# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 1

# FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# Zentalis Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

2834

(Primary Standard Industrial Classification Code Number)

82-3607803 (I.R.S. Employer Identification No.)

incorporation or organization) 530 Seventh Avenue, Suite 2201 New York, New York 10018 Telephone: (212) 433-3791

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Anthony Y. Sun, M.D. Chief Executive Officer Zentalis Pharmaceuticals, Inc. 530 Seventh Avenue, Suite 2201 New York, New York 10018 Telephone: (212) 433-3791

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Delaware

(State or other jurisdiction of

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Approximate date of			
As soon as practicable af	ter this Registratio	n Statement is	declared effective.

As soon as practicable after this Registration Statement is declared effective.		
If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Secubox. $\Box$	rities Act of 1933, check the followi	ng
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following bostatement number of the earlier effective registration statement for the same offering. $\Box$	x and list the Securities Act registrat	ion
If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities earlier effective registration statement for the same offering. $\Box$	rities Act registration statement num	ber of
If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities earlier effective registration statement for the same offering. $\Box$	rities Act registration statement num	ber of
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting corthe definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Hamiltonian filer.		ny. See
Large accelerated filer $\Box$	Accelerated filer	
Non-accelerated filer	Smaller reporting company	$\boxtimes$
	Emerging growth company	$\boxtimes$
If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying accounting standards provided to Section $7(a)(2)(B)$ of the Securities Act. $\Box$	with any new or revised financial	

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JULY 28, 2020 PRELIMINARY PROSPECTUS

3,750,000 Shares



# Zentalis Pharmaceuticals, Inc.

	Common Stock		
We are offering 3,750,000 shares of our common stock.			
Our common stock is listed on The Nasdaq Global Market stock as reported on The Nasdaq Global Market was \$39.6	5	Tuly 24, 2020, the last reported sale pri	ce of our common
We are an "emerging growth company" as defined under to company reporting requirements for this and future filings			

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	\$	\$
Underwriting discounts and commissions (1)	\$	\$
Proceeds, before expenses, to us	\$	\$

<sup>(1)</sup> See "Underwriters" for a description of all compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to 562,500 additional shares of common stock.

The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about

, 2020.

Morgan Stanley

**Jefferies** 

SVB Leerink

Guggenheim Securities

Prospectus dated

, 2020.

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

#### BASIS OF PRESENTATION

The consolidated audited and unaudited financial statements include the accounts of Zentalis Pharmaceuticals, LLC and its subsidiaries. In connection with our initial public offering in April 2020, Zentalis Pharmaceuticals, LLC converted into a Delaware corporation pursuant to a statutory conversion, and changed its name to Zentalis Pharmaceuticals, Inc. All holders of units of Zentalis Pharmaceuticals, LLC became holders of shares of common stock of Zentalis Pharmaceuticals, Inc. In this prospectus, we refer to all transactions related to our conversion to a corporation as the Corporate Conversion.

#### TRADEMARKS AND TRADENAMES

Solely for convenience, trademarks, service marks and tradenames referred to in this prospectus may appear without the <sup>®</sup>, TM or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, service marks and tradenames. This prospectus may also contain trademarks, service marks, tradenames and copyrights of other companies, which are the property of their respective owners.

#### **ABOUT THIS PROSPECTUS**

Except where the context otherwise requires or where otherwise indicated, the terms "Zentalis," "we," "us," "our," "our company," "Company" and "our business" refer: (1) following the consummation of our statutory conversion to a Delaware corporation on April 2, 2020, or the Corporate Conversion, in connection with our initial public offering, or IPO, to Zentalis Pharmaceuticals, Inc. and (2) prior to the completion of the Corporate Conversion, to Zentalis Pharmaceuticals, LLC.

#### PROSPECTUS SUMMARY

This summary highlights, and is qualified in its entirety by, the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information that may be important to you in making your investment decision. You should read this entire prospectus carefully, especially the "Risk Factors" section beginning on page 12 and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.

#### 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, if approved, have the potential to significantly impact clinical outcomes 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 properties. We intend to initiate the Phase 2 monotherapy and combination portions of this Phase 1/2 trial in the first half of 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 mutant 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. 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., or SciClone.

The following table summarizes our product candidate pipeline.

		IND Enabling	Phase 1/2	Phase 3	Collaborator	Anticipated Key Milestones
ZN-c5: Oral SERD	ER+ / HER2- Breast Cancer (2)				Lilly; Pfizer; Zentera	Initiate Phase 1b combination study 2H 2020 Initiate Phase 2 monotherapy and combination studies 1H 2021
ZN-c3: WEE1 Inhibitor	Solid Tumors				Zentera	Topline results from Phase 1 2021
ZN-d5: BCL-2 Inhibitor	Hematological Malignancies <sup>(2)</sup>		,		Zentera	Initiate Phase 1 trial 1H 2021
ZN-e4: EGFR Inhibitor	NSCLC				SciClone	Topline results from Phase 1 2021

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 IND to the FDA in 2021.

# **Our Zentalis Approach**

In the five years since our inception, we have successfully cleared four INDs with the FDA, and expect to submit a fifth IND in 2021. Our Integrated Discovery Engine has enabled us to take our clinical-stage product candidates from initial discovery to IND submission in a capital efficient manner and in less than three years on average. We begin our process of drug discovery by identifying fundamental biological pathways of cancers based on a number of factors, including validation of the pathway through prior clinical outcomes and ability to impact large patient populations. We then analyze existing marketed products and compounds in development that target these cancer pathways and assess their limitations, efficacy, safety, tolerability, pharmacokinetic, or PK, properties, patient convenience, and potential to be used in combination with other therapies. Next, we use our medicinal chemistry expertise and extensive understanding of target-drug structure activity to design proprietary NCEs with properties that we believe can address observed limitations and suboptimal drug characteristics of marketed products or other compounds in development, including potency, solubility, route of administration and PK properties. We believe overcoming these limitations may also allow us to develop these product candidates for use in combination with other therapies, including with our internally developed product candidates, if approved. Finally, we strive to generate preclinical data to support that such candidates could have a differentiated product profile in our expected lead indications before advancing a compound into clinical development. We have used our Integrated Discovery Engine to generate a pipeline of four product candidates targeting solid tumors and hematological malignancies. Longer term, we believe our discovery engine has the potential to generate product candidates addressing a wide range of additional therapeutic areas.

<sup>(1)</sup> We are currently evaluating ZN-c5 in combination with palbociclib, as part of a clinical research collaboration with Pfizer, and intend to evaluate ZN-c5 in combination with abemaciclib, as part of a clinical research collaboration with Eli Lilly and Company, or Lilly. We maintain full ownership of ZN-c5 in each such collaboration. SciClone has development and commercial rights to ZN-e4 in Greater China (including Macau and Hong Kong), South Korea, Taiwan and Vietnam. Zentera, our majority-owned joint venture, has development and commercial rights to ZN-c5, ZN-c3 and ZN-d5 in select Asian countries (including China). Zentera intends to submit an IND in China for each of ZN-c5, ZN-c3 and ZN-d5 in 2021.

<sup>(2)</sup> We plan to explore the combination potential of ZN-c5, our oral SERD, with ZN-d5, our BCL-2 inhibitor, for the treatment of ER+/HER2- breast cancer.

# **Our Zentalis Programs**

# ZN-c5 (Oral SERD)

Our lead product candidate, ZN-c5, is an oral SERD for the treatment of ER+/HER2- advanced or metastatic breast cancer. ER+/HER2-breast cancer affects approximately 70% of all breast cancer patients in the United

States. These tumors depend on the estrogen receptor, or ER, for growth and survival and are currently treated by a number of approved hormonal therapies. We have designed ZN-c5 to overcome limitations of existing hormonal therapies, including the only FDA-approved SERD, fulvestrant (marketed as Faslodex® by AstraZeneca). Despite its limitations, Faslodex® generated worldwide sales of over \$1.0 billion in 2018, the last year prior to generic competition, reflecting part of the significant potential of the SERD therapeutic class in ER+/HER2- breast cancer.

