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, 2020

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.)**
530 Seventh Avenue, Suite 2201 New York, New York	**10018**
(Address of principal executive offices)	**(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 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 11, 2020, the registrant had 40,002,821 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 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” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report, including without limitation statements regarding our future results of operations and financial position, the anticipated impact of the novel coronavirus (“COVID-19”) pandemic on our business, business strategy, prospective products and product candidates, clinical trial timelines and expected timing for the release of data, research and development costs, future revenue, timing and likelihood of success, potential collaboration opportunities, and plans and objectives of management are forward-looking statements.

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 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, 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 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.

BASIS OF PRESENTATION

As used in this Quarterly Report on Form 10-Q, unless the context otherwise requires, references to "we," "us," "our," the "Company," "Zentalis" and similar references refer: (1) following the consummation of our statutory conversion to a Delaware corporation on April 2, 2020 in connection with our initial public offering, to Zentalis Pharmaceuticals, Inc., and (2) prior to the completion of such conversion, to Zentalis Pharmaceuticals, LLC. See "Management's Discussion and Analysis of Financial Condition and Results of Operations"—"Corporate Conversion" in this Quarterly Report on Form 10-Q for further information.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Zentalis Pharmaceuticals, Inc. (Successor to Zentalis Pharmaceuticals, LLC)
FINANCIAL STATEMENTS
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except unit and share amounts)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 96,016	$ 67,246
Marketable securities, available-for-sale	137,175	—
Accounts receivable from government grants, net	73	140
Prepaid expenses and other current assets	5,217	1,505
Total current assets	238,481	68,891
Property and equipment, net	481	501
Operating lease right-of-use assets	2,090	2,335
Prepaid expenses and other assets	3,218	2,134
Deferred financing costs	—	841
Goodwill	3,736	3,736
In-process research and development	8,800	8,800
Restricted cash	411	243
Total assets	$ 257,217	$ 87,481
LIABILITIES, CONVERTIBLE PREFERRED UNITS AND EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 4,217	$ 4,289
Accrued expenses	11,350	10,608
Total current liabilities	15,567	14,897
Deferred tax liability	2,463	2,463
Other long-term liabilities	1,262	1,700
Total liabilities	19,292	19,060
Commitments and contingencies		
Convertible preferred units; Redemption value of $146,944,000 at December 31, 2019	—	141,706
EQUITY (DEFICIT)		
Class A common units; 20,000,000 units authorized; 5,601,478 units issued and outstanding at December 31, 2019	—	709
Class B common units, 3,458,522 units authorized; 2,670,668 units issued and outstanding at December 31, 2019	—	2,178
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2020	—	—
Common stock, $0.001 par value; 250,000,000 shares authorized; 35,878,108 shares issued and outstanding at June 30, 2020	36	—
Additional paid-in capital	339,160	—
Accumulated other comprehensive income	4	—
Accumulated deficit	(125,976)	(82,993)
Total stockholders' equity/members' (deficit)	213,224	(80,106)
Noncontrolling interests	24,701	6,821
Total equity (deficit)	237,925	(73,285)
Total liabilities, convertible preferred units and equity (deficit)	$ 257,217	$ 87,481

See notes to condensed consolidated financial statements.

Zentalis Pharmaceuticals, Inc. (Successor to Zentalis Pharmaceuticals, LLC)
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per unit and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating Expenses				
Research and development	$ 17,452	$ 8,689	$ 30,710	$ 15,778
General and administrative	9,924	1,946	13,065	3,579
Total operating expenses	27,376	10,635	43,775	19,357
Operating loss	(27,376)	(10,635)	(43,775)	(19,357)
Other Income (Expense)				
Investment and other income, net	84	49	248	111
Net loss before income taxes	(27,292)	(10,586)	(43,527)	(19,246)
Income tax expense	—	11	—	14
Net loss	(27,292)	(10,597)	(43,527)	(19,260)
Net loss attributable to noncontrolling interests	(435)	(127)	(544)	(447)
Net loss attributable to Zentalis	$ (26,857)	$ (10,470)	$ (42,983)	$ (18,813)
Net loss per common share outstanding, basic and diluted	$ (0.78)	$ —	$ (2.53)	$ —
Net loss per Class A common unit outstanding, basic and diluted	$ —	$ (1.87)	$ —	$ (3.36)
Common shares/units used in computing net loss per share/Class A common unit, basic and diluted	34,353	5,601	16,978	5,601

See notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	(27,292)	(10,597)	(43,527)	(19,260)
Other comprehensive income:				
Unrealized gain on marketable securities	4	—	4	—
Total comprehensive loss	$ (27,288)	$ (10,597)	$ (43,523)	$ (19,260)
Comprehensive loss attributable to noncontrolling interests	(435)	(127)	(544)	(447)
Comprehensive loss attributable to Zentalis	$ (26,853)	$ (10,470)	$ (42,979)	$ (18,813)

See notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2020	2019
Operating Activities:		
Consolidated net loss	$ (43,527)	$ (19,260)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	76	45
Share-based compensation	8,010	250
Amortization of premiums on marketable securities, net	65	—
Changes in operating assets and liabilities:		
Accounts receivable	67	597
Prepaid expenses and other assets	(4,796)	(384)
Accounts payable and accrued liabilities	1,212	2,701
Operating lease right-of-use assets and liabilities, net	(11)	87
Net cash used in operating activities	(38,904)	(15,964)
Investing activities:		
Purchases of marketable securities	(137,236)	—
Purchases of property and equipment	(56)	(209)
Net cash used in investing activities	(137,292)	(209)
Financing Activities:		
Proceeds from issuance of common stock in initial public offering, net	172,482	—
Contributions from noncontrolling interest owners, net	18,424	—
Proceeds from the issuance of Series C convertible preferred units, net	14,228	—
Net cash provided by financing activities	205,134	—
Net increase/(decrease) in cash, cash equivalents and restricted cash	28,938	(16,173)
Cash, cash equivalents and restricted cash at beginning of period	67,489	25,154
Cash, cash equivalents and restricted cash at end of period	$ 96,427	$ 8,981
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 2,675
Costs incurred in connection with initial public offering included in accounts payable and accrued expenses	$ 70	$ —

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,	
	2020	2019
Cash and cash equivalents	$ 96,016	$ 8,738
Restricted cash, non-current	411	243
Total cash, cash equivalents and restricted cash reported in the Consolidated Statement of Cash Flows	$ 96,427	$ 8,981

See notes to condensed consolidated financial statements.

Zentalis Pharmaceuticals, Inc. (Successor to Zentalis Pharmaceuticals, LLC)
Condensed Consolidated Statements of Changes in Convertible Preferred Units and Members'/Stockholders' Equity/(Deficit)
(In thousands)

	Three Months Ended June 30, 2020														
			Zentalis Members/Stockholders												
	Convertible Preferred Units		Convertible Preferred Units		Class A Common Units		Class B Common Units		Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Equity (Deficit)
	Units	Amount	Units	Amount	Units	Amount	Units	Amount	Shares	Amount					
Balance at March 31, 2020	10,817	$ 155,934	—	$ —	5,601	$ 709	2,607	$ 2,507	—	$ —	$ —	$ —	$ (99,119)	$ 6,712	$ (89,191)
Issuance of common stock in connection with an equity offering, net of underwriting discounts, commissions and offering costs	—	—	—	—	—	—	—	—	10,589	11	172,354	—	—	—	172,365
Contributions from noncontrolling interest owners	—	—	—	—	—	—	—	—	—	—	—	—	—	18,424	18,424
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	7,681	—	—	—	7,681
Conversion of convertible preferred units to common stock	(10,817)	(155,934)	—	—	—	—	—	—	15,011	15	155,919	—	—	—	155,934
Conversion of common and incentive units to common and restricted stock	—	—	—	—	(5,601)	(709)	(2,607)	(2,507)	10,278	10	3,206	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	4	—	—	4
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	—	—	(435)	(435)
Net loss attributable to Zentalis	—	—	—	—	—	—	—	—	—	—	—	—	(26,857)	—	(26,857)
Balance at June 30, 2020	—	$ —	—	$ —	—	$ —	—	$ —	35,878	$ 36	$ 339,160	$ 4	$ (125,976)	$ 24,701	$ 237,925

	Six Months Ended June 30, 2020														
	Zentalis Members/Stockholders														
	Convertible Preferred Units		Convertible Preferred Units		Class A Common Units		Class B Common Units		Common		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interests	Total Equity (Deficit)
	Units	Amount	Units	Amount	Units	Amount	Units	Amount	Shares	Amount					
Balance at December 31, 2019	9,950	$ 141,706	—	$ —	5,601	$ 709	2,671	$ 2,178	—	$ —	$ —	$ —	$ (82,993)	$ 6,821	$ (73,285)
Issuance of Series C convertible preferred units at $17.50 per unit net of issuance costs	867	14,228	—	—	—	—	—	—	—	—	—	—	—	—	—
Cancellation of profit interest awards, net	—	—	—	—	—	—	(64)	—	—	—	—	—	—	—	—
Issuance of common stock in connection with an equity offering, net of underwriting discounts, commissions and offering costs	—	—	—	—	—	—	—	—	10,589	11	172,354	—	—	—	172,365
Contributions from noncontrolling interest owners	—	—	—	—	—	—	—	—	—	—	—	—	—	18,424	18,424
Share-based compensation expense	—	—	—	—	—	—	—	329	—	—	7,681	—	—	—	8,010
Conversion of convertible preferred units to common stock	(10,817)	(155,934)	—	—	—	—	—	—	15,011	15	155,919	—	—	—	155,934
Conversion of common and incentive units to common and restricted stock	—	—	—	—	(5,601)	(709)	(2,607)	(2,507)	10,278	10	3,206	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	4	—	—	4
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	—	—	—	—	—	(544)	(544)
Net loss attributable to Zentalis	—	—	—	—	—	—	—	—	—	—	—	—	(42,983)	—	(42,983)
Balance at June 30, 2020	—	$ —	—	$ —	—	$ —	—	$ —	35,878	$ 36	$ 339,160	$ 4	$ (125,976)	$ 24,701	$ 237,925

Three Months Ended June 30, 2019

	Zentalis Members										
	Convertible Preferred Units		Convertible Preferred Units		Class A Common Units		Class B Common Units		Accumulated Deficit	Noncontrolling Interests	Total Equity (Deficit)
	Units	Amount	Units	Amount	Units	Amount	Units	Amount			
Balance at March 31, 2019	—	$ —	5,103	$ 59,830	5,594	$ 674	1,660	$ 1,725	$ (45,673)	$ 7,216	$ 23,772
Issuance of profit interest awards, net	—	—	—	—	—	—	9	—	—	—	—
Share-based compensation expense	—	—	—	—	—	2	—	119	—	—	121
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	—	(127)	(127)
Net loss attributable to Zentalis	—	—	—	—	—	—	—	—	(10,470)	—	(10,470)
Balance at June 30, 2019	—	$ —	5,103	$ 59,830	5,594	$ 676	1,669	$ 1,844	$ (56,143)	$ 7,089	$ 13,296

Six Months Ended June 30, 2019

	Zentalis Members										
	Convertible Preferred Units		Convertible Preferred Units		Class A Common Units		Class B Common Units		Accumulated Deficit	Noncontrolling Interests	Total Equity (Deficit)
	Units	Amount	Units	Amount	Units	Amount	Units	Amount			
Balance at December 31, 2018	—	$ —	5,103	$ 59,830	5,594	$ 672	1,612	$ 1,598	$ (37,330)	$ 7,536	$ 32,306
Issuance of profit interest awards, net	—	—	—	—	—	—	57	—	—	—	—
Share-based compensation expense	—	—	—	—	—	4	—	246	—	—	250
Net loss attributable to non-controlling interest	—	—	—	—	—	—	—	—	—	(447)	(447)
Net loss attributable to Zentalis	—	—	—	—	—	—	—	—	(18,813)	—	(18,813)
Balance at June 30, 2019	—	$ —	5,103	$ 59,830	5,594	$ 676	1,669	$ 1,844	$ (56,143)	$ 7,089	$ 13,296

See notes to condensed consolidated financial statements.

1. Organization and Business

Organization

Zentalis Pharmaceuticals, Inc. (successor to Zentalis Pharmaceuticals, LLC) ("Zentalis", "We" or the "Company") is a clinical-stage pharmaceutical company focused on discovering and developing clinically differentiated, novel small molecule therapeutics targeting fundamental biological pathways of cancer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. To date, all of the Company's revenue has been generated in the United States. All of the Company's tangible assets are held in the United States.

