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. 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 comparable ex-U.S. regulatory authorities. Such authorities may impose such a suspension or termination 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 comparable ex-U.S. regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, 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 may 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 may do for our product candidates, 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 comparable ex-U.S. regulatory authorities. The FDA or comparable 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 comparable 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 comparable 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.

If we are unable to successfully develop diagnostic tools for biomarkers that enable patient selection, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.

A component of our strategy may include the use of diagnostic tools to guide patient selection of our product candidates. In some cases, a diagnostic tool may be commercially available, for example, on a tumor-profiling panel. If not already commercially available, we may be required to seek collaborations with diagnostic companies for the development of diagnostics for biomarkers associated with our product candidates. We may have difficulty in establishing or maintaining such development relationships, and we will face competition from other companies in establishing these collaborations.

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.

If we, in collaboration with these parties, are unable to successfully develop diagnostic tools for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected. The development of certain diagnostic tools, such as companion diagnostics, require a significant investment of working capital 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.

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 we may not be able to obtain reimbursement for its use without obtaining regulatory approval.

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.

From time to time, 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.

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, our 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 our 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, the availability of diagnostic tools 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 product candidates 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;
- the availability of the approved product candidate for use as a combination therapy;
- 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 any of our product candidates 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 maintenance 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 our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or comparable 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; and
- 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.

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 enrollment of such patients in our clinical trials.

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

We are developing azenosertib and ZN-d5 in combination with one or more other approved or unapproved therapies to treat cancer or other diseases and may in the future develop 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 comparable ex-U.S. regulatory authorities outside of the United States 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 comparable 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.

We also may choose to evaluate our product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or comparable ex-U.S. regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our 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 comparable 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 any 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 our 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 cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. 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 any 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 our 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 treatment of conditions for which we may attempt to develop 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 will 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 other comparable 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 research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or 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 current and future research and development programs, therapeutic platforms and 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 may 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.

In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), 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 (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). For more information about the IRA and pricing regulations at the state level, see "Risks Related to Regulatory Approval and Other Legal Compliance Matters – We may face difficulties from changes to current regulations and future legislation." below.

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 our product candidates. 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 any future product candidates 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 our product candidates. 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 our product candidates.

Our product candidates 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 any 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 and often changes 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. 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 a NDA, 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.

Our current or 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 comparable 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 our 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 and chemotherapy 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 other comparable regulatory authorities or an IRB 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. 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 and not seen during clinical testing may also develop after such approval and 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 other comparable ex-U.S. regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA or other comparable ex-U.S. regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable 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 current GCP requirements; and iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. Furthermore, even where the ex-U.S. study data are not intended to serve as the sole basis for approval, 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 comparable ex-U.S. regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any comparable 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, marketing and 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 other comparable 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;
- 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 revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted 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 are 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.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and 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, 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.

Disruptions at the FDA and other agencies, such as the EMA, following its relocation to Amsterdam and resulting staff changes, 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 recent years, including in 2018 and 2019, the U.S. government 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 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.

Separately, in response to COVID-19, the FDA postponed most inspections of domestic and ex-U.S. manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the entities it regulates, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may have adopted similar restrictions and other policy measures in response to COVID-19.

If we are unable to obtain accelerated approval or any other form of expedited development or review from the FDA or comparable ex-U.S. regulatory authorities, we may be required to conduct additional preclinical studies or 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 may in the future seek accelerated approval or another form of expedited development or review for one or more of our 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 verity 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, in December 2022, the President signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, introduced reforms intended to expand the FDA's ability to regulate products receiving accelerated approval, including by increasing the FDA's oversight over the conduct of confirmatory trials; however, the ultimate impact of these reforms remains unclear.

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.

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 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 our product candidates, 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 other comparable 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 our product candidate 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.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We 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. 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.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures will impact our business. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

In addition, 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 eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

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 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. Most recently, on August 16, 2022, the IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), 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 (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. 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.

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.

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 Physician Payments Sunshine Act (renamed the Open Payments 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 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. Certain states have also adopted comparable privacy and security laws and regulations governing the privacy, processing and protection of personal information. For example, the State of California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023, and significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states, and are continuing to be proposed at the state and federal level, 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. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA 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 EU General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes strict

requirements for processing the personal data of individuals within the European Economic Area, or EEA. 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 or 4% of the annual global revenues of the noncompliant company, whichever is greater. 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. Case law from the Court of Justice of the European Union, or CJEU, states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism—alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. 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. Following a period of legal complexity and uncertainty regarding international personal data transfers, particularly to the United States, we expect the regulatory guidance and enforcement landscape to continue to develop, in relation to transfers to the United States and elsewhere. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Further, from January 1, 2021, we have had to comply with both the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in United Kingdom national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of £17.5 million or 4% of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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 are 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 involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot 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. Recently the SEC and the U.S. Department of Justice have 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 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 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.

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, 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 an internal sales or marketing team 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 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 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 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. 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 other comparable 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. Furthermore, certain of our employees, including members of our management team perform services on behalf of Kalyra Pharmaceuticals, Inc. pursuant to intercompany agreements. As a result, such individuals do not allocate all of their time and resources to us and our other subsidiaries which, coupled with the need to manage growth activities, could further limit their ability to devote a sufficient amount of attention to day-to-day activities of our business.

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 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.

Despite the implementation of security measures, our information systems and those of our current and any future CROs, CMOs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to attack, damage and interruption from computer viruses and malware (e.g., ransomware), malicious code, 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 COVID-19 and continued 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. 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.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to our trade secrets, personal information or other proprietary or sensitive information, it could result in a material disruption of our drug discovery and 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 or proprietary information, we could be exposed to litigation 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.

EU 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 intend to 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 interest rates 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, the current military conflict between Russia and Ukraine 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 U.S., 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.

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, such as COVID-19, and other natural and man-made disasters or events beyond our control. For example, as a result of COVID-19, we have experienced and we may continue to experience disruptions that could adversely impact our business, including our preclinical studies and clinical trials. 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 from a major tornado, flood, fire, earthquake, power loss, terrorist activity, public health crisis, pandemic diseases or other disasters and do not have a 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, 2022, we had available federal and state net operating loss carryforwards, or NOLs, of approximately $390.3 million and $192.4 million, respectively. $369.4 million of our federal NOLs were generated in taxable years beginning after December 31, 2017 and can be carried forward indefinitely, but may only be used to offset up to 80% of our taxable income in future periods. This limitation may require us to pay U.S. federal income taxes in future years despite generating federal NOLs in prior years. Our 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 2033 if not utilized. Our state NOLs begin to expire in 2033.

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 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 not conducted any studies to determine whether any such ownership changes have occurred or the annual limitations, if any, that could result from such ownership changes. Our ability to utilize our NOLs and certain other tax attributes could be limited by an ownership change as described above and consequently, 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 plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will 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 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, or the Dodd-Frank Act, the listing requirements of 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 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 additional 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, including new disclosure requirements surrounding cybersecurity risk and governance, 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 our lead product candidates 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 our lead product candidates 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 such product candidates. 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 our product candidates. 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, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. 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 may be exposed to fluctuations in the value of the local currency in the ex-U.S. countries. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in the ex-U.S. countries, including in China.

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 our 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 our 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 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 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 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. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; 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 do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license, including those 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, ZN-d5, and our BCL-xL product candidate.

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 may 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 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 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 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 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 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 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 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 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 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 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 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 license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors 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 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 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 licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical 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 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 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 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 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 our 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 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 any of our 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 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 our 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, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation 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 patent applications and the enforcement or defense of our 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.

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 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 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 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 our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our 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 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 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, 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 our 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 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 comparable 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 comparable 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 and CROs 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.

COVID-19 and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our preclinical studies and clinical trials.

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. 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 our product candidates for preclinical studies and our 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 our product candidates or drugs 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 our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our 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 our product candidates are sourced, in some cases, from a single-source supplier. We currently mitigate potential supply risks for azenosertib and ZN-d5, if any, through inventory management. If we were to experience an unexpected loss of supply of any of our product candidates 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 any of our 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 their manufacturing facilities. 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 a comparable 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, product recalls 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. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. 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 drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may continue to 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 would 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 comparable 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. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. 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 our competitors’ products;
- 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 COVID-19 and 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 our product candidates 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 any of our 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 June 30, 2023, 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. Moreover, holders of a substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also 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. For example, in August 2020, July 2021, May 2022 and June 2023, we completed underwritten public offerings of our common stock and in April 2022, we completed a direct offering of our common stock. 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 will be 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, or any subsequent testing by our independent registered public accounting firm, 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 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. Now that we are no longer an emerging growth company, our independent registered public accounting firm is required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. 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 may 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 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Director and Officer Trading Arrangements

On May 19, 2023, Melissa Epperly, the Company's Chief Financial Officer, terminated a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c), originally adopted on August 15, 2022, for the sale of up to 55,227 shares of the Company's common stock until August 15, 2023.

On June 6, 2023, Kevin Bunker, the Company's Chief Scientific Officer, terminated a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c), originally adopted on September 16, 2021 and modified on August 18, 2022 by Sundog Ranch, Inc. on behalf of the Bunker Family Protection Trust, the sole shareholder of Sundog Ranch, Inc., for the sale of up to 95,000 shares of the Company's common stock until July 31, 2023.

Item 6. Exhibits.

		Incorporated by Reference				
Exhibit Number	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed/Furnished Herewith**
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	Bylaws of Zentalis Pharmaceuticals, Inc.	8-K	001-39263	3.1	03/19/2021	
10.1†	Third Amended and Restated License Agreement, dated June 5, 2023, by and between Zeno Management, Inc. and Recurium IP Holdings, LLC					*
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).					*
31.2	Certification of Chief 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 Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
101.INS	Inline XBRL Instance Document					*

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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.

† Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

SIGNATURES

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

Zentalis Pharmaceuticals, Inc.

Date: August 9, 2023

By: /s/ Kimberly Blackwell, M.D.
Kimberly Blackwell, M.D.
Chief Executive Officer
(principal executive officer)

Date: August 9, 2023

By: /s/ Melissa B. Epperly
Melissa B. Epperly
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 10.1

Execution Version

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

THIRD AMENDED AND RESTATED LICENSE AGREEMENT

between

Recurium IP Holdings, LLC,

and

Zeno Management, Inc.

Dated: June 5, 2023

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[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

THIRD AMENDED AND RESTATED LICENSE AGREEMENT

THIS THIRD AMENDED AND RESTATED LICENSE AGREEMENT ("**Agreement**"), dated June 5, 2023 (the "**Amendment Date**") and made effective as of December 21, 2017 (the "**Effective Date**"), is by and between Recurium IP Holdings, LLC (f/k/a Zeno Royalties & Milestones, LLC), a Delaware Limited Liability Company ("**LICENSOR**"), and Zeno Management, Inc., a corporation organized and existing under the laws of Delaware ("**LICENSEE**"). LICENSOR and LICENSEE may, from time-to-time, be individually referred to as a "**Party**" and collectively referred to as the "**Parties**".