We believe ZN-c5, which is being developed for convenient oral administration, has the potential to be used as monotherapy and in combinations, and could become the standard of care for hormonal therapy in the treatment of all lines of ER+/HER2- breast cancer, if approved. We are currently evaluating ZN-c5 in a Phase 1/2 clinical trial in patients with ER+/HER2- advanced or metastatic breast cancer, both as monotherapy and in combination with palbociclib (marketed as Ibrance® by Pfizer) as part of a clinical research collaboration with Pfizer. Palbociclib is an inhibitor of cyclin dependent kinases 4 and 6, or CDK4/6, and is FDA approved for ER+/HER2- advanced or metastatic breast cancer in combination with hormonal therapies, such as fulvestrant. 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 CDK4/6 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 believe ZN-c5, if approved, may have a potentially differentiated product profile. Based on results from our ongoing Phase 1/2 clinical trial as of the database cutoff date of June 30, 2020, the PK of ZN-c5, as monotherapy and in combination with palbociclib, was characterized by rapid absorption into the systemic circulation and high drug exposure levels and six of the 15 patients in the Phase 1, monotherapy dose escalation portion of the trial showed stable disease for 24 weeks, leading to a clinical benefit rate of 40% as of such date. In addition, ZN-c5 has been observed to be well tolerated with no dose-limiting toxicities reported. In preclinical studies, ZN-c5 has shown anti-tumor activity, potency and selectivity. We intend to initiate the Phase 2 monotherapy and combination portions of the Phase 1/2 trial in the first half of 2021. We are also currently dosing ZN-c5 in a Phase 1 Window of Opportunity study in patients with ER+/HER2- breast cancer scheduled to undergo surgical resection of the tumor or start neoadjuvant treatment. We expect to report topline results of the Window of Opportunity study in the first half of 2021. In addition, we 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.

#### ZN-c3 (WEE1 Inhibitor)

ZN-c3 is our oral, small molecule inhibitor of WEE1, a DNA damage response protein. The inhibition of WEE1 aims to allow sufficient DNA damage in cancer cells to cause them to undergo programmed cell death, or apoptosis, thereby preventing tumor growth and potentially causing tumor regression. There is currently no FDA-approved WEE1 inhibitor. We believe ZN-c3, if approved, may have broad applicability in a wide range of cancers as monotherapy and in combination, including with chemotherapy agents and other targeted therapies. We are currently conducting a Phase 1/2 clinical trial of ZN-c3 in patients with advanced solid tumors. Based on data from 22 patients dosed in the Phase 1 monotherapy dose escalation portion of our ongoing Phase 1/2 clinical trial as of the database cutoff date of June 19, 2020, ZN-c3 has been observed to be well tolerated with no dose-limiting toxicities reported. We expect to report topline results from the Phase 1 portion of this trial in 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.

# ZN-d5 (BCL-2 Inhibitor)

ZN-d5 is our oral, small molecule inhibitor of BCL-2 that we are initially developing for the treatment of hematologic malignancies. BCL-2 is most notable for its critical role in the regulation of apoptosis. 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 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.

#### ZN-e4 (EGFR Inhibitor)

ZN-e4 is our oral, small molecule product candidate being developed as an irreversible inhibitor of mutant EGFR. EGFR regulates a number of cellular functions, including cell proliferation and survival, and is a driver of tumor growth in certain cancers, including lung cancer. We have designed ZN-e4 to be highly selective against mutant EGFR. We are conducting a Phase 1/2 clinical trial of ZN-e4 in patients with advanced NSCLC with activating EGFR mutations and are currently evaluating potential combination therapies for future clinical development of ZN-e4. We expect to report topline results from the Phase 1 portion of this trial in 2021.

#### Zentera

Pursuant to a collaboration and license agreement entered into in May 2020, we collaborate with Zentera, our majority-owned joint venture, on the development and commercialization of ZN-c5, ZN-c3 and ZN-d5 in select Asian countries (including China). Zentera intends to submit an IND in China for each of ZN-c5, ZN-c3 and ZN-d5 in 2021.

#### **Our Strategy**

Our goal is to become a leading oncology-focused biopharmaceutical company and improve the lives of patients. Our strategy includes the following key components:

- Discover and develop small molecule NCEs that are differentiated from existing marketed therapies by clinical performance and address large patient populations in cancer.
- Rapidly advance the development of our lead product candidate, ZN-c5, our oral SERD, toward regulatory approval for the treatment of ER+/HER2- advanced or metastatic breast cancer.
- Advance our additional pipeline candidates, ZN-c3 (WEE1 Inhibitor), ZN-d5 (BCL-2 Inhibitor) and ZN-e4 (EGFR Inhibitor), across
  multiple cancer indications.
- Continue to evaluate our product candidate pipeline in combination with internally discovered and third-party compounds.
- Deploy our highly efficient Integrated Discovery Engine to further expand our product candidate pipeline.
- Evaluate strategic opportunities to accelerate development timelines and maximize the value of our product candidate pipeline.

#### **Recent Developments**

#### Collaboration with Eli Lilly and Company

In July 2020, we entered into a clinical trial collaboration and supply agreement with Eli Lilly to evaluate the safety, tolerability and efficacy of ZN-c5 in combination with their CDK4/6 inhibitor, abemaciclib, in a planned 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.

See "Business—License Agreement and Strategic Collaborations—Eli Lilly and Company Trial Collaboration and Supply Agreement" for more information.

#### **Our History and Team**

We were founded in December 2014 and began operations in January 2015. We have assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients. Our management team has broad expertise and successful track records in drug discovery, clinical development, regulatory affairs, manufacturing and commercialization of cancer therapies, as well as in business and finance, through previous experiences at leading institutions including Aisling Capital, Array Biopharma, Bayer Healthcare, CureVac AG, Eisai US, Goldman Sachs, IQVIA, Merck, Morgan Stanley, Novartis, Paratek Pharmaceuticals, Pfizer, PsiOxus Therapeutics and R-Pharm US, among others. We are also guided by our board of directors, scientific advisory board and business advisory board. Our renowned scientific and business advisory boards are comprised of key scientific and clinical thought leaders in oncology.

#### COVID-19

We continue to monitor how 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.

# **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

• 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 have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.
- Even if this offering is successful, 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 or eliminate one or more of our research and drug development programs or future commercialization efforts.
- We are substantially dependent on the success of our lead product 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.
- 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.
- We may face additional risks associated with the development of ZN-c5, ZN-c3, ZN-d5, ZN-e4 and potentially other product candidates in combination with other therapies.
- 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.
- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow 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.
- Our success depends on our ability to protect our licensed-in intellectual property and our proprietary technologies.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of
  third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our
  developmental and commercialization efforts.
- The outbreak of the novel strain of coronavirus disease, COVID-19, had adversely impacted and we expect will continue to adversely
  impact our business, including our preclinical studies and clinical trials.

# **Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. As an "emerging growth company" we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

• the option to present only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- not being required to comply with any requirements 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 (i.e., an auditor discussion and analysis);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
   and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the first fiscal year in which our annual gross revenue is \$1.07 billion or more; (ii) the last day of 2025; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the last business day of our most recently completed second fiscal quarter; and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during any three-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus forms a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of this extended transition period.

# **Corporate Information**

We were initially formed as Zeno Pharmaceuticals, Inc., a Delaware corporation, in December 2014. In conjunction with a corporate restructuring, Zeno Pharma, LLC, a Delaware limited liability company, was formed, and in December 2017 acquired Zeno Pharmaceuticals, Inc., pursuant to a merger agreement. As a result of this acquisition, Zeno Pharmaceuticals, Inc. became a wholly-owned subsidiary of Zeno Pharma, LLC. In December 2019, Zeno Pharma, LLC changed its name to Zentalis Pharmaceuticals, LLC. In April 2020 and in connection with our IPO, we converted to a Delaware corporation pursuant to a statutory conversion and changed our name to Zentalis Pharmaceuticals, Inc. We completed our IPO in April 2020. Our common stock is currently listed on The Nasdaq Global Market under the symbol "ZNTL." Our principal executive offices are located at 530 Seventh Avenue, Suite 2201, New York, New York, 10018 and our telephone number is (212) 433-3791. Our website address is www.zentalis.com. The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

# The Offering

Common stock offered by us.

Option to purchase additional shares

Common stock to be outstanding after this offering

Use of proceeds

Risk factors

Nasdaq Global Market symbol

3,750,000 shares.

We have granted the underwriters an option for a period of 30 days to purchase up to 562,500 additional shares of common stock.

39,628,108 shares (or 40,190,608 shares if the underwriters exercise their option to purchase additional shares in full).

We estimate that the net proceeds to us from this offering will be approximately \$138.9 million (or approximately \$159.8 million if the underwriters exercise their option to purchase additional shares in full), based on an assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance and expand our clinical and preclinical development programs, including to fund additional monotherapy and combination clinical studies for ZN-c5, ZN-c3, ZN-d5 and ZN-e4, and for working capital and other general corporate purposes.

You should read the section titled "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.