The Company was formed and incorporated in the state of Delaware as Zeno Pharmaceuticals, Inc. on December 23, 2014. Effective November 21, 2017, Zeno Pharma, LLC was formed by the shareholders of Zeno Pharmaceuticals, Inc. On December 21, 2017, Zeno Pharmaceuticals, Inc. became a wholly owned subsidiary of Zeno Pharma, LLC. In connection with this restructuring, the rights and preferences of the Preferred Stock of Zeno Pharmaceuticals, Inc. were exchanged for preferred units with similar rights and preferences of Zeno Pharma, LLC. As part of the restructuring, the employees, consultants and board members of Zeno Pharmaceuticals, Inc. exchanged their equity grants in Zeno Pharmaceuticals, Inc. stock for Class B common units in Zeno Pharma, LLC. Additionally, existing common stockholders of Zeno Pharmaceuticals, Inc. exchanged their common stock for Class A common units in Zeno Pharma, LLC. All exchanges were made on a one-for-one basis. The restructuring was accounted for as a common control transaction. In December 2019, the Company was renamed to Zentalis Pharmaceuticals, LLC.

Immediately prior to the effectiveness of the registration statement pertaining to the Company's initial public offering ("IPO") on April 2, 2020, the Company converted from a Delaware limited liability company into a Delaware corporation, and changed its name to Zentalis Pharmaceuticals, Inc. Pursuant to the statutory corporate conversion, all of the outstanding units of Zentalis Pharmaceuticals, LLC converted into shares of common stock of Zentalis Pharmaceuticals, Inc. based upon the value of Zentalis Pharmaceuticals, Inc. at the time of the IPO with a value implied by the price of the shares of common stock sold in the IPO. Based on the IPO price of $18.00 per share, the outstanding units converted into 25,288,854 shares of common stock (including 1,160,277 shares of restricted common stock).

On April 7, 2020, the Company completed the IPO in which the Company issued and sold 10,557,000 shares of common stock (including 1,377,000 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a public offering price of $18.00 per share. The Company's aggregate gross proceeds from the sale of shares in the IPO, including the sale of shares pursuant to the full exercise of the underwriters' option to purchase additional shares, was $190.0 million before fees and expenses of $17.6 million.

On May 19, 2020, the Company announced the closing of a Series A financing of Zentera Therapeutics, Ltd. ("Zentera"), a majority owned biopharmaceutical company with headquarters in Shanghai, China. Contributions from non-controlling interest members totaled $20.0 million before issuing costs of $1.6 million. The Company holds 60.2% equity interest in Zentera for purposes of the development and commercialization of ZN-c5, ZN-d5 and ZN-c3 for the treatment or preventions of disease, other than for pain, in the People's Republic of China, Macau, Hong Kong and Taiwan. Two of our executives entered into restricted stock purchase agreements with Zentera. The associated shares vest over four years.

On August 3, 2020, the Company completed a follow-on offering in which the Company issued and sold 4,125,000 shares of common stock at a public offering price of $35.00 per share. The Company's aggregate gross proceeds from the sale of shares in the follow-on offering was $144.4 million before estimated fees and expenses of

$9.4 million. The Company granted the underwriters an option for a period of 30 days to purchase up to 618,750 additional shares of common stock.

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, 2020 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 does not include all disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2019 included in the Company's final prospectus for its IPO, filed pursuant to Rule 424(b) under the Securities Exchange Act of 1933, as amended, with the SEC on April 6, 2020. 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.

The condensed consolidated financial statements include the accounts of our wholly owned subsidiaries, majority-owned or controlled companies, and variable interest entity ("VIE"), Kalyra Pharmaceuticals, Inc. ("Kalyra"), for which we are the primary beneficiary. All intercompany transactions and balances have been eliminated in consolidation.

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.

Though the impact of the COVID-19 pandemic to our business and operating results presents additional uncertainty, we continue to use the best information available to inform our critical accounting estimates.

Marketable Securities

Marketable securities are investments with original maturities of more than ninety days from the date of purchase that we have the ability to liquidate to fund current operations. Accordingly, those investments with contractual maturities greater than one year from the date of purchase are classified as short-term investments on the accompanying condensed consolidated balance sheets Marketable securities are considered available-for-sale and are carried at fair value with unrealized gains and losses recorded in other comprehensive income (loss) and included as a separate component of stockholders' deficit. The cost of marketable securities is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in

investment and other income, net in the interim unaudited condensed consolidated statements of operations. We assess whether our available-for-sale debt securities in an unrealized loss position have credit-related losses and record such losses, and any subsequent improvements as interest income, through an allowance account. We use the specific identification method for calculating realized gains and losses on marketable securities sold. Realized gains and losses on marketable securities, if any, are included in investment and other income, net in the interim unaudited condensed consolidated statements of operations.

Adoption and Pending Adoption of Recent Accounting Pronouncements

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

Standard	Description	Effective Date	Effect on the Financial Statements or Other Significant Matters
In March 2020, the FASB issued ASU 2020-03, Codification Improvements to Financial Instruments	This guidance makes improvements to financial instruments guidance, including the current expected credit losses guidance.	January 1, 2020	We have adopted the new guidance as of January 1, 2020. The impact of the adoption was not material to the consolidated financial statements.
In January 2020, the FASB issued ASU 2020-01, Investments – Equity Securities (Topic 321)	This standard clarifies the interaction between accounting standards related to equity securities (ASC 321), equity method investments (ASC 323), and certain derivatives (ASC 815).	January 1, 2021	We currently do not hold equity securities, have equity method investments or derivatives. We do not believe the adoption will have a material impact on our consolidated financial position or results of operations.
In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. In November 2018 and April and May of 2019, the FASB issued additional guidance related to Topic 326.	The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income.	January 1, 2020	We have adopted the new guidance on January 1, 2020. The impact of the adoption was not material to the consolidated financial statements.
In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes.	The new guidance is intended to simplify aspects of the accounting for income taxes, including the elimination of certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, among other changes.	January 1, 2020	We have adopted the new guidance on January 1, 2020. The impact of the adoption was not material to the consolidated financial statements.

3. Business Combinations

Kalyra Pharmaceuticals, Inc.

On December 21, 2017, we acquired $4.5 million of Kalyra's 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 variable interest entity, 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 the change of control, Zentalis 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, 2020 and December 31, 2019 are as follows (in thousands):

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 430	$ 712
Other current assets	51	21
In-process research and development	8,800	8,800
Goodwill	3,736	3,736
Other long-term assets	—	14
Accounts payable and accrued expenses	65	391
Deferred tax liability	2,463	2,463
Noncontrolling interests	$ 6,643	$ 6,821

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 consolidated balance sheets.

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

	June 30, 2020
Noncontrolling interest at beginning of period	$ 6,821
Net loss attributable to noncontrolling interest	(178)
Noncontrolling interest at end of period	$ 6,643

4. Fair Value Measurement

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

	June 30, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Commercial paper	$ 32,975	$ —	$ (6)	$ 32,969
Corporate Debt Securities	19,957	—	(4)	19,953
US Government Agencies	48,254	19	(4)	48,269
US Treasury	35,985	—	(1)	35,984
	$ 137,171	$ 19	$ (15)	$ 137,175

As of June 30, 2020, fourteen of our available-for-sale debt securities with a fair market value of $83.4 million were in a gross unrealized loss position of fifteen thousand. 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, 2020, 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, 2020
	Estimated Fair Value
Due within one year	$ 127,173
After one but within five years	10,002
	$ 137,175

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

	June 30, 2020			December 31, 2019		
	Level 1	Level 2	Total estimated fair value	Level 1	Level 2	Total estimated fair value
Cash equivalents:						
Money market funds	$ 56,039	$ —	$ 56,039	$ 62,961	$ —	$ 62,961
US Government Agencies	—	10,002	10,002	—	—	—
US Treasury	—	5,020	5,020			—
Corporate Debt Securities	—	3,085	3,085			—
Total cash equivalents:	56,039	18,107	74,146	62,961	—	62,961
Available-for-sale marketable securities:						
Commercial paper	—	32,969	32,969	—	—	—
Corporate Debt Securities	—	19,953	19,953	—	—	—
US Government Agencies	—	48,269	48,269	—	—	—
US Treasury	35,984	—	35,984	—	—	—
Total available-for-sale marketable securities:	35,984	101,191	137,175	—	—	—
Total assets measured at fair value	$ 92,023	$ 119,298	$ 211,321	$ 62,961	$ —	$ 62,961

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the six months ended June 30, 2020. We had no instruments that were classified within Level 3 as of June 30, 2020 or December 31, 2019.

5. Prepaid Expenses and Other Assets

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

	June 30, 2020	December 31, 2019
Prepaid insurance	$ 2,435	$ 150
Prepaid software licenses and maintenance	349	238
Prepaid research and development expenses	5,144	2,985
Other prepaid expenses	507	266
Total prepaid expenses and other current assets	8,435	3,639
Less long-term portion	3,218	2,134
Total prepaid expenses and other assets, current	$ 5,217	$ 1,505

6. Property and Equipment, net

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

	June 30, 2020	December 31, 2019
Computer and Office Equipment	$ 298	$ 243
Lab Equipment	345	401
Leasehold Improvements	24	24
Subtotal	667	668
Accumulated depreciation and amortization	(186)	(167)
Property and equipment, net	$ 481	$ 501

Depreciation and amortization expense for the three months ended June 30, 2020 and 2019 was approximately thirty-eight thousand and twenty-four thousand, respectively. Depreciation and amortization expense for the six months ended June 30, 2020 and 2019 was approximately seventy-six thousand and forty-five thousand, respectively.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Accrued research and development expenses	$ 6,393	$ 5,465
Accrued employee expenses	3,025	2,977
Accrued general and administrative expenses	1,048	1,356
Lease liability	810	781
Other	74	29
Total accrued expenses	$ 11,350	$ 10,608

8. Convertible Preferred Units

Series A Convertible Preferred Units

In September 2015, Zeno Pharmaceuticals, Inc. entered into a Series A Preferred Stock Purchase Agreement (the "Series A Preferred Agreement"). Under the terms of the Series A Preferred Agreement, Zeno Pharmaceuticals, Inc. issued 1,293,104 shares of Series A convertible preferred stock at $11.60 per share for gross proceeds of $15.0 million. The net proceeds of this financing were $14.9 million after issuance costs of $0.1 million. In February and March 2016, Zeno Pharmaceuticals, Inc. issued an aggregate of 286,205 additional shares of Series A convertible preferred stock at $11.60 per share for additional gross proceeds of $3.3 million. The issuance costs of this additional financing were approximately thirty-nine thousand dollars. All Series A convertible preferred stock issued and outstanding by Zeno Pharmaceuticals, Inc. was converted into Series A convertible preferred units of Zentalis Pharmaceuticals, LLC in conjunction with the corporate restructuring and merger.

Series B Convertible Preferred Units

In December 2017, Zentalis Pharmaceuticals, LLC entered into a Series B Preferred Unit Purchase Agreement (the "Series B Preferred Agreement"). Under the terms of the Series B Preferred Agreement, Zentalis Pharmaceuticals, LLC issued 2,735,320 Series B preferred units at $12.43 per unit for gross proceeds of $34.0 million. The net proceeds of this financing were $32.1 million after issuance costs of $1.9 million. In January and August 2018, Zentalis Pharmaceuticals, LLC issued an aggregate of 788,419 additional shares of Series B preferred units at $12.43 per unit for additional gross proceeds of $9.8 million. The net proceeds of this additional financing were $9.5 million after issuance costs of $0.3 million.

Series C Preferred Unit Issuance

In September 2019, Zentalis Pharmaceuticals, LLC entered into a Series C Preferred Unit Purchase Agreement (the "Series C Preferred Agreement"). Under the terms of the Series C Preferred Agreement, Zentalis Pharmaceuticals, LLC issued 4,847,106 units of Series C convertible preferred units at $17.50 per unit for gross proceeds of $84.8 million. The net proceeds of this financing were $81.9 million after issuance costs of $2.9 million. In February 2020, Zentalis Pharmaceuticals, LLC issued 867,194 additional units of Series C preferred units under the Series C Preferred Agreement. The units were issued for $17.50 per unit for gross proceeds of $15.2 million. The net proceeds of this financing were $14.2 million after issuance costs of $1.0 million.