RECITALS

WHEREAS, Kalyra Pharmaceuticals, Inc. and Zeno Pharmaceuticals, Inc. entered into that certain License Agreement dated December 31, 2014 (the ("**Original License Agreement**");

WHEREAS, LICENSOR acquired the Original License Agreement and the Licensed Technology (hereinafter defined) pursuant to that certain Asset Purchase Agreement by and between LICENSOR and Kalyra Pharmaceuticals, Inc. dated as of December 21, 2017;

WHEREAS, Zeno Pharmaceuticals, Inc. assigned its rights and obligations under the Original License Agreement to ZIP Pharma, Inc., effective as of December 21, 2017;

WHEREAS, ZIP Pharma, Inc. and LICENSOR amended and restated the Original License Agreement in that certain Amended and Restated License Agreement, effective as of December 21, 2017 (the "**ARLA**");

WHEREAS, ZIP Pharma, Inc. merged into LICENSEE, effective as of September 3, 2019;

WHEREAS, LICENSEE and LICENSOR amended and restated the ARLA in its entirety pursuant to that certain Second Amended and Restated License Agreement, by and between LICENSOR and LICENSEE, dated September 6, 2019 and made effective as of December 21, 2017 (the "**Second ARLA**");

WHEREAS, LICENSEE entered into each of those certain Amended and Restated Sublicense Agreements with each of Zeno Alpha, Inc., Zeno Beta, Inc., K-Group Alpha, Inc. and K-Group Beta, Inc., each dated September 6, 2019, each as amended by that certain Greater China Amendment, dated as of May 19, 2020 (collectively, the "**Sublicense Agreements**");

WHEREAS, each of Zeno Alpha, Inc., K-Group Alpha, Inc. and K-Group Beta, Inc. entered into each of those certain Collaboration and License Agreements with Zentera Therapeutics ("**ZTCL**") and Zeno Beta, Inc. entered into that certain Option Agreement for a Collaboration and License with ZTCL, each dated as of May 19, 2020 (collectively, the "**Greater China Sublicense Agreements**");

WHEREAS, LICENSEE and ZTCL entered into that certain Option Agreement for Collaboration and License, dated as of May 19, 2020 (the "**Greater China Option Agreement**");

WHEREAS, LICENSOR, LICENSEE and ZTCL entered into that certain Greater China Amendment to the Second Amended and Restated License Agreement, dated as of May 19, 2020 (the "**Greater China Amendment**"), pursuant to which LICENSOR, LICENSEE and ZTCL amended certain payment terms in the Agreement with respect to milestone, royalty and sublicensing fee payments to be made with respect to activities in the People's Republic of China, Macau, Hong Kong, and Taiwan (collectively, "**Greater China**");

WHEREAS, LICENSEE and LICENSOR entered into that certain Compound Specific Patent Rights Amendment to the Second Amended and Restated License Agreement, dated March 17, 2022 (the

"**Compound Specific Amendment**") to further define the scope of licenses granted under the Second ARLA and clarify the consideration therefor and to transfer substantially all rights in the Compound Specific Patents to LICENSEE, subject to the terms in the Compound Specific Amendment; and

WHEREAS, LICENSEE and LICENSOR desire to amend and restate the Second ARLA as set forth below in order to more clearly reflect the original intent of the Parties to the Second ARLA (as amended by the Greater China Amendment and the Compound Specific Amendment).

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS

1.1 "**AAA**" is defined in Section 14.4.1.

1.2 "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity. For purposes of this Agreement, LICENSOR shall not be deemed an Affiliate of LICENSEE and LICENSEE shall not be deemed an Affiliate of LICENSOR.

1.3 "**Affiliated Sublicensee**" is defined in Section 2.2.1.

1.4 "**[***] Program Compound**" means any compound Covered by a Valid Claim of an **[***]** Program Patent or any compound that is an analog of [***].

1.5 "**[***] Program Patents**" means: (a) the patents and patent applications listed in Schedule D hereto; (b) all regular, divisional, continuation, substitution, continuation-in-part and continued prosecution applications that claim priority to those patents or patent applications described in subsection (a); (c) all patents that have issued or in the future issue from any of the foregoing patent applications in subsections (a) and (b), including utility, model and design patents, certificates of invention and applications for certificates of invention; (d) any reissues, renewals, extensions (including patent term extensions and supplemental certificates and the like), adjustments, re-examinations, revalidations, registrations and pediatric exclusivity periods of any of the foregoing; and (e) any foreign equivalents of any of the foregoing.

1.6 "**Applicable Laws**" means all applicable laws, statutes, rules, regulations and guidelines, including, without limitation, all good clinical practices, good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority.

1.7 "**Bankruptcy Code**" is defined in Section 12.3.

1.8 "**Bankruptcy Event**" is defined in Section 12.3.

1.9 "**Bioisosteres**" means substituent(s) (an atom or groups of bonded atoms) that (i) have physical or chemical properties similar to certain atoms within a compound and that (ii) when substituted into such compound, produce biological properties similar to such original compound.

1.10 "**Business Day**" means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York are authorized or required by law to remain closed.

1.11 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31, or portion thereof, during the Term.

1.12 "**Change in Control**" means (a) the acquisition of any voting securities of a Party by any Person other than an Affiliate of such Party, immediately after which such Person has "Beneficial Ownership" (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than fifty percent (50%) of (i) the then-outstanding shares or (ii) the combined voting power of the Party's then-outstanding voting securities, or (b) the sale to a Person other than an Affiliate of such Party of all or substantially all of the assets of such Party. Notwithstanding the foregoing, (1) a stock sale to underwriters of a public offering of a Party's capital stock or other Third Parties solely for the purpose of financing or a transaction solely to change the domicile of a Party or (2) a shift in the majority of the voting power of a Party as a resulting of a financing in which a Party issues convertible preferred shares or other securities to investors (including existing investors) in an arm's length transaction shall not constitute a Change in Control.

1.13 "**Claims**" is defined in Section 10.1.

1.14 "**Commencement**" when used with respect to a clinical trial, means the first dosing of the first subject for such trial.

1.15 "**Commercialize**" or "**Commercialization**" means any and all activities directed to commercialization, including to manufacture for sale (along with any and all activities directed to the manufacture, receipt, incoming inspections, storage, quality control and handling of raw materials and components and the manufacture, formulation, packaging, storage, handling, assembly, production, processing, labeling, testing, disposition, packaging and quality control of any Licensed Product, including manufacturing process development, scale-up and validation), market, promote, distribute, offer for sale and sell (as well as importing and exporting activities in connection therewith).

1.16 "**Commercially Reasonable Efforts**" means: (a) with respect to Development of a Licensed Product, the efforts and expenditures required to obtain Regulatory Approval that would be employed by [***]; and (b) with respect to Commercialization of a Licensed Product, the efforts and expenditures that would be employed by [***].

1.17 "**Competing Product**" means any product that contains the same active pharmaceutical ingredient as a Licensed Product and is approved for the same indication for which such Licensed Product is approved.

1.18 "**Compound Specific Amendment**" has the meaning given in the Recitals.

1.19 "**Compound Specific Improvements**" means any improvement, modification or enhancement to any Know-How that is (a) [***] a Program Compound and (b) Controlled by LICENSOR as of the Effective Date. For clarity and by way of example only, if LICENSOR conceived or reduced to practice [***].

1.20 "**Compound Specific Patent Abandonment Notice**" is defined in Section 6.4.4.

1.21 "**Compound Specific Patent Action**" is defined in Section 7.2.2.

1.22 "**Compound Specific Patents**" means: (a) (i) the patents and patent applications listed in Schedule B hereto, (ii) the [***] Program Patents, (iii) any patents and patent applications with claims Covering inventions within the Licensed Know-How, and (iv) any patents and patent applications with claims Covering any Compound Specific Improvements; (b) all regular, divisional, continuation, substitution, continuation-in-part and continued prosecution applications that claim priority to those patents

or patent applications described in subsection (a); (c) all patents that have issued or in the future issue from any of the foregoing patent applications in subsections (a) and (b), including utility, model and design patents, certificates of invention and applications for certificates of invention; (d) any reissues, renewals, extensions (including patent term extensions and supplemental certificates and the like), adjustments, re-examinations, revalidations, registrations and pediatric exclusivity periods of any of the foregoing; and (e) any foreign equivalents of any of the foregoing. Notwithstanding the foregoing, Compound Specific Patents shall exclude Platform Patents and Reagent Patents.

1.23 "**Confidential Information**" is defined in Section 8.1.

1.24 "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense under Intellectual Property Rights, as applicable, to the other Party pursuant to the terms of this Agreement without breaching an obligation to or other arrangement with a Third Party, having to provide a royalty to a Third Party, or infringing or misappropriating the rights of a Third Party. Notwithstanding the foregoing, upon a Change in Control of LICENSOR that results in LICENSOR being merged into a Third Party and/or all or substantially of LICENSOR's assets being assigned to a Third Party, the term Control shall be limited to only those Intellectual Property Rights that were Controlled by LICENSOR immediately prior to such Change of Control.

1.25 "**Cover**" or "**Covering**" means, with respect to a Patent or claim of a Patent and a product or compound, that the making, use, sale, offer for sale or importation of such product or compound would infringe such claim or Patent, but for the ownership of such Patent or the licenses granted under such Patent in this Agreement.

1.26 "**Deductions**" is defined in Section 1.70.

1.27 "**Designated Affiliate/Third Party**" is defined in Section 12.4.5(c).

1.28 "**Develop**" or "**Development**" means to conduct any and all research and development activities necessary to obtain Regulatory Approval.

1.29 "**Dispute**" is defined in Section 14.2.

1.30 "**Dispute Resolution Period**" is defined in Section 14.2.

1.31 "**Executive Officers**" means the Chief Executive Officer of each Party.

1.32 "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.33 "**Field**" means the Initial Field and, on a Licensed Product-by-Licensed Product basis, the Licensee Extended Field.

1.34 "**First Commercial Sale**" means the first Net Sale generated in an arms-length transaction in a country (or, with respect to Greater China, region) in the Territory.

1.35 "**Force Majeure Event**" is defined in Section 15.4.

1.36 "**GAAP**" means the generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board.

1.37 "**Government Official**" is defined in Section 9.2.2.

1.38 "**Greater China**" has the meaning given in the Recitals.

1.39 "**Greater China Amendment**" has the meaning given in the Recitals.

1.40 "**Greater China Milestone**" is defined in Section 4.1.1(b).

1.41 **Greater China Milestone Payment**" is defined in Section 4.1.1(b).

1.42 "**Greater China Option Agreement**" has the meaning given in the Recitals.

1.43 "**Greater China Sublicense Agreements**" has the meaning given in the Recitals.

1.44 "**Improvement**" means the Compound Specific Improvements and the Platform Improvements.

1.45 "**IND**" means (a) an investigational new drug application filed with the FDA for authorization for the investigation of a Licensed Product and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.46 "**Indemnitee**" is defined in Section 10.3.

1.47 "**Indemnifying Party**" is defined in Section 10.3.

1.48 "**Indication**" means an indication, disease or condition for which a particular medical treatment or procedure is medically advisable

1.49 "**Initial Field**" means any use in humans and/or animals for the treatment or prevention of any diseases, but specifically excluding any use in humans and/or animals for [***].

1.50 "**Intellectual Property Rights**" means all trade secrets, copyrights, patents and other patent rights, trademarks, service marks, moral rights, Know-How and any and all other intellectual property or proprietary rights (including, without limitation, applications relating thereto) in any inventions, compounds, techniques, or discoveries, whether or not patentable, now known or hereafter recognized in any jurisdiction.

1.51 "**Know-How**" means tangible and intangible information, techniques, technology, practices, inventions (whether patentable or not), methods, knowledge, know-how, trade secrets, data and results (including all biological, chemical, pharmacological, toxicological, clinical, analytical and quality control data and methods (including any applicable reference standards), manufacturing assay and related data, data and results relating to drug substance, drug product, starting materials, and radiolabeled compounds, know-how and trade secrets).

1.52 "**License**" is defined in Section 2.1.1.

1.53 "**Licensed Know-How**" means all Know-How Controlled by LICENSOR that relates to a Program Compound or that relates to the inventions and technology described in the Patent Rights, but excluding any Know-How to the extent claimed in any Patent Rights.

1.54 "**Licensed Product**" means any drug product which uses a compound as an active pharmaceutical ingredient, wherein such compound (a) is Covered by the Patent Rights; (b) is Developed using the Licensed Technology; or (c) is a Program Compound, provided that for any compound that is solely covered by this subsection (c) and that is Covered by a valid claim of an acquired or in-licensed (by

LICENSEE) patent or patent application from a Third Party, the use of such acquired or in-licensed compound in a drug product shall not in and of itself cause such drug product to be a Licensed Product. Furthermore, any drug product is excluded from Licensed Product if [***].

1.55 "**Licensed Technology**" means the Patent Rights and the Licensed Know-How.

1.56 "**Licensee Election Notice**" is defined in Section 2.1.2.

1.57 "**Licensee Extended Field**" is defined in Section 2.1.2.

1.58 "**Licensee Indemnitee(s)**" is defined in Section 10.2.

1.59 "**Licensee Inventory**" is defined in Section 12.4.5(c).