"ZNTL"

The number of shares of our common stock to be outstanding after this offering is based on 35,878,108 shares of our common stock outstanding as of June 30, 2020, and excludes:

- 1,986,296 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2020 under our 2020 Incentive Award Plan, or the 2020 Plan, at a weighted average exercise price of \$18.13 per share;
- 1,113,206 shares of our common stock issuable upon the vesting of restricted stock units outstanding as of June 30, 2020 under our 2020 Plan;
- 2,500,908 remaining shares of common stock reserved for future issuance under our 2020 Plan as of June 30, 2020 as well as any
  shares of our common stock that become available pursuant to provisions in the 2020 Plan that automatically increase the share
  reserve under our 2020 Plan or the other provisions of the 2020 Plan pursuant to which additional shares may become available for
  issuance under the 2020 Plan; and
- 450,000 shares of our common stock available for future issuance under our 2020 Employee Stock Purchase Plan, or the ESPP, as of June 30, 2020 as well as shares of our common stock that become

available pursuant to provisions in the ESPP that automatically increase the share reserve under the ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- no exercise of the outstanding options referred to above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock in this offering.

# SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data for the periods indicated. We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019, and the consolidated balance sheet data as of December 31, 2019, from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the three months ended March 31, 2019 and 2020 the balance sheet data as of March 31, 2020 are derived from our unaudited interim consolidated financial statements included elsewhere in this prospectus. In our opinion, these unaudited interim consolidated financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. Our historical results are not necessarily indicative of the results that should be expected for any future period and our operating results for the three month period ended March 31, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2020 or any other interim periods or any future year or period. You should read the following summary consolidated financial data together with the more detailed information contained in "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,				Three Months Ended March 31,			
	2	2018		2019	2019			2020
		(in thousan	ds, exce	ept unit, per ur	nit, shar		ıdited) re amo	unts)
Consolidated Statements of Operations Data:								
Revenue	\$	14	\$		\$	_	\$	_
Operating expenses:								
Research and development		18,921		38,386		7,089		13,258
General and administrative		4,876		8,459		1,633		3,141
Total operating expenses		23,797		46,845		8,722		16,399
Loss from operations	(	(23,783)		(46,845)		(8,722)		(16,399)
Other income:								
Interest income		355		498		74		164
Other expense				(16)		(12)	_	
Net loss before income taxes	(	(23,428)		(46,363)		(8,660)		(16,235)
Income tax expense		4		15		3		_
Net loss	(	(23,432)		(46,378)		(8,663)		(16,235)
Net loss attributable to noncontrolling interest		(2,365)		(715)		(320)		(109)
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$ (	(21,067)	\$	(45,663)	\$	(8,343)	\$	(16,126)
Net loss per Class A common unit attributable to Zentalis		<del></del>						
Pharmaceuticals, LLC, basic and diluted(1)	\$	(3.77)	\$	(8.16)	\$	(1.49)	\$	(2.88)
Weighted average Class A common units outstanding, basic and diluted(1)	5,5	94,385	5	,597,358	5,	594,385	5	5,601,478
	-							

<sup>(1)</sup> See Note 12 to our consolidated financial statements included elsewhere in this prospectus and Note 11 to our unaudited interim consolidated financial statements included elsewhere in this prospectus for additional information regarding the method used to calculate our basic and diluted net loss per share.

		As of March 31, 2020			
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)		
		(in thousands)			
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 63,650	\$254,439	\$ 393,314		
Working capital(3)	49,070	239,859	378,734		
Total assets	87,629	278,418	417,293		
Total liabilities	20,886	20,886	20,886		
Accumulated deficit	(99,119)	(99,119)	(99,119)		
Total equity (deficit)	(89,191)	257,532	396,407		

(1)

The pro forma balance sheet data give effect to (i) the Corporate Conversion, (ii) the issuance of 32,664 shares of our common stock in April 2020 in exchange for shares held by certain security holders of our majority owned subsidiaries, K-Group Alpha, Inc. and K-Group Beta, Inc. as a result of which such subsidiaries became wholly-owned subsidiaries of us, or the Share Exchange, (iii) the sale and issuance of 10,557,000 shares of our common stock in the IPO for aggregate net proceeds of approximately \$172.4 million and (iv) the sale and issuance of equity interests of our majority-owned joint venture, Zentera, for aggregate net proceeds of \$18.4 million.

The proforma as adjusted balance sheet data gives further effect to our issuance and sale of 3,750,000 shares of our common stock in this offering at an assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The proforma as adjusted balance sheet data is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, would increase or decrease pro forma as adjusted cash, cash equivalents and investments, working capital, total assets and total stockholders' equity by approximately \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease pro forma as adjusted cash, cash equivalents and investments, working capital, total assets and total stockholders' equity by \$37.2 million, assuming the assumed public offering price per share remains the same, and after deducting underwriting discounts and commissions and estimated off (2) (3)

#### RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus, including our audited and unaudited consolidated financial statements and related notes appearing elsewhere in this prospectus 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 prospectus also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement 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 IPO. We have incurred net losses of \$46.4 million and \$23.4 million for the years ended December 31, 2019 and 2018, respectively, and \$8.7 million and \$16.2 million for the three months ended March 31, 2019 and 2020, respectively. As of March 31, 2020, we had an accumulated deficit of \$99.1 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. 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-c3, 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.

Even if this offering is successful, 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. Following this offering, we also expect 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 March 31, 2020, we had \$63.7 million in cash and cash equivalents. Based on current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditures requirements into 2023. Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be able to continue to fund our operating expenses and capital expenditures requirements 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 intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance and expand our clinical and preclinical development programs, including to fund additional monotherapy and combination clinical studies for ZN-c5, ZN-c3, ZN-d5 and ZN-e4, and for working capital and other general corporate purposes. Advancing the development of our product candidates will require a significant amount of capital. The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to fund all of the activities that are necessary to complete the development of our product candidates.

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 trials may not be predictive of the success of later clinical trials. Moreover, preclinical 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 to 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 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, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline 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 topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline 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 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, elsewhere in this prospectus. 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 after this offering.

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

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

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

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- 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;
- pricing and the availability of coverage and adequate reimbursement 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 or plan to evaluate 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-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 jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining 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

- 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 FDA 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, 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, several 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 2030 unless additional congressional action is taken, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020 implemented under the Coronavirus Aid, Relief, and Economic Security Act, which was signed into law on March 27, 2020. In addition, 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 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. 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;

- 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. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- 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 provided during the previous year 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, 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 futu

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 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 and retaining 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 avail

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 the Company and 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, 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 the Company and 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 transaction pursuant to Section 381 of the Internal Revenue Code of 1986, as amended, or the Code, or certain other transactions), 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, including as a result of the IPO, and we may experience ownership changes in the future as a result of this offering or subsequent 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 condit

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 issued, 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 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 prospectus, 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 licensors 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.

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 this Offering and 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 following this offering 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. Since the shares were sold in our IPO in April 2020 at a price of \$18.00 per share, the price per share of our common stock has ranged as low as \$22.00 and as high as \$59.32 through July 24, 2020. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, 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 relies in part on 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 the analysis who cover us downgrade our stock or change their opinion of our stock, 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 are able to exert significant influence over matters subject to stockholder approval.

After this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates will beneficially own approximately 44.3% 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.

# If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution.

Investors purchasing shares of our common stock in this offering will pay a price per share that substantially exceeds the as adjusted net tangible book value per share of our outstanding common stock. As a result, investors purchasing common stock in this offering will experience immediate dilution in the pro forma as adjusted net tangible book value per share of \$29.92 per share, representing the difference between our assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, and our as adjusted net tangible book value per share as of March 31, 2020. You will experience additional dilution when those holding stock options or warrants exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. See "Dilution."

# A significant portion of our total outstanding shares are eligible to be sold into the market. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Subject to the restrictions set forth in the 90 day lock up agreements to be entered into by each of our directors and officers and certain of our stockholders in connection with this offering and the 180 day lock up agreements entered into by substantially all of our stockholders in connection with our IPO, each as described elsewhere in this prospectus under the heading "Underwriters" (which restrictions may be waived, with or without notice and at their sole discretion, by Morgan Stanley & Co. LLC, Jefferies LLC and SVB Leerink LLC), 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.

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 a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting 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 in this prospectus;
- · 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 in this prospectus and our periodic reports and proxy statements; 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 first fiscal year in which our annual gross revenue is \$1.07 billion or more; (2) the last day of 2025; (3) the date we qualify as a "large accelerated filer," as defined in Rule 12b-2 under the Exchange Act; and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than \$100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter.

Similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations, such as an exemption from providing selected financial data and an ability to provide simplified executive compensation information and only two years of audited financial statements.

# 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 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 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 this prospectus and in future filings required of a public company, our business and financial condition will 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 are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. 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. 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.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance and expand our clinical and preclinical development programs, including to fund additional monotherapy and combination clinical studies for ZN-c5, ZN-c3 and ZN-d5, and for working capital and other general corporate purposes. See "Use of Proceeds." However, within the scope of our plan, and in light of the various risks to our business, including those discussed in this "Risk Factors" section and elsewhere in this prospectus, our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

## 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 precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan,", "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek an accelerated approval pathway and special designations, such as orphan drug designation, for our product candidates for various diseases;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- risks associated with the COVID-19 outbreak, which may adversely impact our business, preclinical studies and clinical trials;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;

- our plans regarding, and our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our plans to develop our product candidates in combination with other therapies;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from this offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

# INDUSTRY AND OTHER DATA

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

The industry in which we operate is subject to risks and uncertainties due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

#### USE OF PROCEEDS

We estimate that the net proceeds to us from in this offering will be approximately \$138.9 million based on an assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately \$159.8 million.

Each \$1.00 increase (decrease) in the assumed public offering price of \$39.61 per share would increase (decrease) the net proceeds to us from this offering by approximately \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, by \$37.2 million, assuming the assumed public offering price stays the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

- approximately \$65.0 million to advance the clinical development of ZN-c5, including to complete a planned Phase 1b clinical trial evaluating ZN-c5 in combination with abemaciclib (marketed as Verzenio® by Lilly), to complete a planned Phase 1b clinical trial evaluating ZN-c5 in combination with our BCL2 inhibitor product candidate, ZN-d5 and, subject to feedback from the FDA, initiate a potential Phase 2/3 clinical trial in patients with earlier stage breast cancer;
- approximately \$40.0 million to advance the clinical development of ZN-c3, including to complete a planned Phase 2 clinical trial of ZN-c3 in patients with uterine serous carcinoma and to initiate two additional Phase 1 clinical trials evaluating ZN-c3 in combination with chemotherapy and PARP inhibitors focused on ovarian cancer and other targeted indications;
- approximately \$15.0 million to advance the clinical development of ZN-d5, including to complete the planned Phase 1b clinical trial evaluating ZN-d5 in combination with our oral SERD product candidate, ZN-c5; and
- the remainder to advance the clinical development of ZN-e4 the design and development of new product candidates leveraging our Integrated Discovery Engine and for working capital and other general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of any product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

After offering expenses, the net proceeds from this offering (based on an assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020) combined with our current cash and cash equivalents will be approximately \$366.3 million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. The expected net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

# DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

#### CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2020, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the Corporate Conversion, (ii) the Share Exchange, (iii) the sale and issuance of 10,557,000 shares of our common stock in the IPO for aggregate net proceeds of approximately \$172.4 million and (iv) the sale and issuance of equity interests of our majority-owned joint venture, Zentera, for aggregate net proceeds of \$18.4 million; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 3,750,000 shares of our common stock in this offering at an assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other financial information contained in this prospectus.

	As of March 31, 2020			
		Pro Forma(1) sands, except un	Adj iit, sha	o Forma As justed(1)(2) are and
Cash and cash equivalents	\$ 63,650	per share amou \$254,439	ints) \$	393,314
Convertible preferred units:	<del> </del>	<del></del>	<u> </u>	
Series A convertible preferred units: 1,579,309 units issued and outstanding, actual; no units issued or outstanding pro				
forma and pro forma as adjusted	\$ 18,226	\$ —	\$	_
Series B convertible preferred units: 3,523,739 units issued and outstanding, actual; no units issued or outstanding pro				
forma and pro forma as adjusted	41,604	_		_
Series C convertible preferred units: 5,714,300 units issued and outstanding, actual; no units issued or outstanding pro				
forma and pro forma as adjusted	96,104	_		_
Equity:				
Class A common units: 5,601,478 units issued and outstanding, actual; no units issued or outstanding pro forma and pro forma as adjusted	709	_		_
Class B common units: 2,607,309 units issued and outstanding, actual; no units issued or outstanding pro forma and pro forma as adjusted	2,507	_		_
Common stock, \$0.001 par value per share: no shares authorized, issued and outstanding, actual; 250,000,000 shares authorized, pro forma and pro forma as adjusted; 35,878,518 shares issued and outstanding, pro forma; 39,628,518 shares				
issued and outstanding, pro forma as adjusted	_	36		40
Preferred stock, \$0.001 par value per share: no shares authorized, issued and outstanding, actual; 10,000,000 shares				
authorized, pro forma and pro forma as adjusted; no shares issued and outstanding, pro forma and pro forma as adjusted				
Additional paid-in capital	— (00.110)	331,479		470,350
Accumulated deficit	(99,119)	(99,119)		(99,119)
Noncontrolling interest	6,712	25,136	_	25,136
Total equity (deficit)	(89,191)	257,532		396,407
Total capitalization	\$ 66,743	\$257,532	\$	396,407

<sup>(1)</sup> In connection with the Corporate Conversion, Series A convertible preferred units, Series B convertible preferred units and Series C convertible preferred units and Class A common units and Class B common units were reduced to zero to reflect the elimination of all

- outstanding units and other interests in Zentalis Pharmaceuticals, LLC and corresponding adjustments have been reflected as common stock and additional paid-in capital. The pro
- outstanding units and other interests in Zentalis Pharmaceuticals, LLC and corresponding adjustments have been reflected as common stock and additional paid-in capital. The proforma and pro forma as adjusted information is illustrative only.

  Each \$1.00 increase (decrease) in the assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total equity and total capitalization by \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) each of cash and cash equivalents, total equity and total capitalization, by \$37.2 million, assuming the assumed public offering price stays the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. (2) expenses payable by us.

#### DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Pro forma net tangible book value per share represents the book value of our tangible assets less the book value of our total liabilities divided by the number of shares of common stock then issued and outstanding after giving effect to the Corporate Conversion.

The historical net tangible book value as of March 31, 2020 was \$54.2 million or, \$9.68 per Class A common unit. Historical net tangible book value per Class A common unit represents the amounts of our tangible assets less total liabilities, divided by the total number of Class A common units outstanding as of March 31, 2020. On a pro forma basis, after giving effect to (i) the Corporate Conversion, (ii) the Share Exchange, (iii) the sale and issuance of 10,557,000 shares of our common stock in the IPO for aggregate net proceeds of approximately \$172.4 million and (iv) the sale and issuance of equity interests of our majority-owned joint venture, Zentera, for aggregate net proceeds of \$18.4 million, our pro forma net tangible book value as of March 31, 2020 was \$245.0 million, or \$6.83 per share, based on 35,878,518 shares of our common stock outstanding after the IPO. After giving effect to our sale of 3,750,000 shares of common stock in this offering at an assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2020 would have been approximately \$383.9 million, or approximately \$9.69 per share. This amount represents an immediate and substantial dilution of \$29.92 per share to new investors purchasing common stock in this offering. The following table illustrates this dilution:

Assumed public offering price per share		\$39.61
Historical net tangible book value per Class A common unit as of March 31, 2020	\$9.68	
Pro forma net tangible book value per share as of March 31, 2020 before this offering	6.83	
Increase in the pro forma net tangible book value per share attributable to this offering	\$2.86	
Pro forma as adjusted net tangible book value per share after this offering		\$ 9.69
Dilution per share to new investors participating in this offering		\$29.92

A \$1.00 increase (decrease) in the assumed public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$0.09, and dilution in pro forma as adjusted net tangible book value per share to new investors by approximately \$0.91, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1.0 million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by \$0.68 per share and decrease the dilution to new investors purchasing common stock in this offering to \$29.25 per share, assuming the assumed public offering price remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1.0 million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value per share after this offering by \$0.71 per share and increase the dilution to new investors purchasing common stock in this offering to \$30.64 per share, assuming the assumed public offering price remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be \$10.07 per share, and the dilution to new investors would be \$29.54 per share, in each case assuming a public offering price of \$39.61 per share, which is the last reported sale price of our common stock on The Nasdaq Global Market on July 24, 2020, and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us.

# SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected financial data for the periods indicated. We have derived the consolidated statements of operations data for the years ended December 31, 2018 and 2019, and the consolidated balance sheet data as of December 31, 2018 and 2019, from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the three months ended March 31, 2019 and 2020 and the balance sheet data as of March 31, 2020 are derived from our unaudited interim consolidated financial statements included elsewhere in this prospectus. In our opinion, these unaudited interim consolidated financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. Our historical results are not necessarily indicative of the results that should be expected for any future period and our operating results for the three month period ended March 31, 2019 and 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2020 or any other interim periods or any future year or period. You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

	Year Ended December 31,				Three Months Ender March 31.			ıded		
		2018 2019				2019		2020		
			(1	in thousands, e and per sha						
Consolidated Statements of Operations Data:				<b>P</b>		,				
Revenue	\$	14	\$	_	\$	_	\$			
Operating expenses:										
Research and development		18,921		38,386		7,089		13,258		
General and administrative		4,876		8,459		1,633		3,141		
Total operating expenses		23,797 40			46,845 8,72			16,399		
Loss from operations		(23,783) (46,84			(8,722)			(16,399)		
Other income										
Interest income		355		498		74		164		
Other expense				(16)		(12)				
Net loss before income taxes		(23,428)	(46,363)		(46,363)			(16,235)		
Income tax expense		4		15		15		3		
Net loss		(23,432)	(46,378)		(8,663)			(16,235)		
Net loss attributable to noncontrolling interest		(2,365)		(715)		(320)		(109)		
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$ (21,067)		(21,067) \$ (45,66		\$ (45,663) \$ (8,5)		\$	(16,126)		
Net loss per Class A common unit attributable to Zentalis Pharmaceuticals,	<del></del>									
LLC, basic and diluted(1)	\$	(3.77)	\$	(8.16)	\$	(1.49)	\$	(2.88)		
Weighted average Class A common units outstanding, basic and diluted(1)	5,	594,385		5,597,358	5,	,594,385		5,601,478		

<sup>(1)</sup> See Note 12 to our consolidated financial statements included elsewhere in this prospectus and Note 11 to our unaudited consolidated financial statements included elsewhere in this prospectus for additional information regarding the method used to calculate the basic and diluted net loss per common share.

	As of Dec 2018	ember 31, 2019 (in thousands)	As of March 31, 2020
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 25,154	\$ 67,246	63,650
Working capital <sup>(1)</sup>	20,469	53,994	49,070
Total assets	40,998	87,481	87,629
Total liabilities	8,692	19,060	20,886
Accumulated deficit	(37,330)	(82,993)	(99,119)
Total equity (deficit)	32,306	(73,285)	(89,191)

<sup>(1)</sup> We define working capital as current assets less current liabilities.

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

You should read the following discussion and analysis of financial condition and operating results together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of the prospectus captioned "Risk Factors" and elsewhere in this prospectus, 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 portions of this Phase 1/2 trial in the first half of 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 submit an IND to the FDA for our fifth product candidate 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.

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 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 the underwriting discounts and commissions and offering expenses. We had cash and cash equivalents of \$63.7 million as of March 31, 2020. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, 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 \$8.7 million and \$16.2 million for the three months ended March 31, 2019 and March 31, 2020, respectively. We had an accumulated deficit of \$83.0 million as of December 31, 2019. 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, 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 how 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

#### **License Agreements and Strategic Collaborations 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. 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 IPO, based on the IPO price of \$18.00 per share, Recurium Equity, LLC's ownership interest in us was 11.6%, 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. Upon the closing of this offering, based on our issuance and sale of 3,750,000 shares in this offering, Recurium Equity, LLC's ownership interest us would be 10.5%, 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. See "Business—Licensing Agreements and Strategic Collaborations—Recurium IP Holdings, LLC" for more information.

# 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 February 29, 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 prospectus, 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. See "Business—License Agreements and Strategic Collaborations—Mayo Foundation for Medical Education and Research" for more information.

### 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. See "Business—License Agreements and Strategic Collaborations—SciClone International (Cayman) Development Ltd" for more information.

### 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.

See "Business—License Agreement and Strategic Collaborations—Pfizer Clinical Trial Collaboration and Supply Agreement" for more information.

#### 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.

See "Business—License Agreement and Strategic Collaborations—Eli Lilly and Company Trial Collaboration and Supply Agreement" for more information.

# 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.

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 cliam of a licensed patent and the 15<sup>th</sup> anniversary of the first commercial sale of such product in such region. See "Business—License Agreement and Strategic Collaborations—Zentera Therapeutics."

# **Components of Our Results of Operations**

#### Revenue

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

# Research and Development Expenses

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

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

We expense research and development costs as incurred. Reimbursed research and development costs under 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:

	Year Ended December 31,			Months March 31,
	2018	2019	2019	2020
		(in thou	sands)	
ZN-c5	\$ 5,081	\$ 9,733	\$1,006	\$ 4,693
ZN-c3	1,857	6,094	1,087	1,641
ZN-d5	1,401	4,736	814	1,267
ZN-e4	1,525	3,946	570	753
Unallocated research and development expenses	9,057	13,877	3,612	4,904
Total research and development expenses	\$18,921	\$38,386	\$7,089	\$13,258

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

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

- per patient trial costs;
- the number of patients who enroll in each trial;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- any delays in clinical trials 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;
- 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-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 and cash equivalents. We expect our interest income to increase due to the net proceeds from our IPO and from this 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 audited consolidated financial statements and Note 3 to our unaudited consolidated financial statements, in each case, included elsewhere in this prospectus.

# **Results of Operations**

# Comparison of Three Months Ended March 31, 2020 to Three Months Ended March 31, 2019

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

	Three Mont		
	March		Increase
	2020	2019	Decrease
	(	in thousands)	
Operating expenses			
Research and development	\$ 13,258	\$ 7,089	\$ 6,169
General and administrative	3,141	1,633	1,508
Total operating expenses	16,399	8,722	7,677
Loss from operations	(16,399)	(8,722)	7,677
Interest income	164	74	90
Other expense		(12)	12
Net loss before income taxes	(16,235)	(8,660)	(7,575)
Income tax expense		3	(3)
Net loss	(16,235)	(8,663)	(7,572)
Net loss attributable to noncontrolling interest	(109)	(320)	211
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$(16,126)	(8,343)	\$(7,783)

#### Revenue

We did not generate any revenue for the three months ended March 31, 2020 and March 31, 2019.

# Research and Development Expenses

Research and development expenses for the three months ended March 31, 2020 were \$13.3 million, compared to \$7.1 million for the three months ended March 31, 2019. The increase of \$6.2 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 each of ZN-c5, ZN-c3 and ZN-e4. In addition, in the three months ended March 31, 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 \$1.3 million primarily due to \$1.6 million of additional employee related costs associated with increased headcount to support our platform development, partially offset by a decrease of \$0.3 million due to a reduction in expenses in our early stage programs as our lead product candidates advanced into clinical development.

## General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2020 were \$3.1 million, compared to \$1.6 million during the three months ended March 31, 2019. This increase of \$1.5 million was primarily attributable to an increase of \$0.6 million in employee-related costs as we increased our headcount to support our growth and an increase of \$0.8 million in professional services fees for legal, accounting and consulting services.

# Interest Income

Interest income was \$0.2 million for the three months ended March 31, 2020, compared to \$0.1 million for the three months ended March 31, 2019. The increase of \$0.1 million was the result of interest earned on higher invested cash balances.

# Comparison of Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019, together with the changes in those items in dollars:

	Year Ended December 31,				
	2018	2	2019		rease rease)
		(in the	ousands)		
Revenue	\$ 1	4 \$	_	\$	(14)
Operating expenses					
Research and development	18,92	1 3	8,386	19	9,465
General and administrative	4,87	6	8,459	3	3,583
Total operating expenses	23,79	7 4	6,845	23	3,048
Loss from operations	(23,78	3) (4	6,845)	23	3,062
Interest income	35	5	498		143
Other expense			16		16
Net loss before income taxes	(23,42	8) (4	6,363)	22	2,935
Income tax expense		4	15		11
Net loss	(23,43	2) (4	6,378)	22	2,946
Net loss attributable to noncontrolling interest	(2,36	5)	(715)	(1	1,650)
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$(21,06)	7) \$(4	5,663)	\$ 24	1,596

#### Revenue

Revenue for the year ended December 31, 2018 was \$13,922, which was generated solely from payments received for reimbursement of research and development expenses pursuant to the SciClone Agreement. We did not generate any revenue for the year ended December 31, 2019.