There were no authorized, issued, and outstanding shares of convertible preferred units at June 30, 2020. As of December 31, 2019, the authorized, issued, and outstanding units of convertible preferred units were as follows:

	December 31, 2019			
Series	Units Authorized	Units Issued and Outstanding	Liquidation Value	Carrying Value
Series A convertible preferred units	1,579,309	1,579,309	$ 18,319,984	$ 18,225,809
Series B convertible preferred units	3,523,739	3,523,739	43,800,076	41,603,945
Series C convertible preferred units	5,714,300	4,847,106	84,824,355	81,876,092
Total	10,817,348	9,950,154	$ 146,944,415	$ 141,705,846

During 2019, we reclassified the convertible preferred units from members' equity to temporary equity because, in conjunction with the Series C convertible preferred units issuance, all units were now deemed to contain contingent liquidation features that are not solely within our control. During the year ended December 31, 2019 and prior to the conversion of convertible preferred units into common stock in conjunction with our IPO on April 2, 2020, we did not adjust the carrying values of the convertible preferred units to the deemed redemption values of such units since a liquidation event was not probable.

Dividends

Dividends are payable if and when declared by the Board of Directors. No dividends have been declared prior to the conversion of convertible preferred units into common stock in conjunction with our IPO on April 2, 2020.

Conversion

Each Series A preferred unit, Series B preferred unit and Series C preferred unit was convertible at the option of the holder thereof, at any time after the issuance of such unit, into Class A common units at a conversion price equal to the original purchase price (subject to anti-dilution adjustments, discussed below) which was $11.60, $12.43 and $17.50 per unit, respectively. The convertible preferred units automatically converted at the then applicable conversion rate upon the closing of a firm commitment underwritten public offering of shares of a successor corporations' common stock, at a public offering price per share of equal to or greater than the Series C original purchase price (as adjusted for any stock splits, stock dividends, combinations or other similar recapitalization) resulting in aggregate gross cash proceeds of at least $75.0 million (a "Qualified IPO"). Additionally, the convertible preferred units would have automatically converted into common stock, at the then applicable conversion rate, upon written consent of a majority of the then outstanding Series A, Series B and Series C convertible preferred units (voting as a separate class on an as converted to Common Unit basis). In conjunction with our IPO on April 2, 2020, which constituted a Qualified IPO, all convertible preferred units were converted into common stock.

Anti-dilution protection

The holders of the convertible preferred unit had proportional anti-dilution protection for unit splits, unit dividends and similar recapitalizations. Subject to certain exclusions, anti-dilution price protection for additional sales of securities by us for consideration per unit less than the applicable conversion price per unit of any series of convertible preferred stock, was on a broad-based weighted average basis.

Protective rights

The holders of the convertible preferred units had certain protective rights, including, without limitation, regarding the authorization, alteration, redemption, or sale of Class B common units; commencement of a liquidation or deemed liquidation event; entrance into a joint venture or partnership; any incurrence of indebtedness; certain transactions that exceed a certain dollar threshold; changes to our governing documents; or the declaration of any dividends. Such actions were required to be approved by a majority of the then outstanding Series A, Series B and Series C convertible preferred unit holders (voting as a single class and on an as-converted basis), as specified in the amended and restated LLC agreement. An increase or decrease in the authorized number of Directors constituting the Board or the creation of a membership interest or equity security senior to or pari passu with Series C convertible preferred units was required to be approved by a majority of the then outstanding Series C convertible preferred Units (voting as a separate class on an as converted basis).

Redemption

The Series A, Series B and Series C convertible preferred units were not redeemable except in the event of certain effected deemed liquidation events. As of immediately prior to our IPO on April 2, 2020 and December 31, 2019, we had classified convertible preferred units as temporary equity in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events outside of our control, including liquidation, sale or transfer of control of the Company. We did not adjust the carrying value of the convertible preferred units to the deemed redemption values of such units since a liquidation event was not probable.

Liquidation preference

In the event of the dissolution, liquidation, merger or winding up of the Company, the holders of Series C convertible preferred units were entitled to receive, on a pro rata basis in respect of each such Series C convertible

preferred unit, a preference amount of $17.50 per Series C convertible unit (as adjusted for any unit splits, dividends, combinations, recapitalizations or the like).

Subsequent to the payment of the Series C convertible preferred unit preferences, Series A and Series B convertible preferred units were entitled to receive, on a pro rata basis in respect of each convertible preferred unit in proportion to the relative preference amount of each preferred unit, a preference amount of $11.60 and $12.43 per unit of Series A and Series B convertible preferred units (as adjusted for any units splits, dividend, combinations, recapitalizations of the like), respectively.

Subsequent to the payment of the Series C, Series A and Series B convertible preferred unit preferences, Series A, Series B and Series C convertible preferred units were entitled to receive, on an as converted to common unit pro rata basis, an amount equal to distributions made to Class A common units prior to all unit classes sharing in distributions on a pro rata basis. Thereafter, Series A, Series B and Series C convertible preferred units and Series A and Series B common units were entitled to receive the remaining assets of the Company available for distribution to its unit holders pro rata based on the number of common units held by each holder, treating for these purposes as if all units had been converted to common.

Voting Rights

The holders of all units other than Class B common units that were unvested were to vote together as a single class. Each holder of Series A, Series B and Series C convertible preferred units were entitled to the number of votes calculated on an as converted to Class A common unit basis.

9. Equity and Share-based Compensation

In November 2017, Zentalis Pharmaceuticals, LLC was formed in the state of Delaware. In conjunction with a corporate restructuring, Zeno Pharmaceuticals, Inc., a Delaware Corporation formed in 2014, was acquired by the Company pursuant to a merger agreement and became a wholly owned subsidiary of the Company. Per the terms of the merger agreement, each share of Zeno Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the merger was converted into the right to receive one Class A common unit and each share of Zeno Pharmaceuticals, Inc. Series A preferred stock issued and outstanding immediately prior to the effective date of the merger converted into the right to receive one Series A preferred unit. As of the effective time of the merger agreement, all outstanding options to purchase shares of Zeno Pharmaceuticals, Inc. common stock were cancelled and replaced with profit interest awards in the LLC.

In connection with the December 2017 corporate restructuring, we amended and restated the LLC agreement, and as amended, the capital units of the Company consisted of 1,638,000 authorized Series A preferred units, 3,621,000 authorized Series B preferred units, 15,000,000 authorized Class A common units and 872,620 authorized Class B common units.

Class A Common Units

In conjunction with the corporate restructuring in December 2017, 5,187,554 shares of common stock issued and outstanding and 406,831 shares of common stock subject to future vesting provisions of Zeno Pharmaceuticals, Inc. were converted into an equal number of Class A common units of Zentalis Pharmaceuticals, LLC. During the three months ended June 30, 2020 and 2019, we did not issue any Class A common units. As of June 30, 2020 and 2019, zero and 9,572 Class A common units were subject to future vesting conditions, respectively. During the year ended December 31, 2019, 7,093 Class A common units were issued and 9,572 Class A common units were subject to future vesting conditions. In September 2019, the number of authorized Class A common units was increased to 20,000,000.

Class B Common Units

In conjunction with the corporate restructuring in December 2017, 703,000 options exercisable into Zeno Pharmaceuticals, Inc. common stock were converted into an equal number of Class B common units of Zentalis Pharmaceuticals, LLC. In September 2019, the number of authorized Class B common units was increased to 3,458,522.

IPO

On April 2, 2020 and immediately prior to the effectiveness of the Company's IPO, Zentalis Pharmaceuticals, LLC converted from a Delaware limited liability company into a Delaware corporation pursuant to a statutory conversion, and changed its name to Zentalis Pharmaceuticals, Inc. In order to consummate the corporate conversion, a certificate of conversion was filed with the Secretary of State of the State of Delaware. All of the outstanding units of Zentalis Pharmaceuticals, LLC converted into shares of common stock of Zentalis Pharmaceuticals, Inc. based upon the value of Zentalis Pharmaceuticals, Inc. at the time of the IPO with a value implied by the price of the shares of common stock sold in the IPO. No cash or fractional shares of common stock were issued in connection with the corporate conversion. Based on the IPO price of $18.00 per share of common stock, all of the outstanding units converted into an aggregate of 25,288,854 shares of common stock (including 1,160,277 shares of restricted common stock).

In connection with the completion of the IPO, the board and stockholders approved the certificate of incorporation to provide for 250,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

On April 7, 2020, the Company completed an IPO in which the Company issued and sold 10,557,000 shares of common stock (including 1,377,000 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a price of $18.00 per share. The Company's aggregate gross proceeds from the sale of shares in the IPO, including the sale of shares pursuant to the full exercise of the underwriters' option to purchase additional shares, was $190.0 million before fees and expenses of $17.6 million.

Share-based Compensation

In the Company's 2017 Profit Interest Plan (the Plan) as approved and adopted by the Board of Directors on December 21, 2017, the Company was authorized to issue up to 3,458,522 shares of Class B common units, subject to restrictions as described in the Plan. The Plan was terminated in April 2020. In April 2020, the Company's board of directors adopted, and the Company's stockholders approved the 2020 Incentive Award Plan (the 2020 Plan), which became effective upon the corporate conversion. The number of common shares initially available for issuance under the 2020 Plan is 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.

During the six months ended June 30, 2020, the Company granted 70,000 Class B common units to employees and directors under the Plan. The weighted average fair value of incentive units granted in the six months ended June 30, 2020 was $3.06 per unit. In April 2020, each outstanding Class B common unit was converted into a number of shares of common stock and restricted common stock based upon the IPO price. The restricted common stock issued in respect of Class B common units continues to be subject to vesting in accordance with the vesting schedule that was applicable to such Class B common units. The Company granted 1,160,277 shares of restricted common stock to employees, consultants and directors as part of the conversion. From and after the IPO, Company also granted 1,970,671 stock options to purchase shares of common stock to employees and directors who were holders of Class B common units at the time of the incentive unit conversion and in new employee grants. The

weighted average fair value of stock options granted to employees and directors in the six months ended June 30, 2020 was $11.97 per share.

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,	
	2020	2019	2020	2019
Research and development expense	$ 2,291	$ 63	$ 2,426	$ 129
General and administrative expense	5,390	58	5,584	121
Total share-based compensation expense	$ 7,681	$ 121	$ 8,010	$ 250

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Profit Interest Award Units	$ —	$ 121	$ 329	$ 250
Stock Options	1,602	—	1,602	—
RSAs and RSUs	6,079	—	6,079	—
	$ 7,681	$ 121	$ 8,010	$ 250

The fair value of the Class B common unit awards was estimated using an option pricing model with the following assumptions:

	Six Months Ended June 30,	
	2020	2019
Members' equity value (in thousands)	$ 271,207	$ 197,041
Threshold amounts (in thousands)	$ 309,824	$ 143,800
Risk free rate	1.5 %	1.5 %
Volatility	75.0 %	75.0 %
Time to liquidity (in years)	1.1	1.3
Lack of marketability discount	26.5 %	1.9 %
Grant date fair value	$ 3.06	$ 1.88

The Black-Scholes-Merton option pricing model ("Black-Scholes model) is used to estimate the fair value of each Class B common unit award on the date of grant. The members' equity value was based on a recent enterprise valuation analysis performed. The threshold amounts are based on the discretion of the Board of Directors at the time of grant. The expected life of the Class B common unit awards granted during the period presented was determined based on an expected liquidation event under the plan. We applied the risk-free interest rate based on the U.S. Treasury yield in effect at the time of the grant consistent with the life of the award. The expected volatility was based on a peer group in the industry in which the Company does business consistent with the expected time to liquidity. The dividend yield was set at zero as the underlying security does not and is not expected to pay a dividend. The Finnerty model and the Asian Protective Put Model methods were used to estimate the discount for lack of marketability inherent to the awards.

The Class B common units issued have been classified as equity awards, and share-based compensation expense is based on the grant date fair value of the award. During the six months ended June 30, 2020 and 2019, we issued 70,000 and 91,000 Class B common units, respectively. As of June 30, 2020 and December 31, 2019, zero and approximately 1.7 million unvested Class B common units were outstanding, respectively.

The exercise price of stock options granted is equal to the closing price of the 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 three and six months ended June 30, 2020 was determined with the following assumptions:

	June 30, 2020
Expected volatility	77.5 %
Average expected term (in years)	6
Risk-free interest rate	0.5 %
Expected dividend yield	— %

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, 2020	
	Unrecognized Expense	Remaining Weighted-Average Recognition Period (years)
Stock options	$ 22,184	3.67
RSAs	3,030	2.97
RSUs	$ 22,273	1.38

During the six months ended June 30, 2020, we did not issue any shares of common stock in connection with the exercises of stock options. For the six months ended June 30, 2020, we issued 97,241 shares of common stock upon the vesting of certain RSAs. Stock options and unvested restricted awards totaling approximately 2.0 million shares and 1.1 million shares of our common stock were outstanding as of June 30, 2020.