1.60 "**Licensee Withholding Tax Action**" is defined in Section 4.3.1.

1.61 "**Licensor Bioisostere**" means any and all (a) Bioisosteres Controlled by LICENSOR as of the Effective Date and (b) Platform Improvements Controlled by LICENSOR at any time on or after the Effective Date and prior to the expiration or termination of this Agreement or prior to a Change of Control.

1.62 "**Licensor Cap**" is defined in Section 11.2.

1.63 "**Licensor Election Notice**" is defined in Section 3.3.

1.64 "**Licensor Extended Field**" is defined in Section 3.3.

1.65 "**Licensor Extended Field Products**" means any Licensed Product Covered by the Platform Patents for which LICENSOR has properly provided the Licensor Election Notice pursuant to Section 3.3.

1.66 "**Migration Period**" is defined in Section 12.4.5(c).

1.67 "**Milestone**" is defined in Section 4.1.1.

1.68 "**Milestone Payment**" is defined in Section 4.1.1.

1.69 "**NDA**" means (a) a new drug application filed with the FDA for authorization for marketing a Licensed Product and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.70 "**Net Sales**" means, with respect to each Royalty & Milestone Product, the gross amount invoiced by or on behalf of LICENSEE, its Affiliates and their respective sublicensees for sales of such Royalty & Milestone Product (other than sales by LICENSEE, its Affiliates or sublicensees for subsequent resale in which case the final sale to the end user shall be used for calculation of Net Sales), less the following deductions if and to the extent they are included in the gross invoiced sales price of such Royalty & Milestone Product or otherwise directly incurred by LICENSEE, its Affiliates and their respective sublicensees with respect to the sale of such Royalty & Milestone Product: [***].

The following principles shall apply in the calculation of Net Sales:

1.70.1 [***].

1.70.2 [***].

1.70.3 Notwithstanding anything in this Agreement to the contrary, the transfer of Royalty & Milestone Products between or among LICENSEE, its Affiliates and sublicensees will not be considered a sale, provided, that in the event an Affiliate or sublicensee is the end-user of Royalty & Milestone Product, the transfer of Royalty & Milestone Products to such Affiliate or sublicensee shall be included in the calculation of Net Sales at [***] in the relevant period.

1.70.4 Unless otherwise specified herein, Net Sales shall be calculated in accordance with GAAP generally and consistently applied.

1.71 "**Patent Rights**" means the Compound Specific Patents and the Platform Patents.

1.72 "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.73 "**Phase I Clinical Trial**" means any human clinical trial of a Royalty & Milestone Product, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as described under 21 C.F.R. § 312.21(a) (as hereafter modified or amended) and any of its foreign equivalents.

1.74 "**Phase II Clinical Trial**" means any human clinical trial of a Royalty & Milestone Product conducted for purposes of preliminary determination of efficacy and/or preliminary establishment of appropriate dosage ranges for efficacy and safety in patients, as described under 21 C.F.R. § 312.21(b) (as hereafter modified or amended) and any of its foreign equivalents.

1.75 "**Phase III Clinical Trial**" means a clinical study of a Royalty & Milestone Product as described in 21 C.F.R. § 312.21(c) (as hereafter modified or amended) and any of its foreign equivalents.

1.76 "**Platform Improvement**" means any improvement, modification or enhancement to a [***].

1.77 **"Platform Patent Abandonment Notice"** is defined in Section 6.4.2.

1.78 "**Platform Patent Action**" is defined in Section 7.2.1.

1.79 "**Platform Patents**" means: (a) the patents and patent applications listed on Schedule A, hereto; (b) any patents and patent applications with claims Covering any Platform Improvements, but excluding the Reagent Patents; (c) all regular, divisional, continuation, substitution, continuation-in-part, and continued prosecution applications that claim priority to those patents or patent applications described in subsections (a) and (b); (d) all patents that have issued or in the future issue from any of the foregoing patent applications in subsections (a) - (c), including utility, model and design patents, certificates of invention and applications for certificates of invention; (e) any reissues, renewals, extensions (including patent term extensions and supplemental certificates and the like), adjustments, re-examinations, revalidations, registrations and pediatric exclusivity periods of any of the foregoing; and (f) any foreign equivalents of any of the foregoing.

1.80 "**PRC Sublicensee**" means [***] and/or one of its Affiliates.

1.81 "**Proceeding**" shall mean any action, arbitration, audit, hearing, investigation, litigation or suit (whether civil, criminal, administrative, investigative or informal) commenced, brought, conducted or heard by or before, or otherwise involving any governmental entity or arbitrator.

1.82 "**Product Family**" means one or more Royalty & Milestone Products which contain the same active compound(s) (or any isomers, salts, hydrates, solvates, amides, esters, metabolites, or prodrugs of the

active compound(s)) or contain lead compound(s) or backup compound(s) from a development program targeting the same biological target or cell receptor ligand, but irrespective of whether such Royalty & Milestone Products are marketed for the same indications, contain different dosage forms, proportions or formulations of such compound(s) or utilize different inactive ingredients. Notwithstanding the foregoing, a Royalty & Milestone Product based on a compound shall be deemed to be in a distinct Royalty & Milestone Product Family from a Royalty & Milestone Product based on the combination of the same relevant compound with any other active pharmaceutical ingredient. As such, then two distinct sets of milestone payments shall be potentially due under this Agreement, one for each of such two distinct Royalty & Milestone Products.

1.83 "**Program Compound**" means [***].

1.84 "**Proposed Terms**" is defined in Section 14.5.2.

1.85 "**Qualifying Clinical Trial**" is defined in Section 2.1.2.

1.86 "**Reagent Patents**" means: (a) the patents and patent applications listed in Schedule C hereto; (b) all regular, divisional, continuation, substitution, continuation-in-part and continued prosecution applications that claim priority to those patents or patent applications described in subsection (a); (c) all patents that have issued or in the future issue from any of the foregoing patent applications in subsections (a) and (b), including utility, model and design patents, certificates of invention and applications for certificates of invention; (d) any reissues, renewals, extensions (including patent term extensions and supplemental certificates and the like), adjustments, re-examinations, revalidations, registrations and pediatric exclusivity periods of any of the foregoing; and (e) any foreign equivalents of any of the foregoing.

1.87 "**Recipients**" is defined in Section 8.2.

1.88 "**Regulatory Approval**" means, with respect to a Licensed Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Regulatory Authority to market and sell such Licensed Product in such country or jurisdiction.

1.89 "**Regulatory Authority(ies)**" means, collectively, the entities in each country or jurisdiction in the Territory responsible for (i) granting Regulatory Approvals for a Licensed Product in the Territory or (ii) the establishment, maintenance and/or protection of rights related to the Patent Rights, or any other successor entities thereto.

1.90 "**Regulatory Filings**" means, with respect to a Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, NDA, any submission to a regulatory advisory board, any marketing authorization application, and any supplement or amendment thereto.

1.91 "**Relevant Records**" is defined in Section 5.1.

1.92 "**Royalties**" is defined in Section 4.1.2(a).

1.93 "**Royalty & Milestone Product**" means any Licensed Product that comprises or contains a Program Compound.

1.94 "**Royalty Percentage**" is defined in Section 4.1.2(a).

1.95 "**Royalty Term**" means, with respect to a Royalty & Milestone Product in each country (or, with respect to Greater China, region), the period commencing on the First Commercial Sale of such Royalty & Milestone Product in such country (or with respect to Greater China, region) and expiring upon [***].

1.96 "**Subcontractors**" is defined in Section 2.2.4.

1.97 "**Sublicense Agreements**" has the meaning given in the Recitals.

1.98 "**Support Memorandum**" is defined in Section 14.5.2.

1.99 "**Taxes**" is defined in Section 4.3.1.

1.100 "**Term**" is defined in Section 12.1.

1.101 "**Territory**" means worldwide.

1.102 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.103 "**Third Party Expert**" is defined in Section 14.5.1.

1.104 "**Use**" means to make, have made, use, sell, offer for sale and import.

1.105 "**Valid Claim**" means (a) a claim of an issued and unexpired patent included within the Patent Rights that (i) has not been revoked, declared unenforceable or unpatentable, or held invalid by a court or other governmental agency of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (ii) has not been admitted to be rendered invalid or unenforceable through reissue, disclaimer or otherwise, and (iii) has not been finally cancelled, withdrawn, abandoned, allowed to lapse, or rejected by any governmental agency of competent jurisdiction and (b) a pending application within the Licensed Patents, provided that such application has not been pending for more than [***] ([***]) [***] from the date the first action on the merits is received for such application and that has not been canceled, withdrawn, finally determined to be unallowable, or abandoned.

1.106 "**Zentalis**" means Zentalis Pharmaceuticals, Inc.

2. LICENSE GRANT

2.1 License Grant.

2.1.1 **Licensed Technology**. Subject to the terms and conditions of this Agreement, LICENSOR hereby grants to LICENSEE an exclusive (even as against LICENSOR and its Affiliates, except as provided in Sections 2.3 and 3.3), sublicensable (subject to Section 2.2) right and license under the Licensed Technology to Develop and Commercialize Licensed Products (except for any Licensor Extended Field Product) solely for Use within the Field and within the Territory (the "**License**").

2.1.2 **Licensee Rights Outside Initial Field**. If at any time after Commencement of the first Qualifying Clinical Trial for a Licensed Product in the Initial Field LICENSEE and/or its sublicensees desire to market and offer for sale such Licensed Product in any Indication outside the Initial Field, LICENSEE shall have the right and option to notify LICENSOR in writing (the "**Licensee Election Notice**") that LICENSEE and/or its sublicensees desires to Develop and Commercialize such Licensed Product in the Territory for Indications outside the Initial Field (the "**Licensee Extended Field**"). LICENSEE shall provide the structure of the Licensed Product in its Licensee Election Notice, but LICENSEE will not be required to identify which Indication(s)

outside the Initial Field such Licensed Product will be Developed in. If LICENSEE delivers a Licensee Election Notice then any Indication for which such Licensed Product is Developed or Commercialized shall automatically (without any requirement to amend this Agreement) be included in the Licensee Extended Field with respect to such Licensed Product, subject to all of the terms and conditions of this Agreement. For purposes of this Section 2.1.2, the term "**Qualifying Clinical Trial**" shall mean, on a Licensed Product-by-Licensed Product basis [***].

2.1.3 **Reagent License**. Subject to the terms and conditions of this Agreement, LICENSOR hereby grants to LICENSEE a non-exclusive right and license under the Reagent Patents to use compounds Covered by the Reagent Patents solely as reagents for the synthesis of Licensed Products solely for Use within the Field and within the Territory. LICENSEE shall have the right to sublicense the rights granted under this Section 2.1.3 solely to Affiliated Sublicensees. LICENSEE acknowledges and agrees that neither it nor any Affiliated Sublicensee shall use any compound Covered by the Reagent Patents or any simple derivative of such compound in any drug product.

2.2 Sublicense Rights.

2.2.1 LICENSEE shall have the right to sublicense the rights granted under the License in Section 2.1 to one or more of its Affiliates (each an "**Affiliated Sublicensee**"), provided that LICENSEE shall cause such Affiliated Sublicensees to comply with and be bound by those terms and conditions under this Agreement that by their terms are intended to obligate LICENSEE or its Affiliated Sublicensees. Notwithstanding the foregoing, LICENSEE shall remain responsible for complying with such applicable terms and conditions. A breach by any such Affiliated Sublicensee of any such obligation of LICENSEE shall constitute a breach by LICENSEE of this Agreement and shall entitle LICENSOR to exercise its rights hereunder, in addition to any other rights and remedies to which LICENSOR may be entitled.

2.2.2 LICENSEE shall also have the right to sublicense the rights granted under the License in Sections 2.1.1 and 2.1.2 to Third Parties subject to the following: LICENSEE shall provide LICENSOR with an executed copy thereof (provided that LICENSEE shall be permitted to redact confidential financial terms in such agreement) within [***] ([***]) [***] after execution thereof. Each sublicense shall contain covenants by the sublicensee for such sublicensee to observe and perform materially the same terms and conditions as those set out for LICENSEE in this Agreement to the extent applicable. In the event that LICENSEE becomes aware of a material breach of any such sublicense by the sublicensee, LICENSEE shall promptly notify LICENSOR of the particulars of same and use its Commercially Reasonable Efforts to enforce the terms of such sublicense. [***].