# Research and Development Expenses

Research and development expenses for the year ended December 31, 2018 were \$18.9 million, compared to \$38.4 million for the year ended December 31, 2019. The increase of \$19.5 million was primarily due to increases in external research and development expenses related to our lead product candidates, as we initiated our Phase 1/2 clinical trials for each of ZN-c5, ZN-c3 and ZN-e4 in 2019. In addition, in 2019, 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 \$5.1 million of additional employee related costs associated with increased headcount to support our platform development, partially offset by a decrease of \$0.3 million due to a reduction in expenses in our early stage programs as our lead product candidates advanced into clinical development.

# General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2018 were \$4.9 million, compared to \$8.5 million during the year ended December 31, 2019. This increase of \$3.6 million was primarily attributable to an increase of \$1.9 million in employee-related costs as we increased our headcount to support our growth and an increase of \$1.7 million in professional services fees for legal, accounting and consulting services.

# Interest Income

Interest income was \$0.4 million for the year ended December 31, 2018, compared to \$0.5 million for the year ended December 31, 2019. The increase of \$0.1 million was the result of interest earned on higher invested cash balances in 2019.

#### 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 could adversely affect the economies and financial markets 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 March 31, 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. As of March 31, 2020, we had \$63.7 million in cash and cash equivalents and an accumulated deficit of \$99.1 million. We had no indebtedness as of March 31, 2020.

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 offering expenses payable by us.

#### Cash Flows

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

	Year I		Three Months Ende		
	Decem		March 31,		
	2018	2019	2019	2020	
Net cash used in operating activities	\$(24,251)	\$(39,143)	\$(9,006)	\$(16,871)	
Net cash used in investing activities	(227)	(352)	(41)	(31)	
Net cash provided by financing activities	9,472	81,830		13,474	
Increase (decrease) in cash and cash equivalents	\$(15,006)	\$ 42,335	\$(9,047)	\$ (3,428)	

# **Operating Activities**

We have incurred losses since inception. Net cash used in operating activities for the three months ended March 31, 2020 was \$16.9 million, consisting primarily of our net loss of \$16.2 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses, and partially offset by changes in operating assets and liabilities of \$1.0 million and non-cash adjustments of \$0.4 million.

Net cash used in operating activities for the three months ended March 31, 2019 was \$9.0 million, consisting primarily of our net loss of \$8.7 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses.

Net cash used in operating activities for the year ended December 31, 2019 was \$39.1 million, consisting primarily of our net loss of \$46.4 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses, and partially offset by changes in operating assets and liabilities of \$6.5 million and non-cash adjustments of \$0.7 million.

Net cash used in operating activities for the year ended December 31, 2018 was \$24.3 million, consisting primarily of our net loss of \$23.4 million as we incurred expenses associated with research activities for our lead product candidates and incurred general and administrative expenses.

#### **Investing Activities**

Net cash used in investing activities for the three months ended March 31, 2020 was \$31.0 thousand consisting of purchases of property and equipment.

Net cash used in investing activities for the three months ended March 31, 2019 was \$41.0 thousand consisting of purchases of property and equipment.

Net cash used in investing activities for the year ended December 31, 2019 was \$0.4 million consisting of purchases of property and equipment.

Net cash used in investing activities for the year ended December 31, 2018 was \$0.2 million consisting of purchases of property and equipment.

# Financing Activities

Net cash provided by financing activities in the three months ended March 31, 2020 of \$13.5 million primarily relates to net proceeds from the issuance of our Series C convertible preferred units.

There were no cash flows from financing activities in the three months ended March 31, 2019.

Net cash provided by financing activities in the year ended December 31, 2019 of \$81.8 million primarily relates to net proceeds from the issuance of our Series C convertible preferred units.

Net cash provided by financing activities in the year ended December 31, 2018 of \$9.5 million primarily relates to net proceeds from the issuance of our Series B convertible preferred units.

# **Funding Requirements**

Our operating expenses have increased substantially in 2019 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 the anticipated net proceeds from this offering, together with our existing cash and cash equivalents 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 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" 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.

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 following is our contractual obligations and commitments as of December 31, 2019:

		Payments Due By Period			
		Less than 1-3 3-5		3-5	More than
	Total	1 year	years	years	5 years
			in thousands)		
Operating lease obligations(1)	\$2,907	\$ 1,015	\$1,705	\$187	\$ —

(1) Amounts exclude laboratory space in San Diego, California, for which we entered into a lease in January 2020, and a one-time lease modification payment of approximately \$0.9 million in connection with the early termination of this lease in July 2020.

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material and they are not included in the table above.

We have not included milestone or royalty payments or other contractual payment obligations in the table above if the timing and amount of such obligations are unknown or uncertain.

## **Off-Balance Sheet Arrangements**

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

#### Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of \$67.2 million and \$63.7 million as of December 31, 2019 and March 31, 2020, respectively. We generally hold our cash in interest-bearing money market accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

# **Critical Accounting Policies and Use of Estimates**

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

While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

# Goodwill and In-Process Research and Development

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

Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Upon conclusion of the relevant research and development project, we amortize the acquired IPR&D over its estimated useful life or expense the acquired IPR&D should the research and development project be unsuccessful with no future alternative use. We base the useful lives and related amortization expense on our estimate of the period that the assets will generate revenues or otherwise be used. We assess the carrying value of our IPR&D assets at least annually, or more frequently if an event occurs indicating the potential for impairment, which requires us to make assumptions and judgements regarding the future cash flows of these assets. If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by a combination of third-party sources and forecasted discounted cash flows.

Goodwill is reviewed for impairment at least annually, or more frequently if an event occurs indicating the potential for impairment. During the impairment review process, we consider qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than the carrying amount, including goodwill. If we determine that it is not more likely than not that the fair value of our reporting unit is less than the carrying amount, then no additional assessment is deemed necessary. Otherwise, we perform the two-step test for goodwill impairment. The first step involves comparing the estimated fair values of the

reporting units with the carrying values, including goodwill. If the carrying amounts of the reporting units exceed the fair values, the second step of the goodwill impairment test is performed to determine the amount of loss, which involves comparing the implied fair values of the goodwill to the carrying values of the goodwill. We completed our most recent annual evaluation for impairment for goodwill and IPR&D as of December 31, 2019 using the qualitative assessment and determined that no impairment existed, and no charges were recorded.

# Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

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

# **Incentive Unit-based Compensation**

Prior to our IPO, we granted equity awards in the form of Class B common unit awards pursuant to the Zentalis Pharmaceuticals, LLC Profits Interest Plan, or the Profits Interests Plan. Each unvested Class B common unit represents a non-voting equity interest in us that entitles the holder to a percentage of the profits and appreciation in our equity value arising after the date of grant and after such time as an applicable threshold amount is met. Class B common units issued under the Profits Interest Plan with time-based vesting schedules generally vest over a four-year period with cliff vesting for the first year.

The Black Scholes option pricing model, which is a standard option pricing model, is used to estimate the fair value of each profits unit award on the date of grant. This model requires the use of numerous assumptions, including, among others, the expected life of incentive units, volatility of the underlying equity security, risk-free interest rate and dividends. These assumptions reflect our best estimates as we do not have publicly traded equity, have a limited operating history and involve inherent market uncertainties that are outside of our control. The use of different values by management in connection with these assumptions in the Black Scholes option pricing model could produce substantially different results. If we use different assumptions for future grants, unit-based compensation cost could be materially different in future periods.

Following the closing of our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.

# **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 in which our annual gross revenue is \$1.07 billion or more, (2) the last day of 2025, (3) the date that we

become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the last business day of our most recently completed second fiscal quarter; and (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during any three-year period.

# **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 audited consolidated financial statements included elsewhere in this prospectus.

#### BUSINESS

#### 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, if approved, have the potential to significantly impact clinical outcomes 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 advanced 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 portions of this Phase 1/2 trial in the first half of 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 mutant 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, respectively, 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. 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-e4, 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., or SciClone.

The following table summarizes our product candidate pipeline.

		IND Enabling	Phase 1/2	Phase 3	Collaborator	Anticipated Key Milestones
ZN-c5: Oral SERD	ER+ / HER2- Breast Cancer (2)				Lilly; Pfizer; Zentera	Initiate Phase 1b combination study 2H 2020 Initiate Phase 2 monotherapy and combination studies 1H 2021
ZN-c3: WEE1 Inhibitor	Solid Tumors				Zentera	Topline results from Phase 1 2021
ZN-d5: BCL-2 Inhibitor	Hematological Malignancies <sup>(2)</sup>				Zentera	Initiate Phase 1 trial 1H 2021
ZN-e4: EGFR Inhibitor	NSCLC				SciClone	Topline results from Phase 1 2021

(1) We are currently evaluating ZN-c5 in combination with palbociclib, as part of a clinical research collaboration with Pfizer, and intend to evaluate ZN-c5 in combination with abemaciclib, as part of a clinical research collaboration with Eli Lilly and Company, or Lilly. We maintain full ownership of ZN-c5 in each such collaboration. SciClone has development and commercial rights to ZN-e4 in Greater China (including Macau and Hong Kong), South Korea, Taiwan and Vietnam. Zentera, our majority-owned joint venture, has development and commercial rights to ZN-c5, ZN-c3 and ZN-d5 in select Asian countries (including China). Zentera intends to submit an IND in China for each of ZN-c5, ZN-c3 and ZN-d5 in 2021.