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. 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.

Leases

Our commitments include payments related to operating leases. Approximate annual future minimum operating lease payments as of June 30, 2020 are as follows (in thousands):

Year	Operating Leases
2020	$ 512
2021	1,044
2022	661
2023	187
Total minimum lease payments:	2,404
Less: imputed interest	(303)
Total operating lease liabilities	2,101

The weighted-average remaining lease term of our operating leases is approximately 2.4 years. As of June 30, 2020, we had entered an additional lease for real estate that has not yet commenced with total minimum lease payments of approximately $23.1 million. This lease was expected to commence in the first quarter of 2021 and had a lease term of 10 years. In July 2020, we entered into the Lease Termination Agreement (as defined below) with respect to the lease. As consideration for the landlord’s agreement to enter into the Lease Termination Agreement and accelerate the expiration date of the term of the lease, we paid to the landlord a fee of approximately $0.9 million.

11. Net Loss Per Common Share/Class A Common Unit

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net loss attributable to Zentalis	$ (26,857)	$ (10,470)	$ (42,983)	$ (18,813)
Denominator:				
Weighted average number of common shares/Class A common units outstanding, basic and diluted	34,353	5,601	16,978	5,601
Net loss per common share	$ (0.78)	$ —	$ (2.53)	$ —
Net loss per Class A common unit	$ —	$ (1.87)	$ —	$ (3.36)

Our potential and dilutive securities, which include outstanding stock options, unvested RSAs, unvested RSUs and preferred units, have been excluded from the computation of diluted net loss per common share/Class A common unit as the effect would be anti-dilutive. We considered the impact of presenting a separate earnings per unit calculation for Class B common units. However, as earnings and losses are only allocable to Class B common units after the applicable threshold has been met, and such thresholds have not been met for earnings per unit purposes, no losses were allocated to Class B common units.

The following common stock/Class A common unit equivalents have been excluded from the calculations of diluted net loss per common share/Class A common unit because their inclusion would be antidilutive (in thousands).

	June 30,	
	2020	2019
Preferred units, as if converted to Class A common units	—	5,103
Incentive units—Class B common units	—	1,669
Outstanding stock options	1,986	—
Unvested RSAs	1,063	—
Unvested RSUs	1,146	—
	4,195	6,772

12. Related Party Disclosures

On December 21, 2017, we acquired 17,307,692 shares of Series B preferred stock of Kalyra for a per share price of twenty-six cents ($0.26) or approximately $4.5 million. The management team and stockholders of Kalyra are also stockholders of the Company.

Prior to the investment, we entered into a license agreement and a master services agreement with Kalyra. The license agreement was signed and commenced on December 31, 2014 for the exclusive rights to develop and commercialize products derived from Kalyra's technology in the initial area of oncology. The license agreement and all rights were subsequently sold from Kalyra to Recurium IP Holdings, LLC ("Recurium IP"), an entity with

common ownership to Kalyra prior to the Zentalis investment. Under the agreement, we have agreed to make payments to Recurium IP based on specific milestones and based on Recurium Equity, LLC's equity ownership stake in us at the time the milestone is earned. Recurium Equity, LLC ("Recurium Equity") is also an entity with common ownership to Kalyra prior to the Zentalis investment. In addition, the Company shall pay low to mid-single digit percentage royalties on net product sales to Recurium IP and sublicense fees on any consideration paid to us by a sublicensor. The royalty payments are also based on Recurium Equity's then equity ownership in us. The license agreement will terminate upon the later of the last expiration of the patent rights or 15 years from the date of commencement.

The Master Services Agreement was entered into in January 2015 and states that Kalyra may provide research and development services to us and that we shall reimburse such expenses on a time and materials basis based on the initial statements of work. For each of the three months ended June 30, 2020 and 2019, we did not incur any expense wth Kalyra. For the six months ended June 30, 2020 and 2019, we incurred approximately seventeen thousand and five thousand dollars of expense with Kalyra, respectively, that was eliminated in consolidation for research and development services provided. As of June 30, 2020 and 2019, there was no balance due to Kalyra.

We entered into an Intercompany Services Agreement with Kalyra in January 2018 which states that we may provide research and development services to Kalyra and that Kalyra shall reimburse such expenses on a time and materials basis. For each of the three months ended June 30, 2020 and 2019, we provided $0.1 million of research and development services to Kalyra that we eliminated in consolidation. For the six months ended June 30, 2020 and 2019, we provided $0.2 million and $0.3 million of research and development services to Kalyra that was eliminated in consolidation, respectively. As of June 30, 2020 and 2019, $0.1 million and $0.4 million was due from Kalyra and eliminated in consolidation, respectively.

On June 1, 2020, we entered into an equipment purchase and sale agreement with Kalyra to purchase $0.4 million of equipment and related tangible assets to be used in our operations. As of June 30, 2020, there was no balance due to Kalyra for the transaction.

13. Subsequent Events

Lease Termination

On July 14, 2020, Zeno Management, Inc. ("Zeno"), a wholly-owned subsidiary of the Company, entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises with ARE-SD Region No. 44, LLC ("Landlord") for certain premises located at 10578 Science Center Drive, San Diego, California (the "Lease Termination Agreement "). The Lease Termination Agreement provides that the Lease Agreement, dated as of January 14, 2020, by and between Zeno and Landlord (as the same may have been amended, the "Lease") will terminate provided that Landlord enters into a lease agreement with a new tenant on or before August 7, 2020 (the "Condition Precedent"). On July 27, 2020, Landlord delivered notice to Zeno that the Condition Precedent had been satisfied and that the Lease has been terminated as of July 27, 2020.

As consideration for Landlord's agreement to enter into the Lease Termination Agreement and accelerate the expiration date of the term of the Lease to the date the Condition Precedent is satisfied, Zeno paid to Landlord a fee of approximately $0.9 million.

Eli Lilly and Company Clinical Trial Collaboration and Supply Agreement

In July 2020, we entered into a clinical trial collaboration and supply agreement with Eli Lilly and Company ("Lilly"), to evaluate the safety, tolerability and efficacy of ZN-c5 in combination with their CDK4/6 inhibitor, abemaciclib, in a Phase 1b open label multi-center clinical trial that we intend to initiate in the second half of 2020. Pursuant to this agreement, we will be responsible for the conduct and cost of the relevant studies. Lilly is obligated to supply abemaciclib for use in the trial, at no cost to us.

Follow-On Public Offering

On August 3, 2020, pursuant to its registration statement on Form S-1 (Registration No. 333-240115), as amended, filed with the SEC on July 27, 2020, the Company completed a follow-on offering of its common stock. The Company issued and sold 4,125,000 shares of its common stock at a public offering price of $35.00 per share, resulting in net proceeds of approximately $135.0 million, after deducting estimated underwriting discounts and commissions. The Company granted the underwriters an option for a period of 30 days to purchase up to 618,750 additional shares of common stock.

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 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 final prospectus, dated July 29, 2020, filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b)(4) relating to our registration statement on Form S-1 (Registration No. 333-240115), as amended (the "Follow-On Prospectus"). 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 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 use our highly efficient drug discovery engine, which we refer to as our "Integrated Discovery Engine," to identify targets and develop small molecule new chemical entities, or NCEs, with properties that we believe could result in potentially differentiated product profiles. Our discovery engine combines our extensive experience and capabilities across cancer biology and medicinal chemistry. We believe our product candidates are differentiated from current programs targeting similar pathways and have the potential to significantly impact the lives of patients with cancer.

We are developing a broad pipeline of product candidates with an initial focus on validated oncology targets with the potential to address large patient populations. Our lead product candidate, ZN-c5, is an oral selective estrogen receptor degrader, or SERD, currently in a Phase 1/2 clinical trial for the treatment of estrogen receptor-positive, human epidermal growth factor receptor 2-negative, or ER+/HER2-, advanced or metastatic breast cancer. We have designed ZN-c5 to have high potency and selectivity, as well as favorable tolerability and pharmacokinetic, or PK, properties. We intend to initiate the Phase 2 monotherapy and combination (with palbociclib) portions of this Phase 1/2 trial in the first half of 2021. In addition, we plan to initiate a Phase 1b open label, multi-center trial evaluating ZN-c5 in combination with abemaciclib (marketed as Verzenio ® by Lilly) in patients with ER+/HER2- advanced or metastatic breast cancer in the second half of 2020 as part of a clinical research collaboration with Lilly. Abemaciclib is a CDK 4/6 inhibitor FDA approved for the treatment of HR+/HER2- advanced or metastatic breast cancer in combination with fulvestrant, aromatase inhibitors or as a single agent in certain patients with disease progression following treatment with prior endocrine therapy or chemotherapy regimens. We also intend to initiate, subject to feedback from the FDA, a Phase 2/3 clinical trial evaluating ZN-c5 in earlier stage breast cancer patients in 2021 and to initiate a Phase 1b clinical trial evaluating ZN-c5 in combination with ZN-d5, our BCL-2 inhibitor product candidate, in patients with ER+/HER2- breast cancer in 2021. Our other product candidates include ZN-c3, an inhibitor of WEE1, a protein tyrosine kinase, currently in a Phase 1/2 clinical trial for the treatment of advanced solid tumors; ZN-d5, a selective inhibitor of B-cell lymphoma 2, or BCL-2, initially in development for the treatment of hematological malignancies; and ZN-e4, an irreversible inhibitor of epidermal growth factor receptor, or EGFR, currently in a Phase 1/2 clinical trial for the treatment of advanced non-small cell lung cancer, or NSCLC. We expect to report topline results from the Phase 1 portion of the ongoing trials of each of ZN-c3 and ZN-e4 in 2021, and to initiate a Phase 1 clinical trial of ZN-d5 in patients with acute myeloid leukemia, or AML, or B-cell

lymphoma in the first half of 2021. In addition, we plan to initiate a Phase 1b clinical trial evaluating ZN-c3 in combination with chemotherapy in patients with advanced ovarian cancer in the second half of 2020 and a Phase 2 trial evaluating ZN-c3 as monotherapy in patients with uterine serous carcinoma, or USC, in 2021. USC comprises 10%, and has the highest mortality rate, of all endometrial cancers, with approximately 6,000 new cases and 4,500 deaths in the United States per year. We continue to actively evaluate other potential combinations for the future clinical development of ZN-c3, and intend to initiate two additional Phase 1 clinical trials evaluating ZN-c3 in combination with chemotherapy and PARP inhibitors in ovarian cancer and other targeted indications in 2021. In addition, we intend to initiate a Phase 1b clinical trial evaluating ZN-d5 in combination with ZN-c5, our oral SERD product candidate in patients with ER+/HER2- breast cancer in 2021. We currently own worldwide development and commercialization rights to each of our product candidates, other than in select Asian countries (including China) for each of ZN-c5, ZN-c3 and ZN-d5, for which we have out-licensed these rights to our majority-owned joint venture, Zentera Therapeutics (Cayman), Ltd., or Zentera, and for ZN-e4 for which we have out-licensed these rights to SciClone Pharmaceuticals International (Cayman) Development Ltd.

We are also currently advancing multiple small molecule programs in preclinical development for other cancer indications, including select solid tumors and hematological malignancies. We are now in lead optimization for our fifth product candidate and plan to submit an investigational new drug application, or IND, to the FDA in 2021.

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. On April 7, 2020, we completed our initial public offering, or IPO, and issued and sold approximately 10.6 million shares of our common stock at a public offering price of $18.00 per share, including approximately 1.4 million shares in connection with the full exercise of the underwriters' option to purchase additional shares, resulting in net proceeds of approximately $172.4 million, after deducting underwriting discounts and commissions and offering expenses. On August 3, 2020, pursuant to our registration statement on Form S-1 (Registration No. 333-240115), as amended, filed with the SEC on July 27, 2020, we completed a follow-on offering of our common stock and issued and sold 4,125,000 shares of our common stock at a public offering price of $35.00 per share, resulting in net proceeds of approximately $135.0 million, after deducting estimated underwriting discounts and commissions and offering expenses. The Company granted the underwriters an option for a period of 30 days to purchase up to 618,750 additional shares of common stock.

We had cash, cash equivalents and marketable securities of $233.2 million as of June 30, 2020. We believe that our existing cash, cash equivalents and marketable securities as of June 30, 2020, together with the net proceeds from our August 2020 follow-on offering, will enable us to fund our operating expenses and capital expenditure requirements into 2023. 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.