2.2.3 The terms of this Section 2.2 shall apply to each subsequent sublicensee or sub-sublicensee, as if same were LICENSEE's original sublicensee.

2.2.4 LICENSEE and its sublicensees shall have the right to utilize subcontractors, including service providers, manufacturers, clinical research organizations and distributors who are performing services on LICENSEE's and/or its sublicensee's behalf ("**Subcontractors**"). Any use of such Subcontractors shall not require the consent of LICENSOR nor shall such Subcontractors be deemed sublicensees for purposes of this Agreement, including this Section 2.2.

2.3 Retained Rights. LICENSOR reserves all rights with respect to Licensed Know-How, Patent Rights, Reagent Patents and other Intellectual Property Rights that are not specifically granted herein. Without limiting the foregoing, LICENSEE acknowledges and agrees that LICENSOR retains the right under the Licensed Technology (but excluding the Compound Specific Patents) to make, have made and use the Licensor Bioisosteres and/or Licensed Products for research purposes, to Develop and/or

Commercialize the Licensor Bioisosteres and/or Licensed Products outside the Field, and to Develop and/or Commercialize Licensor Extended Field Products in the Licensor Extended Field.

2.4 No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon LICENSEE by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of LICENSOR or its Affiliates other than the Licensed Technology.

2.5 Licensor Covenant. LICENSOR hereby acknowledges and agrees that it shall not license the Compound Specific Patents to any Third Party in any field during the Term.

2.6 Reimbursements. LICENSEE shall reimburse LICENSOR for all reasonable legal and other reasonable and documented costs and expenses incurred by LICENSOR in the administration of this contract within [***] ([***]) [***] of invoice therefor. Upon LICENSEE'S request, LICENSOR shall provide all documentation necessary for LICENSEE to verify such costs and expenses prior to being required to pay the same.

2.7 Paid Up Rights. All rights and licenses granted by LICENSOR to LICENSEE herein are royalty-free and paid-up during the Term of this Agreement, except with respect to Compound Specific Patents for which Milestone Payments, Greater China Milestone Payments, Royalties, and Sublicense Fees shall be payable as and to the extent set forth in Section 4.1.1, 4.1.2, and 4.1.3.

3. DEVELOPMENT AND COMMERCIALIZATION

3.1 Development. LICENSEE shall itself, or through its sublicensees, use Commercially Reasonable Efforts to Develop at least one (1) Royalty & Milestone Product in the Territory. In connection with its efforts to Develop Licensed Products, LICENSEE shall [***] for filing Regulatory Filings in LICENSEE's name and obtaining Regulatory Approval for such Products. LICENSEE shall, on an annual basis, provide LICENSOR with one or more Development plans detailing LICENSEE's plans to Develop Royalty & Milestone Products in the Territory for LICENSOR's review and comment. LICENSEE will use Commercially Reasonable Efforts to timely and diligently execute the activities under such development plans and shall provide to LICENSOR reports regarding LICENSEE's progress within [***] ([***]) [***] following the expiration of each Calendar Quarter.

3.2 Commercialization. LICENSEE shall itself, or through its sublicensees, use Commercially Reasonable Efforts to Commercialize [***] ([***]) [***] in the Territory.

3.3 Licensor's Rights In The Initial Field. If at any time after Commencement by LICENSOR (or its other licensees of any Platform Patent outside the Initial Field) [***] Licensed Product Covered by the Platform Patents outside the Initial Field LICENSOR and/or its other licensees desire to market and offer for sale such Licensed Product in any Indication inside the Initial Field, LICENSOR shall have the right and option to notify LICENSEE in writing (the "**Licensor Election Notice**") that LICENSOR and/or its licensees desires to Develop such Licensed Product in the Territory for Indications inside the Initial Field (the "**Licensor Extended Field**"). LICENSOR shall provide the structure of such Licensed Product in its Licensor Election Notice, but LICENSOR will not be required to identify which Indication(s) outside the Initial Field such Licensed Product will be Developed in. If LICENSOR delivers a Licensor Election Notice then any Indication for which such Licensed Product is Developed shall automatically (without any requirement to amend this Agreement) be included in the LICENSOR Extended Field with respect to such Licensed Product, subject to all of the terms and conditions of this Agreement. Nothing in this Section 3.3 shall give LICENSOR any rights under any Compound Specific Patent.

4. PAYMENT TERMS

4.1 Payment Terms.

4.1.1 **Milestone Payments**.

(a) LICENSEE shall notify LICENSOR as soon as practicable upon achievement of each milestone set forth in the applicable table below (each, a "**Milestone**"). In further consideration of the licenses to Compound Specific Patents granted to LICENSEE, within [***] ([***]) [***] upon achievement of each Milestone, subject to Section 4.1.1(c), LICENSEE shall pay to LICENSOR the amount corresponding to such Milestone in the table below, as a non-creditable and non-refundable milestone payment (each, a "**Milestone Payment**") as determined on a Product Family-by-Product Family basis:

MILESTONE	MILESTONE PAYMENT
(1) Upon Commencement of the first Phase II Clinical Trial in any country for a Royalty & Milestone Product in such Product Family*	[***]
(2) Upon Commencement of the first Phase III Clinical Trial in any country for a Royalty & Milestone Product in such Product Family*	[***]
(3) Upon the first NDA Filing Acceptance in any country for a Royalty & Milestone Product in such Product Family*	[***]
(4) Upon obtaining Regulatory Approval in any country for the first indication of a Royalty & Milestone Product in such Product Family*	[***]
(5) Upon obtaining Regulatory Approval in any country for each additional indication of a Royalty & Milestone Product in such Product Family**	[***]

*such Milestone shall only be payable once per Product Family.
**such Milestone shall only be payable once per each indication.

(b) For all Product Families sublicensed to ZTCL under the Greater China Sublicense Agreements or the Greater China Option Agreement, LICENSEE shall notify LICENSOR as soon as practicable upon achievement by ZTCL (or its sublicensee) of each milestone set forth in the table below (each, a "**Greater China Milestone**"). In further consideration of the licenses and rights granted to LICENSEE, within [***] ([***]) [***] of achievement of each Greater China Milestone, subject to Section 4.1.1(c), LICENSEE shall pay to LICENSOR the amount corresponding to such Greater China Milestone in the table below, as a creditable and non-refundable milestone payment (each, a "**Greater China Milestone Payment**") as determined on a Product Family-by-Product Family basis:

MILESTONE	MILESTONE PAYMENT
(1) Upon Commencement of the first Phase II Clinical Trial in Greater China for a Royalty & Milestone Product in such Product Family*	[***]
(2) Upon Commencement of the first Phase III Clinical Trial in Greater China for a Royalty & Milestone Product in such Product Family*	[***]
(3) Upon the first NDA Filing Acceptance in Greater China for a Royalty & Milestone Product in such Product Family*	[***]
(4) Upon obtaining Regulatory Approval in Greater China for the first indication of a Royalty & Milestone Product in such Product Family*	[***]
(5) Upon obtaining Regulatory Approval in Greater China for each additional indication of a Royalty & Milestone Product in such Product Family**	[***]

*such Greater China Milestone shall only be payable once per Product Family.
**such Greater China Milestone shall only be payable once per each indication.

(c) For any Product Family that is sublicensed to ZTCL under the Greater China Sublicense Agreements or the Greater China Option Agreement, if (i) a Milestone under Section 4.1.1(a) is achieved in the Territory outside of Greater China before it is achieved in Greater China, the corresponding Milestone Payment in Section 4.1.1(a) shall be due to LICENSOR and, if and when the corresponding Greater China Milestone under Section 4.1.1(b) is achieved, no Greater China Milestone Payment shall be due to LICENSOR; and (ii) a Greater China Milestone under Section 4.1.1(b) is achieved in Greater China before the corresponding Milestone under Section 4.1.1(a) is achieved in the Territory outside of Greater China, the Greater China Milestone Payment in Section 4.1.1(b) shall be due to LICENSOR and, if and when the corresponding Milestone under Section 4.1.1(a) is achieved in the Territory outside of Greater China, the corresponding Milestone Payment due to LICENSOR under Section 4.1.1(a) shall be due as set forth therein, provided that such Milestone Payment shall be reduced by the amount previously paid for the corresponding Greater China Milestone Payment under Section 4.1.1(b).

(d) LICENSEE shall also pay to LICENSOR Milestone Payments upon obtaining Regulatory Approval for indications of a Royalty & Milestone Product in a Product Family for use in animals as set forth below.

MILESTONE	MILESTONE PAYMENT
(1) Upon Regulatory Approval for the first indication of a Royalty & Milestone Product in a Product Family*	[***]
(2) Upon Regulatory Approval for the second and each subsequent indication of a Royalty & Milestone Product in a Product Family**	[***]

*such Milestone shall only be payable once per Product Family.
**such Milestone shall only be payable once per each indication.

(e) For the avoidance of doubt and notwithstanding anything to the contrary herein: (i) no Milestone Payment shall be due to LICENSOR in connection with any Milestone (other than a Greater China Milestone) resulting from the Development and/or Regulatory Approval of a Royalty & Milestone Product in a country in the Territory which has been exclusively licensed to the PRC Sublicensee; (ii) payment of a Milestone or Greater China Milestone by a sublicensee, assignee or other transferee of, or Third Party retained by, LICENSEE shall be deemed to have been satisfied by LICENSEE for purposes of this Section 4.1.1; and (iii) if a clinical trial is designed to accomplish the end point of both a Phase II Clinical Trial and a Phase III Clinical Trial, then (A) the Milestone Payment or Greater China Milestone Payment under (1) in the applicable table in Section 4.1.1(a) or Section 4.1.1(b) above for Commencement of the Phase II Clinical Trial will only be due at the Commencement of such combined trial and (B) the Milestone Payment or Greater China Milestone under (2) in the applicable table in Section 4.1.1(a) or Section 4.1.1(b) above, for Commencement of the Phase III Clinical Trial will only be due upon the filing for Regulatory Approval of a Royalty & Milestone Product in the applicable country (or, with respect to Greater China, region) or at the commencement of the necessary subsequent trial required to file, whichever comes first. For the sake of clarity, in the case of (B) in the preceding sentence, LICENSEE must also pay the Milestone Payment or Greater China Milestone Payment due under (3) above, when due.

4.1.2 **Royalty Payments**.

(a) **Royalties**. In consideration of the licenses to Compound Specific Patents, LICENSEE shall pay to LICENSOR a royalty equal to the Royalty Percentage of Net Sales of each Royalty & Milestone Product in the Territory (including, with respect to rights to Product Families sublicensed to ZTCL under the Greater China Sublicense Agreements and Greater China Option Agreement, sales thereof by ZTCL and its sublicensees) during the Royalty Term (collectively, "**Royalties**"). As used herein, "**Royalty Percentage**" means [***] ([***]) [***]. Notwithstanding the prior two sentences, for any royalty payment that the PRC Sublicensee shall provide for, LICENSEE shall only be required to pay to LICENSOR Royalties equal to [***] of the royalty payment actually owed by the PRC Sublicensee to LICENSEE. For the avoidance of doubt, the Royalty Percentage during the Royalty Term is a blended rate that reflects the value of all the rights in Compound Specific Patents granted to LICENSEE

under this Agreement, and is used for the convenience of the Parties to avoid having different rates based on whether particular Royalty & Milestone Products are Covered by a Valid Claim of a Patent Controlled by LICENSOR.

(b) **Quarterly Payments**. LICENSEE shall pay to LICENSOR the applicable Royalties within [***] ([***]) [***] following the expiration of each Calendar Quarter after the date of the First Commercial Sale. Royalties will be payable on a country-by-country (or, with respect to Greater China, region-by-region), Royalty & Milestone Product-by-Royalty & Milestone Product, basis commencing as of the First Commercial Sale of a Royalty & Milestone Product in each country (or, with respect to Greater China, region) until the expiration of the Royalty Term for such Royalty & Milestone Product in each country (or, with respect to Greater China, region).