(2) We plan to explore the combination potential of ZN-c5, our oral SERD, with ZN-d5, our BCL-2 inhibitor, for the treatment of ER+/HER2- breast cancer.

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 IND to the FDA in 2021.

In the five years since our inception, we have successfully cleared four INDs with the FDA, and expect to submit a fifth IND in 2021. Our Integrated Discovery Engine has enabled us to take each of our clinical-stage product candidates from initial discovery to IND submission in less than three years in a capital efficient manner. We begin our process of drug discovery by identifying fundamental biological pathways of cancers based on a number of factors, including validation of the pathway through prior clinical outcomes and ability to impact large patient populations. We then analyze existing marketed products and compounds in development that target these cancer pathways and assess their limitations, efficacy, safety, tolerability, PK, patient convenience, and potential to be used in combination with other therapies. Next, we use our medicinal chemistry expertise and extensive understanding of target-drug structure activity to design proprietary NCEs with properties that we believe can address observed limitations and suboptimal drug characteristics of marketed products or other compounds in development, including potency, solubility, route of administration and PK properties. We believe overcoming these limitations may also allow us to develop these product candidates for use in combination with other therapies, including with our internally developed product candidates, if approved. Finally, we strive to generate preclinical data to support that such candidates could have a differentiated product profile in our expected lead indications before advancing a compound into clinical development. We have used our Integrated Discovery Engine to generate a pipeline of four product candidates targeting solid tumors and hematological malignancies. Longer term, we believe our discovery engine has the potential to generate product candidates addressing a wide range of additional therapeutic areas.

Our lead product candidate, ZN-c5, is an oral SERD for the treatment of ER+/HER2- advanced or metastatic breast cancer. ER+/HER2- breast cancer affects approximately 70% of all breast cancer patients in the United States. These tumors depend on the estrogen receptor, or ER, for growth and survival, and are currently treated by a number of approved hormonal therapies. We have designed ZN-c5 to overcome limitations of existing hormonal therapies, including the only FDA-approved SERD, fulvestrant (marketed as Faslodex® by AstraZeneca). Despite its limitations, Faslodex® generated worldwide sales of over \$1.0 billion in 2018, the last year prior to generic competition, reflecting part of the significant potential of the SERD therapeutic class in ER+/HER2- breast cancer.

We believe ZN-c5, which is being developed for convenient oral administration, has the potential to be used as monotherapy and in combinations, and could become the standard of care for hormonal therapy in the treatment of all lines of ER+/HER2- breast cancer, if approved. We are currently evaluating ZN-c5 in a Phase 1/2 clinical trial in patients with ER+/HER2- advanced or metastatic breast cancer, both as monotherapy and in combination with palbociclib (marketed as Ibrance® by Pfizer) as part of a clinical research collaboration with Pfizer. Palbociclib is an inhibitor of cyclin dependent kinases 4 and 6, or CDK4/6, and is FDA approved for ER+/HER2- advanced or metastatic breast cancer patients in combination with hormonal therapies, such as fulvestrant. 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 CDK4/6 inhibitor FDA approved for the treatment of HR+/HER2- advanced or metastatic breast cancer patients 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 believe ZN-c5, if approved, may have a potentially differentiated product profile. Based on results from our ongoing Phase 1/2 clinical trial as of the database cutoff date of June 30, 2020, the PK of ZN-c5, as monotherapy and in combination with palbociclib, was characterized by rapid absorption into the systemic circulation and high drug exposure levels and six of the 15 patients in the Phase 1, monotherapy dose escalation

portion of the trial showed stable disease for 24 weeks, leading to a clinical benefit rate of 40% as of such date. In addition, ZN-c5 has been observed to be well tolerated with no dose-limiting toxicities reported. In preclinical studies, ZN-c5 has shown anti-tumor activity, potency and selectivity. We intend to initiate the Phase 2 monotherapy and combination portions of the Phase 1/2 trial in the first half of 2021. We are also currently dosing ZN-c5 in a Phase 1 Window of Opportunity study in patients with ER+/HER2- breast cancer scheduled to undergo surgical resection of the tumor or start neoadjuvant treatment. We expect to report topline results of the Window of Opportunity study in the first half of 2021. In addition, we 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.

ZN-c3 is our oral, small molecule inhibitor of WEE1, a DNA damage response protein. The inhibition of WEE1 aims to allow sufficient DNA damage in cancer cells to cause them to undergo programmed cell death, or apoptosis, thereby preventing tumor growth and potentially causing tumor regression. There is currently no FDA-approved WEE1 inhibitor. We believe ZN-c3, if approved, may have broad applicability in a wide range of cancers as monotherapy and in combination, including with chemotherapy agents and other targeted therapies. Based on data from 22 patients dosed in the Phase 1 monotherapy dose escalation portion of our ongoing Phase 1/2 clinical trial as of the database cutoff date of June 19, 2020, ZN-c3 has been observed to be well tolerated with no dose-limiting toxicities reported. We are currently conducting a Phase 1/2 clinical trial of ZN-c3 in patients with advanced solid tumors. We expect to report results from the Phase 1 portion of this trial in 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.

ZN-d5 is our oral, small molecule inhibitor of BCL-2 that we are initially developing for the treatment of hematologic malignancies. We intend 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 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.

ZN-e4 is our oral, small molecule product candidate being developed as an irreversible inhibitor of mutant EGFR. EGFR regulates a number of cellular functions, including cell proliferation and survival, and is a driver of tumor growth in certain cancers, including lung cancer. We have designed ZN-e4 to be highly selective against mutant EGFR. We are conducting a Phase 1/2 clinical trial of ZN-e4 in patients with advanced NSCLC with activating EGFR mutations and are currently evaluating potential combination therapies for future clinical development of ZN-e4. We expect to report topline results from the Phase 1 portion of the trial in 2021.

Pursuant to a collaboration and license agreement entered into in May 2020, we collaborate with Zentera, our majority-owned joint venture, on the development and commercialization of ZN-c5, ZN-c3 and ZN-d5 in select Asian countries (including China). Zentera intends to submit an IND in China for each of ZN-c5, ZN-c3 and ZN-d5 in 2021.

#### **Our History and Team**

We began operations in January 2015. We have assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients. Our management team has broad expertise and successful track records in drug discovery, clinical development, regulatory affairs, manufacturing and commercialization of cancer therapies, as well as in

business and finance, through previous experiences at leading institutions including Aisling Capital, Array Biopharma, Bayer Healthcare, CureVac AG, Eisai US, Goldman Sachs, IQVIA, Merck, Morgan Stanley, Novartis, Paratek Pharmaceuticals, Pfizer, PsiOxus Therapeutics and R-Pharm US.

We are guided by our board of directors, scientific advisory board and business advisory board. Our scientific advisory board works with our management team in planning, development and execution of scientific, clinical, and research and development initiatives and strategies, while our business advisory board works with our management team on business and operational initiatives and strategies. Our renowned scientific and business advisory boards are comprised of key scientific and clinical thought leaders in oncology: Stephen Ansell, M.D., Ph.D., Andrew Badley, M.D., Robert Glassman, M.D., Shaji Kumar, M.D., Anthony Letai, M.D., Ph.D., Ross Levine, M.D., Donald McDonnell, Ph.D., Chad Robins, M.B.A., and Kwok-Kin Wong, M.D., Ph.D. These individuals are associated with the following leading institutions: Adaptive Biotechnologies, Credit Suisse, Duke University, Harvard Medical School, Mayo Clinic, Memorial Sloan Kettering Cancer Center and NYU Langone Health.

We believe our experienced and diverse team is well positioned to leverage our highly efficient, Integrated Discovery Engine to identify targets and develop small molecule NCEs targeting fundamental biological pathways of cancers that are differentiated from existing marketed therapies by clinical performance, and address large patient populations.