Since inception, we have incurred significant operating losses. Our net losses were $46.4 million for the year ended December 31, 2019, and $43.5 million and $19.3 million for the six months ended June 30, 2020 and June 30, 2019, respectively. Our net losses were $27.3 million and $10.6 million for the three months ended June 30, 2020 and June 30, 2019, respectively. We had an accumulated deficit of $126.0 million as of June 30, 2020. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our commercialization capabilities to support product sales, marketing and distribution activities, either alone or in collaboration with others. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

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. 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.

Corporate Conversion

In connection with our IPO, we converted from a Delaware limited liability company into a Delaware corporation pursuant to a statutory conversion, and changed our name from Zentalis Pharmaceuticals, LLC to Zentalis Pharmaceuticals, Inc. We refer to all transactions related to our conversion to a corporation as the Corporate Conversion. As a result of the Corporate Conversion, all holders of units of Zentalis Pharmaceuticals, LLC became holders of shares of common stock of Zentalis Pharmaceuticals, Inc.

In connection with the Corporate Conversion, our outstanding Series A convertible preferred units, Series B convertible preferred units, Series C convertible preferred units, Class A common units and Class B common units, or Units, converted into an aggregate of 25,288,854 shares of our common stock (including 1,160,277 shares of restricted common stock) based on the IPO price of $18.00 per share of common stock.

Impact of COVID-19 Pandemic

We continue to monitor the COVID-19 pandemic is affecting our employees, business, preclinical studies and clinical trials. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. Disruptions caused by the COVID-19 pandemic have resulted in difficulties including delays in initiating new trial sites and certain supply chain activities, suspension of enrollment at some of our existing trial sites, and the incurrence of additional costs as a result of preclinical study and clinical trial delays and adjustments. Limited operations at our laboratory facilities have also resulted in delays in our research-stage programs. As a result, we expect that the COVID-19 pandemic will continue to impact our business, results of operations, clinical development timelines and financial condition. At this time, there is significant uncertainty relating to the trajectory of the COVID-19 pandemic and impact of related responses. The impact of COVID-19 on our future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the continued impact on financial markets and the global economy, and the effectiveness of the global response to contain and treat the disease. See “Risk Factors— The outbreak of the novel coronavirus disease, COVID-19, has adversely impacted and we expect will continue to adversely impact our business, including our preclinical studies and clinical trials.” in Part II, Item 1.A. of this Quarterly Report on Form 10-Q.

License Agreements and Strategic Collaboration Agreements

Recurium IP Holdings, LLC

In December 2014, and as amended and restated effective as of December 2017 and September 2019 and as amended in May 2020, we entered into a license agreement, or the Recurium Agreement, with Recurium IP Holdings, LLC, or Recurium IP, under which we were 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 pain. In connection with the May 2020 amendment, we clarified certain aspects of the sublicensing payment provisions. We have the right to sublicense our rights under the Recurium Agreement, subject to certain conditions. We are required to use commercially reasonable efforts to develop and commercialize at least one product that comprises or contains a licensed compound and to execute certain development activities.

Our payment obligations under the Recurium Agreement are based on the percentage of ownership interest Recurium Equity, LLC, an affiliated company of Recurium IP, has in us. Under the terms of the Recurium

Agreement, we are obligated to make development and regulatory milestone payments, pay royalties for net sales and make sublicensing payments with respect to certain licensed products directed to one of ten specific biological targets, including ZN-c5, ZN-c3 and ZN-e4. We are obligated to make development and regulatory milestone payments for such licensed products of up to $44.5 million if Recurium Equity, LLC has less than 10% ownership percentage of us, or up to $21.5 million if the ownership percentage is 10% or more but no more than 15%. If the percentage of ownership interest Recurium Equity, LLC has in us is greater than 15% then no development and regulatory milestone payments will be due. In addition, we are obligated to make milestone payments up to $150,000 for certain licensed products used in animals. We are also obligated to pay royalties on sales of such licensed products at a mid- to high-single digit percentage if Recurium Equity, LLC's ownership percentage in us is less than 10%, at a mid-single digit percentage if such ownership percentage is 10% or more but no more than 15%, and at a low-single digit percentage if such ownership percentage is above 15%. In addition, if we choose to sublicense or assign to any third parties our rights under the Recurium Agreement with respect to such licensed products, we must pay to Recurium IP 20% of sublicensing income received in connection with such transaction if Recurium Equity, LLC has less than 10% ownership percentage of us, or a percentage of 10% if the ownership percentage is 10% or more but no more than 15%. If the percentage of ownership interest Recurium Equity, LLC has in us is greater than 15% then no sublicensing payments will be due. Upon the closing of our August 2020 follow-on offering, Recurium Equity, LLC's ownership interest in us was 10.4%, requiring potential payment of aggregate development and regulatory milestone payments of $21.5 million and royalties of mid-single digit percentage on sales of the relevant licensed products.

Mayo Foundation for Medical Education and Research

In February 2016, and as amended in April 2017 and December 2017, we entered into an option agreement, or the Mayo Agreement, with Mayo Foundation for Medical Education and Research under which we were granted an exclusive option to obtain a nonexclusive worldwide license to know-how and an exclusive worldwide license related to patent rights created by Mayo under the Mayo Agreement. We have the right to sublicense our rights under the Mayo Agreement, subject to certain conditions. We are required to use commercially reasonable efforts to develop and commercialize licensed products. Under the terms of the Mayo Agreement, we are obligated to pay royalties on sales for each licensed product at a low-single digit percentage as well as grants of equity interests to be negotiated on a case-by-case basis. In addition, in consideration for the grant of know-how we provided grants of common stock on the first anniversary and Class A common units on the second and third anniversaries following entry into the Mayo Agreement. As of June 30, 2020, we have granted equity securities which amount to 15,435 shares of common stock under the Mayo Agreement. The Mayo Agreement will expire on the date of the last to expire of the Mayo patent rights or, if no Mayo patent rights arise, on February 11, 2021. As of the date of this filing, no Mayo patent rights have been created under the Mayo Agreement. The Mayo Agreement may be terminated in its entirety or in part by Mayo in the event of an uncured material breach by us, in the event that we bring suit against Mayo, except for an uncured material breach of the Mayo Agreement by Mayo, or in the event we are subject to specified bankruptcy, insolvency or similar circumstances.

SciClone Pharmaceuticals International (Cayman) Development Ltd.

In December 2014, and as amended in December 2016 and December 2017, we entered into a collaboration and license agreement, or the SciClone Agreement, with SciClone Pharmaceuticals International (Cayman) Development Ltd., or SciClone, under which we granted an exclusive license certain intellectual property rights in the People's Republic of China (including the territories of Macao and Hong Kong), South Korea, Taiwan and Vietnam, or the SciClone Territory, for SciClone to develop and commercialize a licensed product for the treatment or prevention of oncologic diseases and an exclusive option to obtain a similar license for up to two additional licensed products. Under the SciClone Agreement, SciClone is responsible for clinical development activities required in order to obtain regulatory approval in the SciClone Territory. SciClone paid to us a one-time upfront payment of $1.0 million upon entering into the SciClone Agreement, and $4.0 million in aggregate milestone payments. No additional development or commercial milestones or reimbursement for research and development expenses are payable under the SciClone Agreement, as amended. We are entitled to receive a mid-single digit royalty on net sales of licensed products in the SciClone Territory, which royalty is subject to certain reductions in the event that SciClone is unable to achieve certain gross margins or if generic products are sold or if technology covering a licensed product is

licensed from a third party. We have also agreed to pay SciClone tiered royalties pursuant to the terms of the SciClone Agreement, the applicable rate of which are determined based on whether a compound is developed to a successful dual IND submission and the costs incurred by SciClone for the development of such product candidate. Following the December 2016 amendment to the SciClone Agreement, SciClone retains the exclusive license to develop and commercialize our EGFR inhibitor product candidate, ZN-e4, in the SciClone Territory, and the exclusive option to obtain an exclusive license to develop up to two specified compounds under the SciClone Agreement for which we submit an IND by providing notice and paying $5 million to us. SciClone's and our royalty obligations will expire on a licensed product-by-licensed product and country-by-country basis on the later of fifteen years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product in such country.

Pfizer Clinical Trial Collaboration and Supply Agreement

In May 2018, we entered into a clinical trial collaboration and supply agreement with Pfizer, Inc. to evaluate the safety, tolerability and efficacy of ZN-c5 in combination with their CDK4/6 inhibitor, palbociclib, in our ongoing Phase 1/2 clinical trial of ZN-c5. Pursuant to this agreement, we will be 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 Pfizer that meets quarterly. Pfizer will supply palbociclib for use in the trial, at no cost to us.

Eli Lilly and Company Clinical Trial Collaboration and Supply Agreement

In July 2020, we entered into a clinical trial collaboration and supply agreement with Eli Lilly and Company, or Lilly, to evaluate the safety, tolerability and efficacy of ZN-c5 in combination with their CDK4/6 inhibitor, abemaciclib, in a Phase 1b open label multi-center clinical trial that we intend to initiate in the second half of 2020. Pursuant to this agreement, we will be responsible for the conduct and cost of the relevant studies. Lilly is obligated to supply abemaciclib for use in the trial, at no cost to us. We are required to provide to Lilly clinical data and other reports at major decision points during the trial and no later than 60 days following completion of the planned Phase 1b clinical trial.

This agreement does not grant any right of first negotiation to participate in future clinical trials, and each of the parties retains all rights and ability to evaluate their respective compounds in any clinical studies, either as monotherapy or in combination with any other product or compound, in any therapeutic area.

The agreement with Lilly will expire upon completion of all obligations of the parties thereunder or upon termination by either party. We and Lilly 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. Lilly also has the right to terminate this agreement if it notifies us in writing that it reasonably and in good faith believes that abemaciclib 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

In May 2020, each of our subsidiaries Zeno Alpha, Inc., K-Group Alpha, Inc. and K-Group Beta, Inc. entered into a collaboration and license agreement with our majority-owned joint venture, Zentera Therapeutics (Cayman), Ltd., or Zentera (the "Zentera Sublicenses"), pursuant to which we collaborate with Zentera on the development and commercialization of ZN-c5, ZN-d5 and ZN-c3, respectively, whether alone or in a licensed product ("Collaboration Products"), in each case for the treatment or preventions of disease, other than for pain (the "Zentera Field"), in the People's Republic of China, Macau, Hong Kong and Taiwan (the "Zentera Collaboration Territory"). Under each Zentera Sublicense, Zentera will lead development, and upon regulatory approval, the commercialization, of the Collaboration Products in the Zentera Collaboration Territory. On May 19, 2020, Zentera issued an aggregate of 60.2% of its issued shares of common stock to Zeno Alpha, Inc., K-Group Alpha, Inc., K-Group Beta, Inc., Zeno Management, Inc. and Zeno Beta, Inc. Anthony Y. Sun, M.D., our President and Chief Executive Officer, serves as

Chief Executive Officer and a member of the board of directors of Zentera and Kevin D. Bunker, Ph.D, our Chief Operating Officer, serves as a member of the board of directors of Zentera.

Under each Zentera Sublicense, we granted Zentera an exclusive, royalty-bearing license under certain of our technology, including technology licensed from Recurium under the Recurium Agreement, to develop and commercialize the Collaboration Products in the Zentera Field and in the Zentera Collaboration Territory, subject to certain rights that we retain, and upon a successful manufacturing transfer, a non-exclusive license under certain of our manufacturing technology to manufacture Collaboration Products in the Zentera Field and in the Zentera Collaboration Territory. Zentera has the right to sublicense its rights under the Zentera Sublicenses subject to certain conditions.

Under the terms of the Zentera Sublicenses, Zentera is responsible for the costs of developing the Collaboration Products in the Zentera Collaboration Territory, and we are responsible for the costs of developing the Collaboration Products outside the Zentera Collaboration Territory, provided that Zentera will 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 Collaboration Product. Under the Zentera Sublicenses, we will be eligible to receive future development and regulatory milestones based upon Recurium Equity LLC's aggregate direct or indirect ownership percentage of the furthest down-stream sublicensee which is an affiliate of Zeno Management, Inc. of the applicable Collaboration Product (such ownership percentage, the "Recurium Equity Percentage"). At the Recurium Equity Percentages of less than 10%, and 10% but no more than 15%, we will be eligible to receive development and regulatory milestones of up to $4.45 million and $2.15 million per Collaboration Product, respectively. If the Recurium Equity Percentage is greater than 15%, then no development and regulatory milestone payments will be due. Zentera will pay us royalties on net sales of Collaboration Products in the Zentera Collaboration Territory at a mid- to high-single digit percentage if the Recurium Equity Percentage is less than 10%, at a mid-single digit percentage if the Recurium Equity Percentage is 10% or more but no more than 15%, and at a low-single digit percentage if the Recurium Equity Percentage is above 15%, in each subject to certain reductions. In addition, if Zentera or its affiliate chooses to sublicense or assign to any third parties its rights under the Zentera Sublicenses with respect to any Collaboration Product, Zentera must pay to us 20% of sublicensing income received by Zentera or its affiliates in connection with such transaction if the Recurium Equity Percentage is less than 10%, or a percentage of 10% if the Recurium Equity Percentage is 10% or more but no more than 15%. If the Recurium Equity Percentage is greater than 15% then no sublicensing payments will be due.