(c) **Reports**. All payments of Royalties shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation of Net Sales of Royalty & Milestone Product (including all Deductions) and all Royalties payable to LICENSOR for the applicable Calendar Quarter (including any foreign exchange rates employed)

(d) **Anti-Stacking**. Royalties may be reduced with respect to Net Sales in a particular country (or, with respect to Greater China, region) by deducting [***] ([***]) of any and all royalties paid by LICENSEE, its Affiliates and/or sublicensees to any Third Party for the Royalty & Milestone Product in such country (or, with respect to Greater China, region), up to a maximum reduction of [***] ([***]) in the aggregate of the Royalties owing for Net Sales in such country (or, with respect to Greater China, region) for: (i) any license that LICENSEE or its Affiliates or their sublicensees determines in good faith would be prudent to obtain given the potential to resolve or avoid any claims that any Royalty & Milestone Product infringes or misappropriates the Intellectual Property Rights of any Third Party in such country (or, with respect to Greater China, region); (ii) any final, unappealed judgment awarded against LICENSEE, its Affiliates or sublicensees for damages for infringement of Third Party Intellectual Property Rights with respect to Use of a Royalty & Milestone Product in such country (or, with respect to Greater China, region); or (iii) any license for technology that is necessary to Develop or Commercialize a Royalty & Milestone Product in such country (or, with respect to Greater China, region). LICENSEE shall use Commercially Reasonable Efforts to minimize any such royalties or other payments to Third Parties on account of sales of Royalty & Milestone Products hereunder.

(e) **Combination Products**. In the event that a Royalty & Milestone Product is Commercialized in combination with one or more products which are themselves not Royalty & Milestone Products under this Agreement for a single price, the Net Sales for such Royalty & Milestone Product shall be calculated by [***]. If the fair market value for any product sold in combination with a Royalty & Milestone Product cannot be reasonably determined, the price attributed to such product will be based on [***], as determined in accordance with GAAP. In addition, in the event that a Royalty & Milestone Product is sold with any other product(s) or if any giveaways, discounts, rebates or charge-backs (whether as part of a customer loyalty, bundling or “loss leader” program, or otherwise) are provided for a Royalty & Milestone Product to promote or sell

other products or otherwise, the Net Sales for such Royalty & Milestone Product shall be [***].

4.1.3 **Sublicense Fees**. In consideration of the licenses to Compound Specific Patents granted to LICENSEE hereunder, LICENSEE shall pay to LICENSOR [***] ([***]) of all Third Party Fees payable from any of LICENSEE's and/or Affiliates' sublicensees, assignees and other transferees (including without limitation the PRC Sublicensee but excluding any sublicensee, assignee or transferee that is an Affiliate of LICENSEE immediately following the applicable sublicense, assignment or transfer) (the "**Sublicense Fees**") as set forth below. As used herein, "**Third Party Fees**" means any and all consideration in any form provided by sublicensees, assignees and other transferees (including without limitation the PRC Sublicensee) hereunder for rights under the Licensed Technology related to the Royalty & Milestone Products, excluding: (a) royalties (which shall be subject to Section 4.1.2 above); (b) reimbursement of actual research and Development expenses for Royalty & Milestone Product; (c) manufacturing costs for the Royalty & Milestone Product; (d) payments for prosecution, enforcement or maintenance of any Licensed Technology; (e) milestone payments which are less than the Milestone Payments due to LICENSOR hereunder, if for achievement of the same Milestone event; and (f) any consideration received in connection with a Change in Control of LICENSEE and/or its Affiliates. LICENSEE shall pay all Sublicense Fees received during each Calendar Quarter within [***] ([***]) [***] following the expiration of each such Calendar Quarter. All payments shall be accompanied by a report that includes a calculation of all Sublicense Fees payable to LICENSOR for the applicable Calendar Quarter. For clarity, all Sublicense Fees due under this Agreement resulting from activity concerning each and every sublicensee, assignee and transferee of LICENSEE and/or its Affiliates anywhere in the Territory, including the sublicensees pursuant to the Greater China Sublicense Agreements, shall be determined pursuant to this Section 4.1.3.

4.1.4 **Downstream Sublicense Fee Disputes**. LICENSOR hereby acknowledges and agrees that, in the event that a dispute arises concerning Sublicense Fees under

(a) any Sublicense Agreements, it acknowledges and agrees that to the extent it participates in any such dispute brought pursuant to Section 14.5 of the applicable Sublicense Agreements, (i) it will comply with the provisions of Sections 14.5 and 14.6 of the applicable Sublicense Agreement and (ii) it will be bound by any binding baseball arbitration proceeding brought pursuant to Section 14.5 of the applicable Sublicense Agreement; or

(b) any of the Greater China Sublicense Agreements or the Greater China Option Agreement, it acknowledges and agrees that to the extent it participates in any such dispute brought pursuant to Section 16.5 of the applicable Greater China Sublicense Agreements or the Greater China Option Agreement, (i) it will comply with the provisions of Sections 16.5 and 16.6 of the applicable agreement and (ii) it will be bound by any binding baseball arbitration proceeding brought pursuant to Section 16.5 of the applicable Greater China Sublicense Agreements or the Greater China Option Agreement.

4.1.5 **Other Payments**. LICENSEE shall pay to LICENSOR any other amounts due under this Agreement within [***] ([***]) [***] following receipt of invoice.

4.1.6 **Late Payments**. In the event that any payments due hereunder are not made when due, each such payment shall accrue interest from the date due until paid at [***], plus [***] ([***]). The payment of such interest shall not limit or otherwise be deemed to be in satisfaction of LICENSOR exercising any other rights it may have under this Agreement arising from LICENSEE's failure to make such payment when due.

4.1.7 **After Royalty Term**. After the expiration of the Royalty Term in any relevant country (or, with respect to Greater China, region) for a Royalty & Milestone Product, LICENSEE shall not have any further obligation under this Agreement to pay royalties to LICENSOR in such country or region for such Royalty & Milestone Product.

4.2 Payment Method.

4.2.1 Any payments that are recorded in currencies other than the US Dollar shall be converted into US Dollars at the average of the daily foreign exchange rates published in the Wall Street Journal, Western Edition (or any other qualified source that is acceptable to both Parties) for the Calendar Quarter in which such payments or expenses occurred, or for periods less than a Calendar Quarter, the average of the daily rates published in the Wall Street Journal, Western Edition for such period.

4.2.2 All payments from LICENSEE to LICENSOR shall be made by wire transfer in US Dollars to the credit of such bank account as may be designated by LICENSOR in writing to LICENSEE. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

4.3 Taxes.

4.3.1 It is understood and agreed between the Parties that any amounts payable by LICENSEE to LICENSOR hereunder are exclusive of any and all applicable sales, use, VAT, GST, excise, property, and other taxes, levies, duties or fees (collectively, "**Taxes**"), which shall be added thereon as applicable. LICENSEE shall be responsible for billing and collection from its customers and remitting to the appropriate taxing authority any and all Taxes which it is required to collect or remit. Each Party will be responsible for their own income and property taxes. If LICENSEE is required to make a payment to LICENSOR subject to a deduction of tax or withholding tax, (i) if such withholding or deduction obligation arises as a direct result of any failure on the part of LICENSEE to comply with applicable tax laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a "**LICENSEE Withholding Tax Action**"), then the sum payable by LICENSEE (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that LICENSOR receives a sum equal to the sum which it would have received had no such LICENSEE Withholding Tax Action occurred, (ii) otherwise, the sum payable by LICENSEE (in respect of which such deduction or withholding is required to be made) shall be made to LICENSOR after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable law.

4.3.2 To the extent LICENSEE is required to deduct and withhold taxes on any payments to LICENSOR, LICENSEE shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to LICENSOR an official tax certificate or other evidence of such withholding sufficient to enable LICENSOR to claim such payments of taxes. LICENSOR shall provide to LICENSEE any tax forms that may be reasonably necessary in order for LICENSEE not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

4.3.3 The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made by LICENSEE to LICENSOR under this Agreement.

5. RECORDS; AUDIT RIGHTS

5.1 Relevant Records. LICENSEE shall maintain accurate financial books and records pertaining to the sublicensing of the Licensed Technology pursuant to Section 2.2 and LICENSEE's sale of each Royalty & Milestone Product, including any and all calculations of the applicable Fees (collectively, "**Relevant Records**"). LICENSEE shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) [***] ([***]) [***] following expiration or termination of this Agreement.

5.2 Audit Request. LICENSOR shall have the right during the Term and for [***] ([***]) [***] thereafter to engage, at its own expense, an independent auditor reasonably acceptable to LICENSEE to examine the Relevant Records from time-to-time, but no more frequently than [***] ([***]) [***], as may be necessary to verify compliance with the terms of this Agreement. Such audit shall be requested in writing at least [***] ([***]) [***] in advance, and shall be conducted during LICENSEE's normal business hours and otherwise in manner that minimizes any interference to LICENSEE's business operations.

5.3 Audit Fees and Expenses. LICENSOR shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment of LICENSEE of more than [***] ([***]) as to the period subject to the audit, LICENSEE shall reimburse LICENSOR for any reasonable and documented out-of-pocket costs and expenses of the audit within [***] ([***]) [***] after receiving invoices thereof.

5.4 Payment of Deficiency. If any audit establishes that LICENSEE underpaid any amounts due to LICENSOR under this Agreement, then LICENSEE shall pay LICENSOR any such deficiency within [***] ([***]) [***] after receipt of written notice thereof unless it disputes the results of such audit in accordance with Section 14 (Dispute Resolution) of this Agreement. For the avoidance of doubt, such payment will be considered a late payment, subject to Section 4.1.6. If any audit establishes that LICENSEE overpaid any amounts due to LICENSOR under this Agreement, then LICENSEE shall be credited any such overpayment against future Royalties.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 Pre-existing IP. Each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to the Effective Date or independent of this Agreement.

6.2 Inventions. Inventorship of inventions conceived or reduced to practice in the course of research and other Development activities under this Agreement shall be determined by application of United States patent laws pertaining to inventorship. Subject to Section 6.3, if such inventions are jointly invented in the course of such Development activities by or on behalf of both Parties, such inventions shall be jointly owned ("**Joint Invention**"), and if one or more claims included in an issued patent or pending patent application which is filed in a patent office in the Territory claim such Joint Invention, such patent or patent application shall be jointly owned. Subject to Section 6.3, if such an invention is solely invented by or on behalf of a Party, such invention shall be solely owned by such Party, and any patent filed claiming such solely owned invention shall also be solely owned by such Party.

6.3 Improvements. Notwithstanding Section 6.2, any Improvement conceived or reduced to practice by or on behalf of LICENSEE and/or any sublicensee on or after [***] and prior to the earlier of [***], shall be owned exclusively by LICENSOR, and LICENSEE hereby assigns all right, title and interest to any such Improvement (including all rights to sue for infringement, including past infringement) to LICENSOR. LICENSEE shall disclose any such Improvement to LICENSOR in writing within [***] ([***]) [***] after its actual or constructive reduction to practice. LICENSEE hereby agrees to sign all

necessary papers and do all lawful acts reasonably requisite in connection with the prosecution, assignment and enforcement of each and every patent application related to any Improvement, without further compensation, but at the expense of LICENSOR or its successors and assigns.

6.4 Patent Prosecution.

6.4.1 **Platform Patents**. Except as set forth in subsection (b) below, LICENSOR has the first right but not the obligation to conduct, control and pay for the prosecution, maintenance, challenges against validity and unenforceability or patentability with respect to the Platform Patents in the Territory. At LICENSOR's reasonable request, LICENSEE shall reasonably cooperate with and assist LICENSOR in connection with such activities. As between the Parties, LICENSEE shall be responsible for the cost of the prosecution and maintenance of the Platform Patents.

6.4.2 **Failure to Prosecute or Maintain Platform Patents**. In the event that LICENSOR elects to forgo the prosecution or maintenance of any of the Platform Patents, LICENSOR shall notify LICENSEE of such election at least [***] ([***]) [***] prior to any filing or payment due date, or any other due date that requires action ("**Platform Patent Abandonment Notice**"). Upon receipt of a Platform Patent Abandonment Notice, LICENSEE shall have the right, but not the obligation, upon written notice to LICENSOR, at its sole discretion and expense, to file or to continue the prosecution or maintenance of such Platform Patent in such country in LICENSOR's name and on LICENSOR's behalf using counsel of its own choice and at its own expense.