Zentera's royalty obligations will expire on a Collaboration Product-by-Collaboration Product and region-by-region basis upon the later of the date on which such product is no longer covered by a valid claim of a licensed patent and the 15th anniversary of the first commercial sale of such product in such region.

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

- 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 government grant 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, 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 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
ZN-c5	$ 6,180	$ 2,148	$ 10,873	$ 3,154
ZN-c3	2,520	1,408	4,161	2,495
ZN-d5	1,412	1,160	2,679	1,974
ZN-e4	274	1,646	1,027	2,216
Unallocated research and development expenses	7,003	2,327	11,907	5,939
Total research and development expenses	$ 17,452	$ 8,689	$ 30,710	$ 15,778

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. 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 as a result of the COVID-19 pandemic;
- 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; and
- 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; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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 increased research and development activities relating to ZN-c3, ZN-c5, ZN-d5, ZN-e4, and any other product candidate we may develop. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Interest Income

Interest income consists of interest earned on cash, cash equivalents and available-for-sale marketable securities. We expect our interest income to increase due to the net proceeds from our IPO and August 2020 follow-on offering.

Income Taxes

Since our inception in December 2014, our corporate subsidiaries have generated cumulative federal and state net operating loss for which we have not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within their respective carryforward periods.

Net Loss Attributable to Noncontrolling Interest

Since December 21, 2017, the date of our initial investment in Kalyra Pharmaceuticals, Inc., or Kalyra, we have consolidated the financial results of our affiliate, Kalyra. Although we do not have a controlling interest in Kalyra, we determined that Kalyra was a variable interest entity, of which we were the primary beneficiary. For more information on the treatment of Kalyra as a variable interest entity, please see Note 3 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

On May 19, 2020, our majority-owned subsidiary, Zentera, closed a Series A financing resulting in net proceeds of approximately $18.4 million after deducting offering costs. We have a controlling interest in Zentera and have consolidated the financial results of Zentera into our consolidated financial statements.

Results of Operations

Comparison of Three Months Ended June 30, 2020 to Three Months Ended June 30, 2019

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)
	2020	2019	
	(in thousands)		
Operating expenses			
Research and development	$ 17,452	$ 8,689	$ 8,763
General and administrative	9,924	1,946	7,978
Total operating expenses	27,376	10,635	16,741
Loss from operations	(27,376)	(10,635)	(16,741)
Investment and other income, net	84	49	35
Other expense	—	—	—
Net loss before income taxes	(27,292)	(10,586)	(16,706)
Income tax expense	—	11	(11)
Net loss	(27,292)	(10,597)	(16,695)
Net loss attributable to noncontrolling interest	(435)	(127)	(308)
Net loss attributable to Zentalis	$ (26,857)	$ (10,470)	$ (16,387)

Revenue

We did not generate any revenue for the three months ended June 30, 2020 and June 30, 2019.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2020 were $17.5 million, compared to $8.7 million for the three months ended June 30, 2019. The increase of $8.8 million was primarily due to increases in external research and development expenses related to our lead product candidates, as we advanced our Phase 1/2 clinical trials for ZN-c5 and ZN-c3. In addition, in the three months ended June 30, 2020, we conducted additional preclinical studies, incurred additional manufacturing costs, and incurred increased costs for study and lab materials. Unallocated research and development expenses increased by $4.8 million primarily due to $3.3 million of additional employee related costs associated with increased headcount to support our platform development, $0.6 million of outside services, $0.6 million of facilities and other allocable overhead expenses and reduced grant reimbursements of $0.3 million.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2020 were $9.9 million, compared to $1.9 million during the three months ended June 30, 2019. This increase of $8.0 million was primarily attributable to an increase of $5.9 million in employee-related costs of which $5.2 million was driven by non-cash stock-based compensation from incentive grants issued during the quarter and increased headcount to support our growth. Professional service fees for legal, accounting and consulting services increased $1.0 million to support the increased operations of the organization, insurance costs increased by $0.7 million related to operating as a public company, and facilities and other allocable overhead expenses increased by $0.4 million.

Investment and Other Income, Net

Investment and other income was $0.1 million for the three months ended June 30, 2020, compared to a nominal amount for the three months ended June 30, 2019. The increase was the result of interest earned on higher invested cash and marketable securities balances.

Comparison of Six Months Ended June 30, 2020 to Six Months Ended June 30, 2019

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

	Six Months Ended June 30,		
	2020	2019	Increase (Decrease)
		(in thousands)	
Operating expenses			
Research and development	$ 30,710	15,778	$ 14,932
General and administrative	13,065	3,579	9,486
Total operating expenses	43,775	19,357	24,418
Loss from operations	(43,775)	(19,357)	(24,418)
Investment and other income, net	248	111	137
Net loss before income taxes	(43,527)	(19,246)	(24,281)
Income tax expense	—	14	(14)
Net loss	(43,527)	(19,260)	(24,267)
Net loss attributable to noncontrolling interest	(544)	(447)	(97)
Net loss attributable to Zentalis	$ (42,983)	(18,813)	$ (24,170)

Revenue

We did not generate any revenue for the six months ended June 30, 2020 and June 30, 2019.

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2020 were $30.7 million, compared to $15.8 million for the six months ended June 30, 2019. The increase of $14.9 million was primarily due to increases in external research and development expenses related to our lead product candidates, as we advanced our Phase 1/2 clinical trials for ZN-c5 and ZN-c3. In addition, in the six months ended June 30, 2020, we conducted additional preclinical studies, incurred additional manufacturing costs, and incurred increased costs for study and lab materials. Unallocated research and development expenses increased by $6.1 million primarily due to $5.1 million of additional employee related costs, of which $1.8 million was driven by non-cash stock-based compensation from incentive grants issued during the quarter and increased headcount to support our platform development, and $0.7 million was attributable to increased facilities and other allocable overhead expenses.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2020 were $13.1 million, compared to $3.6 million during the six months ended June 30, 2019. This increase of $9.5 million was primarily attributable to an increase of $6.5 million in employee-related costs of which $5.3 million was driven by non-cash stock-based compensation from incentive grants issued during the quarter and increased headcount to support our growth. Professional service fees for legal, accounting and consulting services increased $2.0 million to support the increased operations of the organization, insurance costs increased by $0.6 million related to operating as a public company, and facilities and other allocable overhead expenses increased by $0.4 million.

Investment and Other Income, Net

Investment and other income was $0.2 million for the six months ended June 30, 2020, compared to $0.1 million for the six months ended June 30, 2019. The increase of $0.1 million was the result of interest earned on higher invested cash and marketable securities balances.

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 economic downturn and ongoing uncertainty related to the COVID-19 pandemic. The COVID-19 pandemic has and could continue to adversely affect the economies and financial markets of the global economy, resulting in an economic downturn that could also affect our operations, our ability to conduct our clinical trials, our ability to raise additional funds through public offerings and the volatility of our stock price and trading in our stock. Even after the COVID-19 pandemic has subsided, we expect

we will continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future. 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, 2020, we raised a total of $162.1 million in gross proceeds from the sale of shares of our Series A, B and C convertible preferred units. On April 7, 2020, we completed our IPO and issued and sold approximately 10.6 million shares of our common stock including approximately 1.4 million shares in connection with the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $18.00 per share, resulting in net proceeds of approximately $172.4 million, after deducting the underwriting discounts and commissions and estimated offering expenses. As of June 30, 2020, we had $96.0 million in unrestricted cash and cash equivalents, $137.2 million in marketable securities, and an accumulated deficit of $126.0 million. We had no indebtedness as of June 30, 2020.

On August 3, 2020, we completed a follow-on offering of our common stock and issued and sold approximately 4.1 million shares of our common stock at a public offering price of $35.00 per share, resulting in net proceeds of approximately $135.0 million, after deducting estimated underwriting discounts and commissions and offering expenses. The Company granted the underwriters an option for a period of 30 days to purchase up to 618,750 additional shares of common stock.

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (38,904)	$ (15,964)
Net cash used in investing activities	(137,292)	(209)
Net cash provided by financing activities	205,134	—
Net increase/(decrease) in cash and cash equivalents	$ 28,938	$ (16,173)

Operating Activities

We have incurred losses since inception. Net cash used in operating activities for the six months ended June 30, 2020 was $38.9 million, consisting primarily of our net loss of $43.5 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses, increased by changes in operating assets and liabilities of $3.5 million, and partially offset by non-cash adjustments of $7.9 million.

Net cash used in operating activities for the six months ended June 30, 2019 was $16.0 million, consisting primarily of our net loss of $19.3 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses, partially offset by changes in operating assets and liabilities of $3.0 million and non-cash adjustments of $0.3 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2020 of $137.3 million was attributable to the net investment of excess cash of $137.2 million and the purchases of property and equipment of fifty-six thousand.

Net cash used in investing activities for the six months ended June 30, 2019 was $0.2 million consisting of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities in the six months ended June 30, 2020 of $205.1 million primarily relates to net proceeds from the completion of our initial public offering of $172.5 million, the issuance of our Series C convertible preferred units of $14.2 million and contributions from noncontrolling interest owners of $18.4 million.

There were no cash flows from financing activities in the six months ended June 30, 2019.

Funding Requirements

Our operating expenses have increased substantially in 2019 and to date in 2020 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 ZN-c5, ZN-c3 and ZN-e4 for the treatment of oncology indications;
- pursue the preclinical and clinical development of other current and future research programs and product candidates, including ZN-d5;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel in research, manufacturing and regulatory and clinical development as well as management personnel;
- seek regulatory approval for any 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, 2020, together with the net proceeds from our August 2020 follow-on offering, will enable us to fund our operating expenses and capital expenditure requirements into 2023. 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 ZN-c5, ZN-c3 and ZN-e4;

- the progress, costs and results of additional research and preclinical studies in ZN-d5 and other research programs we initiate in the future;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs 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; and
- 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.

In addition, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements is uncertain as of the filing date of this Quarterly Report on Form 10-Q, as the pandemic continues to evolve globally. We have considered and will continue to consider the availability of relief provided by such legislative actions as the Families First Act and the CARES Act, and have opted to pursue certain, but not all measures including the deferral of employer payroll taxes, but not including Payroll Protection Plan loans. See "Impact of COVID-19 Pandemic" above and "Risk Factors— The outbreak of the novel coronavirus disease, COVID-19, has adversely impacted and we expect will continue to adversely impact our business, including our preclinical studies and clinical trials." in Part II, Item 1A. of this Quarterly Report on Form 10-Q for a further discussion of the potential impact of the COVID-19 pandemic on our business.

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, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements and marketing and distribution arrangements.

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.

Contractual Obligations

The disclosure reported in "Contractual Obligations" in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Follow-On Prospectus contains a table summarizing our contractual obligations and commitments as of December 31, 2019. During the period ended June 30, 2020, there

were no material changes to our principal contractual obligations, other than exclusion of certain laboratory space from our operating lease obligations as reported in our Follow-On Prospectus.

Critical Accounting Policies and Use of Estimates

There have been no significant changes to our critical accounting policies from our disclosure reported in "Critical Accounting Policies and Estimates" in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our final prospectus, dated April 2, 2020, filed with the SEC pursuant to Rule 424(b) relating to our registration statement on Form S-1 (Registration No. 333-236959), as amended, filed in connection with our IPO, except as described in Note 2 to the interim unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards; and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, or December 31, 2025, (b) in which we have total annual gross revenues of $1.07 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common stock held by non-affiliates exceeds $700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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.

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 Chief Executive Officer and Chief 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 Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

Changes in Internal Control over Financial Reporting

During the three months ended June 30, 2020, we implemented an integrated accounting and consolidation system. The implementation involved changes in processes and systems that required changes to our system of internal controls.

We reviewed the system as it was being implemented and the controls affected by the implementation of the new system and made appropriate changes to the affected internal controls during the implementation process.

Other than the described above, 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, 2020 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 unaudited 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. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. 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 factors, including those set forth below.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, have not completed any clinical trials, 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 Phase 1/2 clinical trials of ZN-c5, ZN-c3 and ZN-e4. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product 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 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, have not generated any revenue from product sales to date and have financed our operations principally through private financings and our initial public offering, or IPO. We have incurred net losses of $46.4 million for the year ended December 31, 2019, and $43.5 million and $19.3 million for the six months ended June 30, 2020 and June 30, 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $126.0 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. Three of our product candidates, ZN-c5, ZN-c3 and ZN-e4, are in clinical trials, and we intend to initiate a Phase 1 clinical trial of ZN-d5 in patients with AML or B-cell lymphoma in the first half of 2021. In addition, we plan to submit an IND to the FDA for our fifth product candidate in 2021. Our other programs are in preclinical research. As a result, 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 ZN-c5, ZN-c3, ZN-d5 and ZN-e4 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 the COVID-19 pandemic or other causes;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and internationally, of our product candidates, including ZN-c5, ZN-c3, ZN-d5 and ZN-e4 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;
- 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 patent protection, trade secret protection 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 coverage and adequate 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.

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, ZN-c5, ZN-c3, ZN-d5, ZN-e4 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 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. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, including ZN-c5, ZN-c3, ZN-d5 and ZN-e4, 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. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of June 30, 2020, we had cash, cash equivalents and marketable securities of $233.2 million. In August 2020, we completed an underwritten public offering of our common stock generating approximately $135.0 million in net proceeds. Based on current business plans, we believe that our existing cash, cash equivalents and marketable securities as of June 30, 2020, together with the net proceeds from our August 2020 follow-on offering, will be sufficient to fund our operating expenses and capital expenditures requirements into 2023, 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 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 the COVID-19 pandemic 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 candidate, ZN-c5, which is currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize ZN-c5 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 ZN-c5, our lead product candidate. We are investing significant efforts and financial resources in the research and development of ZN-c5. We are conducting a Phase 1/2 trial of ZN-c5 as monotherapy and in combination with palbociclib, a CDK4/6 inhibitor, in patients with ER+/HER2- advanced or metastatic breast cancer. ZN-c5 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 ZN-c5, or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of ZN-c5 will depend on several factors, including the following:

- the successful and timely completion of our ongoing clinical trials of ZN-c5;
- the initiation and successful patient enrollment and completion of additional clinical trials of ZN-c5 on a timely basis;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of ZN-c5 both in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals for ZN-c5 from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development of ZN-c5;
- 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 ZN-c5 if approved, including for supplies of drugs that we are testing in combination with ZN-c5;
- obtaining and maintaining patent protection, trade secret protection 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 ZN-c5, which would materially harm our business. If we do not receive marketing approvals for ZN-c5, we may not be able to continue our operations.

There is currently no FDA-approved oral SERD, and our development of ZN-c5 may never lead to a marketable product.

We are developing ZN-c5 as an oral SERD. There is currently no FDA-approved oral SERD. We have not received regulatory approval for ZN-c5 and cannot be certain that our approach will lead to the development of an approvable or marketable product, alone or in combination with other therapies. We may not succeed in demonstrating safety and efficacy of ZN-c5 in our ongoing Phase 1/2 clinical trial or in larger-scale clinical trials. Advancing ZN-c5 as an oral SERD creates significant challenges for us, including:

- obtaining marketing approval, as the FDA, EMA or other regulatory authorities have never approved an orally available SERD;
- if ZN-c5 is approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our ZN-c5 into existing treatment regimens, including in combination with other treatments for breast cancer; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

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
- adverse events 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, EMA and other comparable foreign 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. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA, EMA and other comparable foreign 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, EMA and other comparable foreign 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.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

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

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign 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, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to 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, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;

- the FDA, EMA or other comparable foreign 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; and

- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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. 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, EMA or other comparable foreign regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign 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. 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. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

In addition, we may rely in part on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, 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 foreign 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;
- IRBs 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 adverse effects;
- occurrence of serious adverse events 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 foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice, or cGMP, regulations 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, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- 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.

In addition, disruptions caused by the COVID-19 pandemic have caused and we expect will 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 foreign 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 foreign 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 for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign 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 foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign 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 foreign regulatory authorities. The FDA or comparable foreign 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 foreign 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 foreign 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.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. We do not know whether ZN-c5, ZN-c3, ZN-d5 and ZN-e4 will perform in current or future clinical trials as ZN-c5, ZN-c3, ZN-d5 and ZN-e4 have performed in preclinical studies, or, with respect to ZN-c5, ZN-c3 and ZN-e4, ongoing clinical trials to date. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign 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. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Interim, initial, "top-line", 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 preliminary or top-line data from our preclinical studies and clinical trials, which is 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 top-line 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. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line 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. For example, we have reported interim data from our ongoing Phase 1/2 clinical trials of ZN-c5, ZN-c3 and ZN-e4, as of June 30, 2020, June 19, 2020 and February 5, 2020, respectively. 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 preliminary or 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 interim, top-line, 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;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, 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, EMA or other comparable foreign 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 intend to develop ZN-c5, ZN-c3, ZN-d5, ZN-e4 and potentially other product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop ZN-c5, ZN-c3, ZN-d5, ZN-e4 and likely other future product candidates in combination with one or more other approved or unapproved therapies to treat cancer or other diseases. For example, we are currently evaluating ZN-c5 in combination with certain approved agents, including palbociclib and abemaciclib.

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, EMA or comparable foreign 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, EMA or comparable foreign 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 ZN-c5, ZN-c3, ZN-d5, ZN-e4 or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell ZN-c5, ZN-c3, ZN-d5, ZN-e4 or 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 FDA approval.

If the FDA, EMA or comparable foreign 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.

We intend to initially focus our product candidate development on treatments for various oncology indications. 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 prove 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, EMA or other comparable foreign 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, EMA or other comparable foreign 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, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA 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, will apply to 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.

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 countries of the European Union, 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 approval. 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 foreign 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.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

We may be unable to obtain U.S. or foreign 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 foreign 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 foreign 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. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA 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 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. 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 foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

Our current or future product candidates may cause significant adverse events, 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 adverse events 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 foreign 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 adverse events 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 adverse events 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 adverse events 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 adverse events 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, EMA, 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, EMA and other comparable foreign 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, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign 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 or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign 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 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 foreign regulatory approvals and establishing and maintaining compliance with foreign 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 foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event 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 and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events 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, EMA and other comparable foreign 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. 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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.

If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If safe and effective use of any of our product candidates depends on an *in vitro* diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise 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 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 ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, or 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 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. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. 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.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, 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 an accelerated approval for our 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 post-approval confirmatory studies to verity and describe the drug’s clinical benefit. If such post-approval studies fail to confirm the drug’s clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. 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 any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign 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. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the ACA. 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 included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2029 unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

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 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. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration's budget proposal for the fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Beilina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, as well as 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 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 federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors 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 and state 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. 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 false claims and civil monetary penalties 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;

- 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, as defined by such law, certain other healthcare providers starting in 2022 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 foreign 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.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU. In addition, on June 28, 2018, 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 is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to 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. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, 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, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state 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 foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign 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 foreign officials under the FCPA. Recently the SEC and 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 foreign 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

The outbreak of the novel coronavirus disease, COVID-19, has adversely impacted and we expect will continue to adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus continues to spread globally, including within the United States, and, in March 2020, the World Health Organization declared COVID-19 a pandemic. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. As a result of the COVID-19 pandemic, we have experienced and we expect to continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- continued delays or difficulties in enrolling patients in our clinical trials;
- continued delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- risk that we are unable to enroll participants in our clinical trials in adequate numbers;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;

- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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 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 currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, 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.

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 executive officers to manage. 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, if we 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.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

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. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

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.

As of June 30, 2020, we had 75 full-time employees, including 55 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial 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, EMA and other comparable foreign regulatory agencies' review process for ZN-c5, ZN-c3, ZN-d5 and ZN-e4 and any other future 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, ZN-c5, ZN-c3, ZN-d5 and ZN-e4 and any other future 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., a corporation that is 25% owned by us, pursuant to intercompany service 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 ZN-c5, ZN-c3, ZN-d5 and ZN-e4 and any other future 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 ZN-c5, ZN-c3, ZN-d5 and ZN-e4 and any other future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as HIPAA, Health Information Technology for Economic and Clinical Health Act and GDPR), it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign 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 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 foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, 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 European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery 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 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.

In addition, in most foreign countries, including the European Economic Area, or EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union 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 European Union 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.

A portion of our manufacturing of our lead product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in 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 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 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 in China, 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 Chinese governments, political unrest or unstable economic conditions 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. Any recall 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. 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 China. 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 China.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our facility is located in a region which experiences 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 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 of our corporate subsidiaries may be limited.

The net operating loss, or NOL, carryforwards of our corporate subsidiaries could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, signed into law on March 27, 2020, NOLs arising in tax years beginning after December 31, 2017, and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs of our corporate subsidiaries generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2020 may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, a “Separate Return Limitation Year” (“SRLY”) generally encompasses all separate return years of a member (or predecessor in a Section 381 or other transaction), including tax years in which it joins a consolidated return of another group. According to Treasury Regulation Section 1.1502-21, NOLs of a member that arises in a SRLY may be applied against consolidated taxable income only to the extent of the loss member’s cumulative contribution to the consolidated taxable income. As a result, this SRLY limitation may also increase the tax liability to the Company (by reducing the carryforward of certain NOLs that otherwise might be used to offset the amount of taxable gain), potentially decreasing the value of our common stock. As of December 31, 2019, our corporate subsidiaries had available NOL carryforwards of approximately $89.2 million for federal income tax purposes, of which $68.2 million were generated in and after 2018 and can be carried forward indefinitely. The remaining federal NOLs of $21.0 million, which were generated prior to 2018, will start to expire in 2033 if not utilized. We do not anticipate carrying back any NOLs of our corporate subsidiaries.

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 our ownership by “5-

percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes 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 annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOLs 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 foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign 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 foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign 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 geo-political 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.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our in-licensed intellectual property and our proprietary technologies.

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 as well as our and our licensors' ability to operate without infringing the proprietary rights of others. 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 abroad related to our product candidates, proprietary technologies and their uses that are important to our business. Our in-licensed 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 in-licensed 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 not be infringed, designed around, invalidated or rendered unenforceable 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 foreign countries, we cannot be certain that the claims in our other in-licensed U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign 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 foreign countries, nor can we be certain that the claims in our in-licensed 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 jurisdiction;
- 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 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. 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 foreign 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, third-party manufacturers, 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 a number of 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, in September 2019, we entered into an exclusive license agreement with Recurium IP Holdings, LLC, or Recurium IP, to obtain an exclusive license to certain intellectual property rights to develop and commercialize ZN-e5, ZN-c3 and ZN-c4.

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 its 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 our rights under our existing license agreement with Recurium with respect to any licensed product, we may be required to pay to Recurium a specified percentage of all revenue 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 in-licensed patent rights are highly uncertain. Our pending and future in-licensed 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 is 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 licensed-in 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 foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity of our in-licensed 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 in-licensed 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 are aware, 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 in-licensed 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 cost 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 of form in the preparation or filing of our in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. 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 of third parties, we 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 have not had and do 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 fail 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 in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of 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 has been discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. 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 covered by 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 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, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign 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 are issued, 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 upon 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 Quarterly Report on Form 10-Q, 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 in-licensed 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, and our licensor 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 counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty or 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 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 foreign 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 will be prosecuted and may 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 will be prosecuted and also may 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 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 involve 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 foreign 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 foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

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

We may also be subject to claims that former employees or other third parties have an ownership interest in our in-licensed 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 or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign 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 in-licensed 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 foreign 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 in-licensed inventions in all countries outside the United States or from selling or importing products made using our in-licensed inventions in and into the United States or other jurisdictions. Competitors may use our in-licensed 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 foreign jurisdictions. The legal systems of many foreign 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 foreign 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 foreign 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 foreign 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 the confidentiality of 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 such publication 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 and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products 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 foreign 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. 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 or state 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.

The COVID-19 pandemic 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. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. 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. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

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 to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors 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 contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party 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 contract manufacturing partners for compliance with cGMP regulations 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 contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA 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, EMA or a comparable foreign 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, product recalls or spoilage. 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 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.

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. For example, we are currently evaluating entering into a strategic geographic collaboration and licensing agreement for the development and commercialization rights in China for certain of our clinical and preclinical assets. However, there can be no assurance that we will be able to enter into this, or any, strategic geographic collaboration in the future.