6.4.3 **Compound Specific Patents**. Except as set forth in subsection (d) below, LICENSEE has the first right, but not the obligation, to conduct and control the prosecution, maintenance, and challenges against validity and unenforceability or patentability in LICENSOR'S name before any patent office or other equivalent intellectual property regulatory authority with respect to the Compound Specific Patents, provided that LICENSEE pays the costs and expenses in connection with the same.

6.4.4 **Failure to Prosecute or Maintain Compound Specific Patents**. In the event that LICENSEE elects to forgo the prosecution or maintenance of any of the Compound Specific Patents, LICENSEE shall notify LICENSOR of such election at least [***] ([***]) [***] prior to any filing or payment due date, or any other due date that requires action ("**Compound Specific Patent Abandonment Notice**"). Upon receipt of an Compound Specific Patent Abandonment Notice, LICENSOR (or a licensee of the Platform Patents designated by LICENSOR) shall have the right, but not the obligation, upon written notice to LICENSEE, at its sole discretion and expense, to file or to continue the prosecution or maintenance of such Compound Specific Patent in such country in LICENSOR'S name and on LICENSEE'S behalf using counsel of its own choice and at its own expense.

6.4.5 **Information Rights**. The Party which is then responsible for prosecuting and maintaining a Patent Right in the Territory shall: (a) keep the other Party reasonably informed as to the status of such Patent Right in the Territory; (b) consider in good faith the reasonable requests, suggestions and advice of the other Party with respect to the prosecution, maintenance and defense of such Patent Right in the Territory; and (c) promptly provide the other Party with copies of correspondence and materials received from or filed with any Regulatory Authority within the Territory related to the Patent Rights.

6.4.6 **Patent Term Extension**. If election with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country with respect to a Licensed Product becomes available, upon Regulatory Approval or otherwise, the Parties will discuss in good faith which of the Patent Rights, if any, will be extended. LICENSEE will have final

decision making authority for which of the Patent Rights, if any, to extend, provided that LICENSOR will have the right to prevent a Platform Patent from being subject to such extension.

6.4.7 **Reagent Patents**. For clarity, the Section 6.4 shall not be deemed to apply to the Reagent Patents, for which LICENSOR retains sole rights.

7. INFRINGEMENT; MISAPPROPRIATION

7.1 Notification. Each Party will promptly notify the other Party in writing of any actual, suspected or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Technology in the Field and in the Territory of which it becomes aware.

7.2 Enforcement Action.

7.2.1 **Enforcement of Platform Patents**. LICENSEE or any of its sublicensees shall have the first right, but not the obligation, using counsel of its choice, to enforce the Platform Patents against any actual or suspected infringement of the Platform Patents with respect to the Development or Commercialization of a Competing Product in the Field and Territory by a Third Party or defend any declaratory action with respect thereto brought by such Third Party (a "**Platform Patent Action**"), at its expense, and LICENSOR shall provide all reasonable assistance to LICENSEE in such Platform Patent Action, including joining, at LICENSEE's reasonable expense, such Platform Patent Action if necessary to maintain the Platform Patent Action, or to seek additional or alternative damages or injunctive relief under such Platform Patent Action. Notwithstanding anything to the contrary herein, neither LICENSEE nor any of its sublicensees shall, without the prior written consent of LICENSOR, enter into any settlement that would: (i) adversely affect the validity, enforceability or scope of any of the Platform Patents anywhere in the world; (ii) give rise to liability of LICENSOR or its Affiliates; or (iii) otherwise impair LICENSOR'S rights in the Platform Patents or under this Agreement.

7.2.2 **Enforcement of Compound Specific Patents**. LICENSEE shall have the sole right, but not the obligation, using counsel of its choice, to enforce the Compound Specific Patents or defend any declaratory action with respect thereto in the Field in the Territory (an "**Compound Specific Patent Action**"), at its expense, and LICENSOR shall provide all reasonable assistance to LICENSEE in such Compound Specific Patent Action, including joining, at LICENSEE'S reasonable expense, if necessary to maintain the Compound Specific Patent Action, or to seek additional or alternative damages or injunctive relief under such Compound Specific Patent Action.

7.2.3 **Recoveries**. Any recovery received as a result of any Platform Patent Action shall be used first to reimburse the Parties for their costs and expenses (including attorneys' and professional fees) incurred in connection with such action (and not previously reimbursed), and any remaining amount of such recovery shall be awarded to [***] unless otherwise agreed by the Parties. Any recovery received as a result of any Compound Specific Patent Action shall be used first to reimburse the Parties for their costs and expenses (including attorneys' and professional fees) incurred in connection with such action (and not previously reimbursed), and any remaining amount of such recovery shall be awarded to [***].

7.2.4 **Reagent Patents**. For clarity, this Section 7.2 shall not be deemed to apply to the Reagent Patents, for which LICENSOR retains sole rights.

7.3 Infringement Claimed by Third Parties.

7.3.1 In the event a Third Party commences, or threatens to commence, any Proceeding against a Party to this Agreement alleging infringement of a Third Party's Intellectual Property Rights by the use, sale, offer for sale, export and/or import by LICENSEE, its Affiliates or sublicensees of the Licensed Product, the Party against whom such Proceeding is threatened or commenced shall give prompt notice to the other Party.

7.3.2 Except to the extent LICENSEE seeks indemnification under Section 10.2, LICENSEE shall control the defense and settlement of any such Proceeding under this Section 7.3 at its own Cost and shall pay and indemnify LICENSOR from and against any and all damages and Costs awarded to such Third Party; provided that, in the event that the validity and enforceability of the claims of Platform Patents are in issue in any such Proceeding under this Section 7.3, LICENSOR may (but shall have no obligation to do so) control the defense and settlement of any such Proceeding at its own Cost solely to the extent that such defense and settlement relates to validity and enforceability of the claims of the Platform Patents.

8. CONFIDENTIALITY

8.1 Definition. "**Confidential Information**" means all types of financial, business, scientific, technical (including but not limited to information concerning Bioisosteres, biological materials, gene or protein sequences, antibodies, antigens, cell lines, compounds, assays or test results), economic or engineering information, including without limitation, business strategies, business forecasts, product development plans, promotional and marketing objectives, results of operations, customer lists, supplier lists, patent disclosures, unpublished patent applications, Know-How, trade secrets, compilations, ideas, inventions, discoveries, techniques, methods, processes, procedures, formulae, designs, patterns, drawings, schematics, plans, configurations, specifications, data sheets, mock-ups, models, compounds, compositions, structures, prototypes, clinical trial protocols, clinical data and analysis, formulae, software programs, source documents, programs, code, materials, equipment, samples, test results, opinions, data, analysis and other proprietary information, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing, which is disclosed by one Party to the other Party hereunder or obtained by a Party through observation or examination of the other Party's facilities, information and/or materials (such observation or examination hereinafter also referred to as "disclosure" for purposes of this Agreement).

8.2 Obligations. The receiving Party shall protect all the disclosing Party's Confidential Information against unauthorized disclosure to Third Parties with the same degree of care as the receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The receiving Party may disclose the disclosing Party's Confidential Information to its Affiliates, and their respective directors, officers, employees, Subcontractors, sublicensees, consultants, attorneys, accountants, acquirers, merger partners, banks and investors and other potential sources of funding or evaluating an actual or potential investment or acquisition, and in the case of LICENSOR as the receiving Party to an actual or prospective assignee of LICENSOR's rights to receive some or all of the Fees payable hereunder (collectively, "**Recipients**") who have a need-to-know such information for purposes related to this Agreement or for due diligence purposes, but only to the extent necessary to fulfill such purpose, provided that the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

8.3 Exceptions.

8.3.1 The obligations under this Section 8 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the disclosure thereof by or on behalf of the disclosing Party;

(c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates outside of this Agreement, as evidenced by its written records, without use of the Confidential Information.

8.3.2 The receiving Party may disclose the disclosing Party's Confidential Information if required to do so under Applicable Laws or a court order or other governmental order, provided that the receiving Party (to the extent allowed by the Applicable Law): (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted; (b) affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure; and (c) if the disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel. In the event of a limited disclosure of the disclosing Party's Confidential Information that is required by law or regulation, the receiving Party shall continue to treat such disclosed information as the disclosing Party's Confidential Information for all other purposes and subject to the other terms and conditions of this Agreement.

8.4 **Right to Injunctive Relief**. LICENSEE agrees that breaches of this Section 8 may cause irreparable harm to LICENSOR and shall entitle LICENSOR, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

8.5 **Ongoing Obligation for Confidentiality**. Except to the extent necessary for LICENSEE to practice or enjoy the rights granted to LICENSEE under Section 12.4.1, upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one (1) copy which may be retained in its confidential files for archive purposes.

8.6 **Publicity Review**. Subject to this Section 8.6, the Parties shall jointly discuss and must mutually agree, based on the principles of this Section 8.6, on any statement to the public regarding this Agreement, subject in each case to disclosure otherwise required by Applicable Laws or the rules of any applicable securities exchange. When a Party elects to make any such statement or disclosure required under Applicable Law, it will give the other Party at least [***] ([***]) [***] notice to review and approve such statement, unless the applicable Regulatory Authority requires disclosure such that a Party is prohibited by Applicable Law to provide such advance review by the other Party (in which case it shall be disclosed according to such requirement and notice will be provided as soon as possible). Notwithstanding anything in this Section 8.6 to the contrary, the terms of this Agreement may be disclosed to Regulatory Authorities, including the United States Securities and Exchange Commission or any other exchange or securities commission having authority over a Party, where required by and in accordance with Applicable Law with redaction of financial information not otherwise required to be disclosed under Applicable Laws, in the reasonable judgment of the Party subject to such disclosure requirement, in which event the

disclosing Party shall provide in advance of submission to the other Party for review and comment a copy of such redactions made to this Agreement.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Representations, Warranties and Covenants by Each Party. Each Party represents, warrants and covenants to the other Party as of the Effective Date that:

9.1.1 it is a company duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

9.1.2 it has full power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

9.1.3 this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

9.1.4 all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

9.1.5 the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any agreement to which it is a Party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

9.2 Additional Representations, Warranties and Covenants by LICENSEE.

9.2.1 LICENSEE represents and warrants to LICENSOR that it shall comply with all Applicable Law with respect to the performance of rights and its obligations hereunder; and

9.2.2 Without limiting the generality of Section 9.2.1, LICENSEE shall comply with the U.S. Foreign Corrupt Practices Act of 1977 (as modified or amended). LICENSEE represents and warrants that it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence any Government Official. If LICENSEE is itself a Government Official, LICENSEE represents and warrants that it has not accepted, and will not accept in the future, such a payment or transfer. As used herein, "**Government Official**" means: (a) any elected or appointed government official (e.g., a member of a ministry of health); (b) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (c) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) an employee or person acting for or on behalf of a public international organization; or (e) any person otherwise categorized as a government official under local law. "Government" is meant to include all levels and subdivisions of non-U.S. governments (i.e., local, regional, or national and administrative, legislative, or executive). LICENSEE will update these warranties if it or any of its employees, or a relative of such an individual, becomes a Government Official, or if a Government or Government Official becomes an owner of LICENSEE.

9.3 Additional Representations, Warranties and Covenants by LICENSOR. LICENSOR, hereby represents, warrants and covenants to LICENSEE that:

9.3.1 All licenses to Third Parties granted by LICENSOR under the Platform Patents will be consistent with LICENSEE'S rights under Section 2.1.2 and will incorporate terms and conditions sufficient to enable LICENSEE to practice the full scope of its rights under Section 2.1.2;

9.3.2 All licenses to Third Parties granted by LICENSOR under the Platform Patents will incorporate terms and conditions effecting assignment of any licensee Improvements to LICENSOR and requiring licensees to disclose all Improvements to LICENSOR.