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, EMA or comparable foreign 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.

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

We have and may in the future seek third-party collaborators for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We may have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. 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 product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, 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 that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, 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 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;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will be maintained for our common stock.

An active public trading market for our common stock may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

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;
- 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 the COVID-19 pandemic. The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic 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.

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.

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.

Current beneficial owners of 5% or more of our common stock and management own a significant percentage of our stock and are able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 43.9% of our outstanding common stock. As a result, these stockholders will be able to significantly influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. 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 could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Subject to the restrictions set forth in the 90 day lock up agreements entered into by each of our directors and officers and certain of our stockholders in connection with the recently completed follow-on offering and the 180 day lock up agreements entered into by substantially all of our stockholders in connection with our IPO, 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 have registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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.

In August 2020, we completed an underwritten public offering of our common stock. We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.
- We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, or December 31, 2025, (b) in which we have total annual gross revenues of $1.07 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common stock held by non-affiliates exceeds $700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

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 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 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.

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 will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years from the date of our IPO. 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.

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.

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 are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- 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 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 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 bylaws 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 will preclude 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds

On April 7, 2020, we completed our IPO and issued and sold 10,557,000 shares of our common stock (including 1,377,000 shares of our common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $18.00 per share.

As of June 30, 2020, net proceeds of approximately $172.4 million from our initial public offering have been invested in investment grade, interest-bearing instruments. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus, dated April 2, 2020, filed with the SEC pursuant to Rule 424(b) relating to our registration statement on Form S-1 (Registration No. 333-236959), as amended, filed in connection with our IPO.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Plan of Conversion Converting Zentalis Pharmaceuticals, LLC (a Delaware limited liability company) into Zentalis Pharmaceuticals, Inc. (a Delaware corporation)	10-Q	001-39263	2.1	05/15/2020	
2.2	Certificate of Conversion Converting Zentalis Pharmaceuticals, LLC (a Delaware limited liability company) into Zentalis Pharmaceuticals, Inc. (a Delaware corporation)	10-Q	001-39263	2.2	05/15/2020	
3.1	Certificate of Incorporation of Zentalis Pharmaceuticals, Inc.	S-8	333-237593	4.1	04/07/2020	
3.2	Bylaws of Zentalis Pharmaceuticals, Inc.	S-8	333-237593	4.2	04/07/2020	
10.1	Release Agreement, dated May 10, 2020, by and between Zeno Management, Inc. and Robert Winkler, M.D.	10-Q	001-39263	10.11	05/15/2020	
10.2	Agreement for Termination of Lease and Voluntary Surrender of Premises, dated July 14, 2020, by and between Zeno Management, Inc. and ARE-SD-Region NO. 44, LLC	S-1/A	333-240115	10.23	07/28/2020	
10.3†	Greater China Amendment to the Second Amended and Restated License Agreement, dated May 19, 2020, 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 Principal Executive Officer pursuant to 18 U.S.C. Section 1350.					**

Exhibit Number	Description	Incorporated by Reference				Filed/Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

* 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 13, 2020 By: /s/ Anthony Y. Sun, M.D.
Anthony Y. Sun, M.D.
Chief Executive Officer, President and Chairman

Date: August 13, 2020 By: /s/ Melissa B. Epperly
Melissa B. Epperly
Chief Financial Officer

Exhibit 10.3

[***] 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.

GREATER CHINA AMENDMENT TO THE

SECOND AMENDED AND RESTATED LICENSE AGREEMENT

between

Recurium IP Holdings, LLC,

and

Zeno Management, Inc.

Dated: May 19, 2020

[***] 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.

GREATER CHINA AMENDMENT

TO THE

SECOND AMENDED AND RESTATED LICENSE AGREEMENT

THIS GREATER CHINA AMENDMENT TO THE SECOND AMENDED AND RESTATED LICENSE AGREEMENT ("Amendment"), dated May 19, 2020, 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") and shall only become effective if and when Zentera Therapeutics (Cayman) Ltd. ("ZTCL") Series A financing has its initial closing (the "Effective Date"). LICENSOR and LICENSEE may, from time-to-time, be individually referred to as a "Party" and collectively referred to as the "Parties".

RECITALS

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

WHEREAS, LICENSOR and LICENSEE entered into that certain Second Amended and Restated License Agreement, dated September 6, 2019 (the "Agreement");

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 the date hereof, (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 ZTCL and Zeno Beta, Inc. entered into that certain Option Agreement for a Collaboration and License with ZTCL, each dated as of the date hereof (collectively, the "Greater China Sublicense Agreements");

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

WHEREAS, LICENSOR and LICENSEE desire to amend 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").

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 amend the Agreement as follows:

AMENDMENT

1. Capitalized terms used but not defined herein will have the meaning ascribed to them in the Agreement.

2. First Amendment to the Agreement. Section 4.1.3 of the Agreement is hereby replaced in its entirety with the following:

[***] 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.

"4.1.3 Sublicense Fees. In consideration of the licenses and rights granted to LICENSEE hereunder, LICENSEE shall pay to LICENSOR the applicable percentage of all Third Party Fees payable from any of LICENSEE's and/or its 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.

Sublicense Fees Percentage by LICENSOR's Product Family Equity

	Percentage of Third Party Fees By LICENSOR Ownership		
LICENSOR's Product Family Equity	[***]	[***]	[***]
Percentage of Third Party Fees	[***]	[***]	[***]

For clarity, all sublicense fees due under the 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 Section 4.1.3 as amended herein.

3. Second Amendment to Agreement. Article 14 of the Agreement is hereby replaced in its entirety with the following:

"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.

[***] 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.

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 three (3) 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 first of the three (3) arbitrators 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 the second arbitrator. Thereafter, the first and second arbitrators shall have [***] to choose the third arbitrator. 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 first two (2) arbitrators within [***] of such failure who shall thereafter pick the third 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 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 [***] days 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."

4. Greater China Milestones and Royalties. For all Product Families sublicensed to ZTCL under the Greater China Sublicense Agreements or the Greater China Option Agreement, all milestone and royalty payments due under the Agreement resulting from activity anywhere in the Territory shall be determined pursuant to this Amendment, notwithstanding anything to the contrary in Sections 4.1.1 or 4.1.2 of the Agreement.

5. Any Milestone First Accrued Outside Greater China. For any Product Family that is sublicensed to ZTCL under the Greater China Sublicense Agreements or the Greater China Option Agreement, if a Milestone under Section 4.1.1 of the Agreement 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 of the Agreement shall be due to LICENSOR and, if and when, the corresponding Greater China Milestone (as defined in Paragraph 7 of this Amendment) is achieved no Greater China Milestone Payment (as defined in Paragraph 7 of this Amendment) shall be due to LICENSOR.

6. Any Milestone First Accrued Inside Greater China. For any Product Family that is sublicensed to ZTCL under the Greater China Sublicense Agreements or the Greater China Option Agreement, if a Greater China Milestone under Paragraph 7 of this Amendment is achieved in Greater China before the corresponding Milestone is achieved in the Territory outside of Greater China, the Greater China Milestone Payment in Paragraph 7 of this Amendment shall be due to LICENSOR as set forth in

Paragraph 7 and, if and when, the corresponding Milestone in Section 4.1.1 of the Agreement is achieved in the Territory outside of Greater China, the corresponding Milestone Payment due to LICENSOR under Section 4.1.1 of the Agreement shall be due as set forth therein, provided that the amount due under Section 4.1.1 of the Agreement for the milestone achieved in the Territory outside of Greater China shall be reduced by the amount previously paid for the corresponding Greater China Milestone Payment.

7. Greater China Milestone Payments. LICENSEE shall notify LICENSOR as soon as practicable upon achievement by ZTCL (or its sublicensee) of each milestone set forth in the applicable table below (each, a "Greater China Milestone"). In further consideration of the licenses and rights granted to LICENSEE, within [***] days of achievement of each Greater China Milestone set forth in the applicable table below, LICENSEE shall pay to LICENSOR the corresponding creditable and non-refundable milestone payment (each, a "Greater China Milestone Payment") as determined on a Product Family-by-Product Family basis according to Recurium Equity, LLC's ("Recurium Equity") aggregate direct and/or indirect equity ownership percentage (on a fully diluted basis) of ZTCL or the furthest downstream Affiliated Sublicensee of the applicable Product Family in the case of a Product Family that has been further sublicensed by ZTCL to an Affiliated Sublicensee (the applicable percentage with respect to a Product Family is referred to herein as "**Recurium's Product Family** Equity") at the time such Greater China Milestone is achieved by ZTCL or its sublicensee (or with respect to Royalties under Paragraph 8, at the time the applicable Net Sales are made), as set forth below; provided that any sales by Recurium Equity of direct or indirect equity of ZTCL owned by Recurium Equity as of the Effective Date shall be disregarded for purposes of the foregoing calculations, such that Recurium Equity cannot unilaterally reduce its ownership percentage. (For example, if Recurium Equity's equity ownership percentage of LICENSEE is [***] and LICENSEE's equity ownership percentage of ZTCL is [***], then Recurium's Product Family Equity with respect to such Product Family would be [***] (i.e., [***] multiplied by [***]).)

(a) If Recurium's Product Family Equity is less than [***] with respect to an applicable Product Family:

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*	[***]

[***] 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.

MILESTONE	MILESTONE PAYMENT
(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.

(b) If Recurium's Product Family Equity is not less than [***], but no greater than [***] with respect to an applicable Product Family:

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) IF Recurium's Product Family Equity is greater than [***] at the time ZTCL achieves any specific Greater China Milestone, no payments will be due resulting from such Greater China Milestone.

(d) For the avoidance of doubt and notwithstanding anything to the contrary herein: (i) payment of a 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 Paragraph 7; and (ii) 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 Greater China Milestone Payment under (1) above for Commencement of the Phase II Clinical Trial will only be due at the

Commencement of such combined trial and (B) the Greater China Milestone Payment under (2) 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 Greater China 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 Greater China Milestone Payment due under (3) above, when due.

8. Greater China Royalties. In consideration of the licenses and rights granted to LICENSEE hereunder, LICENSEE shall pay to LICENSOR a royalty equal to the Royalty Percentage of Net Sales of Royalty & Milestone Product by ZTCL (and its sublicensees) during the Royalty Term (collectively, "Royalties"). As used herein, "Royalty Percentage" means a percentage, as determined by Recurium's Product Family Equity, as set forth below.

Recurium's Product Family Equity	Above [***]	[***]	Below [***]
Royalty Percentage	[***]	[***]	[***]

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

10. 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).

11. Anti-Stacking. Royalties may be reduced with respect to Net Sales in a particular country (or region) in Greater China 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 region), up to a maximum reduction of [***] in the aggregate of the Royalties owing for Net Sales in such country (or 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 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 region); or (iii) any license for technology that is necessary to Develop or Commercialize a Royalty & Milestone Product in such country (or 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.

12. Combination Products. In the event that a Royalty & Milestone Product is Commercialized in Greater China 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 in Greater China cannot be reasonably determined, the price attributed to such

product will be based on the relative cost of goods for such product, as determined in accordance with GAAP. In addition, in the event that a Royalty & Milestone Product is sold in Greater China 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 no less than the fair market value of such Royalty & Milestone Product on a stand-alone basis (excluding any such discounts, rebates or charge-backs).

13. 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.

14. General Provisions. Article 15 of the Agreement is incorporated herein by reference in its entirety.

[Signatures on next page]

IN WITNESS WHEREOF, the parties have duly executed this Amendment as of the Effective Date.

LICENSOR:	LICENSEE:
RECURIUM IP HOLDINGS, LLC	ZENO MANAGEMENT, INC.
By: /s/ Ned A. Israelsen	By: /s/ Anthony Y. Sun, M.D.
Ned A. Israelsen	Anthony Y. Sun, M.D.

Exhibit 31.1

CERTIFICATION

I, Anthony Y. Sun, 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)) 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) [omitted];

   (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 13, 2020

By: /s/ Anthony Y. Sun, M.D.

Anthony Y. Sun, M.D.

Chief Executive Officer, President and Chairman

(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)) 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) [omitted];

   (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 13, 2020

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, 2020 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 13, 2020

By: /s/ Anthony Y. Sun, M.D.

Anthony Y. Sun, M.D.

Chief Executive Officer, President and Chairman

(principal executive officer)

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, 2020 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 13, 2020

By: /s/ Melissa B. Epperly

Melissa B. Epperly
Chief Financial Officer
(*principal financial officer*)