9.3.3 It has the full right, power and authority to grant all of the licenses granted to LICENSEE under this Agreement;

9.3.4 It is the sole and exclusive owner of all right, title and interest in and to the Patent Rights existing as of the Effective Date;

9.3.5 Except for any license granted to a Third Party under the rights reserved for LICENSOR pursuant to Section 3.3, as of the Effective Date, LICENSOR has not granted to any Third Party any license to any of the Patent Rights in the Initial Field with respect to which LICENSEE has been granted a license hereunder; and

9.3.6 As of the Effective Date, there is no pending Proceeding that has been commenced by or against LICENSOR or any of its Affiliates specifically regarding the Patent Rights or the Licensor Bioisosteres. To the knowledge of LICENSOR no such Proceeding has been threatened.

9.4 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. ANY INFORMATION AND INVENTORY PROVIDED BY LICENSOR OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED. LICENSEE acknowledges and agrees that any Licensed Bioisosteres are experimental in nature and may have unknown characteristics. LICENSEE shall use prudence and reasonable care in the use, handling, storage, transportation, disposition, and containment of the Licensed Bioisosteres. LICENSOR makes no representations or warranties, and assumes no liability, for LICENSEE's use of the Licensed Bioisosteres.

10. INDEMNIFICATION

10.1 Indemnification by LICENSEE. LICENSEE agrees to indemnify, hold harmless and defend LICENSOR and its Affiliates, licensees and distributors and their respective officers, directors, employees, contractors, agents and permitted assigns, from and against any and all Claims arising or resulting from: (a) the Development of a Licensed Product by any LICENSEE Indemnitee; (b) the Commercialization of a Licensed Product by any LICENSEE Indemnitee; (c) the negligence, recklessness or wrongful intentional acts or omissions or violations of Applicable Law by any LICENSEE Indemnitee in exercising its rights or carrying out its obligations hereunder; (d) breach by any LICENSEE Indemnitee of any representation, warranty or covenant as set forth in this Agreement; or (e) breach by any LICENSEE Indemnitee of the scope of the license set forth in Section 2.1. As used herein, "**Claims**" means collectively, any and all Third Party demands, claims and Proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees).

10.2 Indemnification by LICENSOR. LICENSOR hereby agrees to indemnify, defend and hold harmless LICENSEE, its Affiliates, licensees or distributors or their respective officers, directors,

employees, contractors, agents and permitted assigns ("**LICENSEE Indemnitee(s)**") from and against any and all Claims arising or resulting from any breach of a representation or warranty made by LICENSOR.

10.3 Indemnification Procedure. Promptly after receipt by a party seeking indemnification under this Section 10 (an "**Indemnitee**") of notice of any pending or threatened Claim against it, such Indemnitee shall give written notice to the Party from whom the Indemnitee is entitled to seek indemnification pursuant to this Section 10 (the "**Indemnifying Party**") of the commencement thereof; provided that the failure so to notify the Indemnifying Party shall not relieve it of any liability that it may have to any Indemnitee hereunder, except to the extent the Indemnifying Party demonstrates that it is materially prejudiced thereby. The Indemnifying Party shall be entitled to participate in the defense of such Claim and, to the extent that it elects within [***] ([***]) [***] of its receipt of notice of the Claim from the Indemnitee, to assume control of the defense and settlement of such Claim (unless the Indemnifying Party is also a party to such proceeding and the Indemnifying Party has asserted a cross claim against the Indemnified Party or a court has otherwise determined that such joint representation would be inappropriate) with counsel reasonably satisfactory to the Indemnitee and, after notice from the Indemnifying Party to the Indemnitee of its election to assume the defense of such Claim, the Indemnifying Party shall not, as long as it diligently conducts such defense, be liable to the Indemnitee for any Litigation Costs subsequently incurred by the Indemnitee. No compromise or settlement of any Claim may be effected by the Indemnifying Party without the Indemnitee's written consent, which consent shall not be unreasonably withheld or delayed, provided no consent shall be required if: (A) there is no finding or admission of any violation of Applicable Laws or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (B) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (C) the Indemnitee's rights under this Agreement are not restricted by such compromise or settlement.

11. LIMITATION OF LIABILITY

11.1 Consequential Damages Waiver. EXCEPT FOR [***], NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

11.2 Liability Cap. IN NO EVENT SHALL LICENSOR'S LIABILITY FOR DAMAGES IN CONNECTION WITH THIS AGREEMENT EXCEED THE LICENSOR CAP, REGARDLESS OF WHETHER LICENSOR HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE). "**LICENSOR CAP**" MEANS [***].

12. TERM; TERMINATION

12.1 Term. The term of this Agreement shall commence as of the Effective Date and shall expire on the later of (a) on a country-by-country basis or, with respect to Greater China, on a region-by-region basis, upon the date of expiration of the last-to-expire Royalty Term for all Licensed Products in such country or region and (b) December 21, 2032 (collectively, the "**Term**").

12.2 Termination for Cause. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in its entirety in the event the other Party has materially breached any of its obligations hereunder and fails to cure such breach within [***] ([***]) [***] of receiving written notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such [***] ([***]) [***] period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period

exceed [***] ([***]) [***]. For the avoidance of doubt, LICENSEE's failure to [***] shall constitute a material breach by LICENSEE under this Agreement.

12.3 Termination for a Bankruptcy Event. Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [***] ([***]) [***] after they are instituted; (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature; (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code; (d) appointment of a receiver for all or substantially all of a Party's assets; or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

12.4 Effect of Termination or Expiration.

12.4.1 Upon the natural expiration of this Agreement, LICENSOR hereby grants to LICENSEE a royalty-free, fully paid-up right and non-exclusive license to use the Licensed Know-How for the purpose of the Development and Commercialization of the Licensed Products in the Field within the Territory.

12.4.2 Upon termination or the natural expiration of this Agreement, LICENSEE shall pay to LICENSOR all amounts due to LICENSOR as of the effective date of termination or expiration within [***] ([***]) [***] following the effective date of termination or expiration.

12.4.3 Upon termination of this Agreement, LICENSEE shall have the right to sell its remaining inventory of Licensed Product for a period of [***] ([***]) [***] following the termination of this Agreement so long as LICENSEE is able to do so in compliance with Applicable Laws and has fully paid, and continues to fully pay when due, any and all Royalties, Milestone Payments and Sublicense Fees owed to LICENSOR, and LICENSEE otherwise is not in material breach of this Agreement.

12.4.4 Subject to Section 12.4.3, upon termination of this Agreement, all licenses granted by LICENSOR to LICENSEE shall terminate, provided that any sublicenses granted by LICENSEE hereunder shall survive; provided further that each sublicensee is then in full compliance with its sublicense agreement and promptly agrees in writing to be bound by the applicable terms of this Agreement and agrees to pay directly to LICENSOR the amounts due thereunder.

12.4.5 Upon termination of this Agreement for LICENSEE's breach pursuant to Section 12.2 or termination under Section 12.3:

(a) LICENSEE hereby grants to LICENSOR a non-exclusive, royalty-bearing (pursuant to subsection (d) below), worldwide, transferable, perpetual and irrevocable license, with the right to sublicense, to Use any Improvements Controlled by LICENSEE that are necessary for the Development or Commercialization of the Licensed Products and were not already required to be assigned to LICENSOR pursuant to Section 6.3.

(b) To the extent permitted by applicable Regulatory Authorities, LICENSEE shall at LICENSOR's sole cost and expense (i) transfer to LICENSOR all Regulatory

Filings, Regulatory Approvals and data (including safety data) held by LICENSEE with respect to the Licensed Products and (ii) to the extent subsection (i) is not permitted by the applicable Regulatory Authority, permit LICENSOR to cross-reference and rely upon any Regulatory Approvals and Regulatory Filings filed by LICENSEE with respect to the Licensed Products.

(c) Upon LICENSOR's request and so long as LICENSOR was not otherwise in breach of this Agreement, LICENSEE shall use Commercially Reasonable Efforts to continue, at LICENSOR's sole cost and expense, all on-going Development for a mutually agreed upon migration period after termination of this Agreement, which period shall not be less than [***] ([***]) [***] unless otherwise agreed to by the Parties ("**Migration Period**"). During the Migration Period, LICENSEE shall use Commercially Reasonable Efforts to provide such knowledge transfer and other training to LICENSOR or its Affiliates or a Third Party, at LICENSOR's sole costs and expense that is designated in writing by LICENSOR ("**Designated Affiliate/Third Party**") as reasonably necessary for LICENSOR or the Designated Affiliate/Third Party to continue such activities. In connection with such transfer, LICENSEE shall, at LICENSOR's option: (i) transfer to LICENSOR or the Designated Affiliate/Third Party all Licensed Product at the cost paid by LICENSEE to manufacture such Licensed Product; (ii) transfer to LICENSOR or the Designated Affiliate/Third Party all Licensee Inventory owned by LICENSEE at the cost paid by LICENSEE for such Licensee Inventory; and (iii) assign to LICENSOR or the Designated Affiliate/Third Party any agreements with Third Parties related exclusively to the Development or Commercialization of the Licensed Products. As used herein, "**Licensee Inventory**" means all components and works in process produced or held by LICENSEE with respect to the manufacture of Licensed Product.

(d) The licenses and assignments to be granted to LICENSOR pursuant to this Section 12.4 shall be subject to the following royalties on Net Sales by LICENSOR and its sublicensees for any Licensed Product that is covered by a claim of an issued patent arising from LICENSEE's (or its Affiliates' or sublicensees') Development of the Licensed Product:

(i) [***] ([***]) until the total amount of such royalties paid pursuant to this Section (d) equal, in aggregate, the actual, auditable out-of-pocket expenses spent on Development by LICENSEE; and thereafter:

(ii) [***] ([***]) if the termination occurs prior to completion of a Phase I Clinical Trial for such Licensed Product; and

(iii) [***] ([***]) if the termination occurs after completion of a Phase I Clinical Trial for such Licensed Product but prior to completion of a Phase II Clinical Trial for such Licensed Product;

(iv) [***] ([***]) if the termination occurs after completion of a Phase II Clinical Trial for such Licensed Product but prior to completion of a Phase III Clinical Trial for such Licensed Product; and

(v) [***] ([***]) if the termination occurs after completion of a Phase III Clinical Trial for such Licensed Product.

All royalties shall be paid by LICENSOR pursuant to the terms of Section 4.1.2 and LICENSEE shall have audit rights consistent with the terms of Section 5, in each case *mutatis mutandis*.

12.5 Remedies. All of the non-breaching/terminating Party's remedies shall be cumulative, and the exercise of one remedy hereunder by the non-defaulting/terminating Party shall not be deemed to be an election of remedies. These remedies shall include the non-breaching/terminating Party's other rights of recovery for such breach with or without terminating this Agreement.

12.6 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 1, 5, 6.1, 6.2, 6.3, 8, 10, 11, 12.4, 12.5, 12.6, 13, 15.3 and 15.8 shall survive expiration or termination of this Agreement.

13. LICENSEE INSURANCE

13.1 Insurance Requirements. Prior to the Commencement of any Phase I Clinical Trial for a Licensed Product or otherwise Commercializing the Licensed Product, LICENSEE shall, at its sole cost and expense, obtain and keep in force during the Term and for a period of not less than (a) [***] ([***]) [***] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Licensed Products have expired, commercial general liability insurance from [***] with coverage limits of not less than [***] ([***]) per occurrence and [***] ([***]) in the aggregate. LICENSEE has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on LICENSEE's liability hereunder. Such policies shall name LICENSOR and its Affiliates as additional insured and provide a waiver of subrogation in favor of LICENSOR and its Affiliates. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to LICENSOR or its Affiliates. Any deductibles for such insurance shall be assumed by LICENSEE.

13.2 Policy Notification. LICENSEE shall provide LICENSOR with a certificate of insurance signed by an authorized representative of LICENSEE's insurance underwriter evidencing the insurance coverage required by this Agreement: (a) prior to Commencement of any Phase I Clinical Trial for a Licensed Product; (b) [***] ([***]) [***] prior to expiration, termination, or reduction of such insurance coverage; and (c) upon LICENSOR's request.

13.3 Third Parties. LICENSEE shall use Commercially Reasonable Efforts to cause Third Parties engaged by LICENSEE to perform LICENSEE's obligations under this Agreement to maintain such types of insurance coverages and for such period of time as are customary for such Third Parties given the nature of the services to be provided.

14. DISPUTE RESOLUTION/DAMAGES

14.1 General. Except for disputes for which injunctive or other equitable relief is sought to prevent the unauthorized use or disclosure of proprietary materials or information or prevent the infringement or misappropriation of a Party's Intellectual Property Rights, the following procedures shall be used to resolve any dispute arising out of or in connection with this Agreement.

14.2 Meeting. Promptly after the written request of either Party, each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute arising out of or resulting from this Agreement ("**Dispute**"). If such designated representatives do not resolve such Dispute within [***] ([***]) [***] of such written request, then the Executive Officer of each Party shall meet in person or by telephone to review and attempt to resolve such Dispute in good faith, and such Executive Officers shall have [***] ([***]) [***] to attempt to resolve such dispute (such total [***]

([***]) [***] the "**Dispute Resolution Period**"). If the Parties are unable to resolve a Dispute within a Dispute Resolution Period then such Dispute shall be resolved in accordance with Sections 14.3 and 14.4 or Section 14.5, as applicable.

14.3 Mediation. If the Parties are unable to resolve a Dispute (other than a Dispute subject to Section 14.5) within a Dispute Resolution Period in accordance with Section 14.2, then either Party may submit such Dispute (other than a Dispute subject to Section 14.5) for resolution by mediation pursuant to the Center for Public Resources Model Procedure for Mediation of Business Disputes as then in effect. The mediation shall be conducted in San Diego County, California. At the request of either Party, the mediator will be asked to provide an evaluation of the Dispute and the Parties' relative positions. Each Party shall bear its own costs with respect to the mediation effort. The Parties shall have [***] ([***]) [***] to attempt to resolve the dispute through mediation.

14.4 Arbitration.

14.4.1 Any Disputes (other than a Disputes subject to Section 14.5) that are not resolved by the Parties in accordance with Section 14.2 and 14.3 shall be submitted to binding arbitration with the office of the American Arbitration Association ("**AAA**") in San Diego County, California in accordance with the then-prevailing commercial arbitration rules of the American Arbitration Association. Such Dispute shall be heard by a panel of [***] ([***]) arbitrators appointed in accordance with such rules.

14.4.2 All such arbitration proceedings shall be held in English and a transcribed record shall be prepared in English. The Party submitting the Dispute to arbitration shall select the [***] and shall provide notice of the same at the time it submits the Dispute to arbitration. The non-initiating Party shall then have [***] ([***]) [***] to select [***]. Thereafter, the [***] shall have [***] ([***]) [***] to choose [***]. If no arbitrator is appointed within the times herein provided or any extension of time which is mutually agreed upon, the AAA shall make such appointment of the [***] within [***] ([***]) [***] of such failure who shall thereafter pick [***] as set forth herein. Each Party in any arbitration proceeding commenced hereunder shall initially bear such Party's own costs and expenses (including expert witness and attorneys' fees) of investigating, preparing and pursuing such arbitration claim. The fees and expenses of the arbitrators, will be shared equally by the Parties. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the Dispute as necessary to protect either Party's name, Confidential Information, Intellectual Property Rights or any other proprietary rights. If the Dispute involves scientific or technical matters, each arbitrator chosen hereunder shall have educational training and experience relevant to the field of pharmaceuticals. The award rendered by the arbitrators shall be written, final and non-appealable, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The prevailing Party shall be entitled to recover from the losing Party the prevailing Party's attorneys' fees and costs. The arbitrator shall have the right to apportion liability between the Parties, but will not have the authority to award any damages or remedies not available under the express terms of this Agreement. The arbitration award will be presented to the Parties in writing, and upon the request of either Party, will include findings of fact and conclusions of law. The award may be confirmed and enforced in any court of competent jurisdiction.

14.5 Baseball Arbitration for Certain Sublicensing Fee Related Disputes. In the event of any Dispute arising under Section 4.1.3 (including if the Parties fail to agree on apportionment of the amount of proceeds that are and are not Sublicense Fees subject to Section 4.1.3), the Parties shall submit such Dispute to mediation and binding baseball arbitration pursuant to the mediation and baseball arbitration process set forth under this Section 14.5. The purpose of the mediation and baseball arbitration shall be to resolve only those issues that remain in dispute under Section 4.1.3 following good faith negotiations

within a Dispute Resolution Period in accordance with Section 14.2. The mediation and baseball arbitration shall be conducted in San Diego County, California under the applicable AAA rules (except as modified by this Section 14.5 below) and the proceedings shall be held in English. Each Party shall bear its own costs with respect to the mediation and baseball arbitration proceedings and share the cost of the Third Party Expert (defined below).

14.5.1 Any Dispute arising under Section 4.1.3 that the Parties are unable to resolve within a Dispute Resolution Period in accordance with to Section 14.2 shall, on the written request of either Party, be submitted to a Third Party expert (a "**Third Party Expert**") mutually acceptable to the Parties having relevant expertise with respect to the Dispute and who is independent, conflict-of-interest-free, and not affiliated or consulting with either Party or its Affiliates, (or in the event that the Parties fail to agree on the selection of such Third Party Expert within [***] ([***]) [***] of the submission of such matter to resolution in accordance with this Section 14.5, by an appropriately qualified, independent, conflict-of-interest-free individual not affiliated or consulting with either Party or its Affiliates, and appointed by AAA). The Parties shall use reasonable efforts to mutually agree on the Third Party Expert within [***] ([***]) [***] after either Party designates the Dispute for resolution under this Section 14.5. The Third Party Expert shall initially attempt to resolve the Dispute through non-binding mediation. At the request of either Party, the mediator will be asked to provide an evaluation of the Dispute and the Parties' relative positions. If the Third Party Expert is unable to resolve the Dispute through non-binding mediation within [***] ([***]) [***] of submission of such Dispute to mediation, the Dispute will, upon the written request of either Party, be resolved through Section 14.5.2.

14.5.2 Within [***] ([***]) [***] of completion of non-binding mediation, each Party will deliver to both the Third Party Expert and the other Party a detailed written proposal setting forth its proposed terms for the resolution of the Dispute (the "**Proposed Terms**") and a memorandum (the "**Support Memorandum**") in support thereof, not exceeding [***] ([***]) [***] in length each. The Parties will also provide the Third Party Expert with a copy of this Agreement, as amended through such date. Within [***] ([***]) [***] after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the Third Party Expert (with a copy to the other Party) a response to the other Party's Proposed Terms and Support Memorandum, such response not exceeding [***] ([***]) [***] in length. Neither Party may have any other communications (either written or oral) with the Third Party Expert; provided that the Third Party Expert may, in its discretion, convene a hearing to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms and Support Memorandum and response to the other Party's Proposed Terms and Support Memorandum, at which time each Party shall have an agreed upon time to argue and, if requested by the Third Party Expert, present witnesses in support of its Proposed Terms.

14.5.3 Within [***] ([***]) [***] after the Third Party Expert is appointed, the Third Party Expert shall select one of the two Proposed Terms (without modification) provided by the Parties which most closely reflects a commercially reasonable interpretation of the terms of this Agreement. In making its selection, (i) the Third Party Expert shall only have the authority to accept one or the other Party's Proposed Terms and shall not modify the terms or conditions of either Party's Proposed Terms nor shall the Third Party Expert combine provisions from both Proposed Terms and (ii) the Third Party Expert shall consider the terms and conditions of this Agreement, the relative merits of the Proposed Terms, the Support Memorandums and, if applicable, the oral arguments of the Parties. Subject to the foregoing, the Third Party Expert shall make its decision known to both Parties as promptly as possible by delivering written notice to both Parties. The decision of the Third Party Expert shall be final and binding on the Parties, and specific performance may be ordered by any court of competent jurisdiction.

14.6 Confidentiality of Disputes. The existence, content and/or results of any Dispute, as well as any mediation or arbitration proceedings conducted under this Section 14, shall be the Confidential Information of both Parties.

15. GENERAL PROVISIONS

15.1 Assignment. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: [***].

15.2 Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

15.3 Governing Law. This Agreement shall be governed by and construed under the laws in effect in the State of California, without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result, except that issues subject to the arbitration clause and any arbitration hereunder shall be governed by the applicable commercial arbitration rules and regulations.

15.4 Force Majeure. Except with respect to delays or nonperformance by a Party caused by the negligent or intentional act or omission of such Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts or failures to act of the government (including any Regulatory Authority) or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a "**Force Majeure Event**"), provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for [***] ([***]) [***] or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

15.5 Waivers and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

15.6 Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between LICENSOR and LICENSEE, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

15.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

15.8 Notices. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (receipt requested); or (c) when received by the

addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to LICENSOR:

Recurium IP Holdings, LLC
Attention: Chief Business Officer
10275 Science Center Drive
Suite 200
San Diego, CA 92121

If to LICENSEE:

Zeno Management, Inc.
Attention: Chief Executive Officer
10275 Science Center Drive
Suite 200
San Diego, CA 92121

With a copy to:

Zeno Management, Inc.
Attention: General Counsel (legal@zentalis.com)
10275 Science Center Drive
Suite 200
San Diego, CA 92121

15.9 Further Assurances. LICENSEE and LICENSOR hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate, at the cost of the requesting Party (unless otherwise set forth herein), to carry out the intent and purposes of this Agreement.

15.10 No Third Party Beneficiary Rights. Except as expressly stated herein, this Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

15.11 Entire Agreement.

15.11.1 This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter.

15.11.2 In the event of any conflict between a provision of this Agreement and any Schedule hereto, the Agreement shall control.

15.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15.13 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

15.14 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

15.15 Amendment. It is the intent of the Parties that this Agreement be construed as amendment to and restatement of the Second ARLA in its entirety (as previously amended by the Compound Specific Amendment and Greater China Amendment), and not as a new agreement. Accordingly, obligations of any Party that have been satisfied prior to the Amendment Date (including Milestone Payments paid prior to the Amendment Date) will be deemed to have been satisfied for purposes of this Agreement, and representations and warranties set forth in this Agreement will be deemed to have been made as of the Effective Date, and will not be made again as of the Amendment Date.

[Signatures on next page]

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of June 5, 2023.

LICENSOR:

Recurium IP Holdings, LLC

By: /s/ Ned Israelsen
Ned Israelsen
Manager

LICENSEE:

Zeno Management, Inc.

By: /s/ Kimberly Blackwell
Kimberly Blackwell
Chief Executive Officer

CONTENTS OF ATTACHMENT OMITTED FROM FILED EXHIBIT PURSUANT TO REGULATION S-K ITEMS 601(B)(10) AND 601(A)(5).

SCHEDULE A: PLATFORM PATENTS

[***]

CONTENTS OF ATTACHMENT OMITTED FROM FILED EXHIBIT PURSUANT TO REGULATION S-K ITEMS 601(B)(10) AND 601(A)(5).

SCHEDULE B: COMPOUND SPECIFIC PATENTS

[***]

CONTENTS OF ATTACHMENT OMITTED FROM FILED EXHIBIT PURSUANT TO REGULATION S-K ITEMS 601(B)(10) AND 601(A)(5).

SCHEDULE C: REAGENT PATENTS

[***]

CONTENTS OF ATTACHMENT OMITTED FROM FILED EXHIBIT PURSUANT TO REGULATION S-K ITEMS 601(B)(10) AND 601(A)(5).

SCHEDULE D: [***] PROGRAM PATENTS

[***]

Exhibit 31.1

CERTIFICATION

I, Kimberly Blackwell, M.D. certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 9, 2023

By: /s/ Kimberly Blackwell, M.D.

Kimberly Blackwell, M.D.

Chief Executive Officer

(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Melissa B. Epperly, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 9, 2023

By: /s/ Melissa B. Epperly

Melissa B. Epperly

Chief Financial Officer

(*principal financial officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Zentalis Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 9, 2023

By: /s/ Kimberly Blackwell M.D.
Kimberly Blackwell, M.D.
Chief Executive Officer
(*principal executive officer*)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Zentalis Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 9, 2023

By: /s/ Melissa B. Epperly
Melissa B. Epperly
Chief Financial Officer
(principal financial and accounting officer)