#### Strategy

Our goal is to become a leading oncology-focused biopharmaceutical company. Our strategy includes the following key components:

- Discover and develop differentiated small molecule NCEs that address large patient populations in cancer. We have leveraged our broad industry experience and know-how, and the guidance of our scientific and business advisory boards, to build our Integrated Discovery Engine. This engine integrates our extensive capabilities across cancer biology and medicinal chemistry. We use our Integrated Discovery Engine to identify validated and fundamental targets and develop small molecule NCEs that are differentiated from existing marketed therapies by clinical performance, and, if approved, could offer meaningful benefits for patients. In addition, in April 2020 we entered into a discovery platform agreement with Tavros Therapeutics, Inc., or Tavros, to apply Tavros' functional genomic discovery platform to develop next generation targeted small molecule drug candidates, with an initial goal of expanding our oncology product candidate pipeline. We will continue to pursue opportunities for new technologies to enhance the Zentalis approach.
- Rapidly advance the development of our lead product candidate, ZN-c5, our oral SERD, toward regulatory approval for the treatment of ER+/HER2- advanced or metastatic breast cancer. We have designed ZN-c5 to overcome limitations of existing hormonal therapies including fulvestrant, the only FDA-approved SERD. Based on data observed in our preclinical studies and results from our ongoing Phase 1/2 clinical trial, we believe ZN-c5, if approved, may have a differentiated product profile. We are evaluating ZN-c5 as a treatment of ER+/HER2- advanced or metastatic breast cancer. ER+/HER2- breast cancer affects approximately 70% of all breast cancer patients in the United States. We are currently evaluating ZN-c5 in an ongoing Phase 1/2 clinical trial in patients with ER+/ HER2- advanced or metastatic breast cancer both as monotherapy and in combination with palbociclib and an ongoing Phase 1 Window of Opportunity study in patients with ER+/HER2- breast cancer scheduled to undergo surgical resection of the tumor or start neoadjuvant treatment. We intend to initiate the Phase 2 monotherapy and combinations portions of the Phase 1/2 trial, and to report topline results of the Window of Opportunity study, in the first half of 2021. In addition, we intend to initiate a Phase 1b open label, multi-center trial evaluating ZN-c5 in combination with abemaciclib 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, 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, and, subject to feedback from the FDA, a Phase 2/3 clinical trial evaluating ZN-c5 in earlier stage breast cancer patients in 2021.

- Advance our additional product candidates, ZN-c3 (WEE1 Inhibitor), ZN-d5 (BCL-2 Inhibitor) and ZN-e4 (EGFR Inhibitor), across multiple cancer indications. We are advancing the development of our other small molecule NCEs targeting fundamental biological cancer pathways. These product candidates are designed to be small molecule NCEs with differentiated product profiles. ZN-c3 is currently in a Phase 1/2 clinical trial for the treatment of advanced solid tumors; ZN-d5 is initially in development for the treatment of hematological cancers; and ZN-e4 is currently in a Phase 1/2 clinical trial for the treatment of advanced NSCLC. We expect to report topline results from the Phase 1 portions of the ongoing clinical 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 AML or B-cell lymphoma in the first half of 2021. In addition, we intend to initiate a Phase 1b clinical trial evaluating ZN-c3 in combination with chemotherapy in patients with uSC in 2021, and 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. We also 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.
- Continue to evaluate our product candidate pipeline in combination with internally discovered and third-party compounds. We believe the future of cancer treatment is to target multiple fundamental biological pathways through combination therapies. In our preclinical studies and clinical trials, our product candidates have shown the potential for combination with other approved and development- stage cancer therapies. For example, we are dosing ZN-c5, our oral SERD, in combination with palbociclib for the treatment of ER+/HER2- advanced or metastatic breast cancer and intend to initiate a Phase 1b clinical trial evaluating ZN-c5 in combination with abemaciclib for the treatment of ER+/HER2- advanced or metastatic breast cancer in the second half of 2020. We also plan to explore other potential combinations for our product candidates with internally developed compounds. For example, we plan to explore the combination potential of ZN-c5, our oral SERD, with ZN-d5, our BCL-2 inhibitor, for the treatment of breast cancer.
- Deploy our highly efficient Integrated Discovery Engine to further expand our product candidate pipeline. Our robust product candidate pipeline is enabled by our highly efficient drug discovery engine, which we plan to continue to leverage to discover and develop additional differentiated small molecule NCEs for the treatment of cancer. In the five years since our inception, we have successfully cleared four INDs with the FDA and expect to submit a fifth IND in 2021. Our Integrated Discovery Engine has enabled us to take our clinical-stage product candidates from initial discovery to acceptance of IND in less than three years per program and in a capital efficient manner. We are also currently advancing multiple small molecule programs in preclinical studies for other cancer indications, including select solid tumors and hematological malignancies.
- Evaluate strategic opportunities to accelerate development timelines and maximize the value of our product candidate pipeline. We currently own the worldwide development and commercial 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 outlicensed these rights to Zentera, our majority-owned joint venture, and for ZN-e4, for which we have out-licensed these rights to SciClone. We intend to evaluate additional collaborations that could maximize the value of our product candidate pipeline, either through the evaluation of our product candidates in combination with compounds owned by third-parties or through geographic collaborations outside of the United States that allow us to leverage the existing infrastructure of other companies.

#### **Our Zentalis Approach**

We have leveraged our extensive industry experience and know-how, and the guidance of our scientific advisory board, to build our Integrated Discovery Engine that integrates our extensive capabilities across cancer biology and medicinal chemistry. This engine enables us to identify targets for which small molecule NCEs with high potency, high exposure and other optimized drug properties could yield potentially differentiated product profiles. Our approach centers on utilizing our Integrated Discovery Engine to identify such targets and subsequently develop product candidates that address targets with large cancer patient populations. At the core of our Integrated Discovery Engine is our experienced and proven management team, as well as our renowned chemistry team that has over 150 years of combined discovery expertise and who have collectively brought 35 product candidates into clinical development, including 27 oncology product candidates. Due in large part to our Integrated Discovery Engine, we have four active INDs with the FDA, and expect to submit a fifth IND in 2021.

Our Integrated Discovery Engine is executed through the following process:

- First, identify fundamental biological pathways of cancers, considering a number of factors, including prior clinical outcomes, input from
  our scientific and business advisory boards, large unmet medical need and market opportunity.
- **Second**, identify and analyze key products or compounds targeting these cancer pathways and assess their limitations, including with respect to efficacy, safety, tolerability, PK, patient convenience, and their potential to be used in combination.
- *Third*, use our medicinal chemistry expertise and deep understanding of target-drug structure activity relationships to create proprietary NCEs that are designed to improve upon and address observed limitations of existing products or compounds.
- Fourth, generate strong preclinical data to support our view that such candidates could have potentially differentiated product profiles in
  our expected lead indications, if approved, before moving a compound into clinical development.

Our highly efficient Integrated Discovery Engine has enabled us to develop, a diverse pipeline of product candidates entirely in-house and in a capital efficient manner. Across our clinical-stage programs, we have synthesized an average of approximately 80 compounds and have progressed from initial concept to submission of IND in less than three years on average, a significantly shorter period than the 66 month average among large pharmaceutical institutions. The estimated direct costs of each of these clinical-stage programs from initial concept to acceptance of IND were less than \$10.0 million.

#### First Four Programs Generated Using Zentalis' Integrated Discovery Engine

Programs	Oral SERD WEE1 Inhibitor		BCL-2 Inhibitor	EGFR Inhibitor
Initial Indication	ER+ / HER2- Breast Cancer	Solid Tumors	Hematological Malignancies	NSCLC
# of Compounds Screened	67	151	86	18
Time to IND	28 months	33 months	37 months	31 months

We have initially chosen to focus on targets that have been validated clinically and, in most cases, commercially. This provides us with a clear understanding of the indications we will target and endpoints that have been required for regulatory approval of products for these indications in the past, as well as the potential for clinical adoption and commercial success. This strategy has enabled us to begin our drug discovery and development process at an advanced state relative to where the process would otherwise begin in focusing on uncharacterized targets. We believe this ability provides us with an efficient path to identifying novel drug compounds and advancing them into clinical development in a capital efficient manner.

#### **Our Product Candidates**

#### ZN-c5, an Oral SERD for the Treatment of ER+/HER2- Breast Cancer

#### Overview

We are developing ZN-c5, an oral, small molecule product candidate targeting the ER, a key driver of tumor growth and survival in ER+/HER2-breast cancer. These tumors are currently treated by a number of hormonal therapies; however, in contrast to most ER binders that simply block or modulate ER activity, ZN-c5 is also designed to cause degradation of the ER. As such, ZN-c5 is known as a Selective ER Degrader, or SERD. Fulvestrant, marketed as Faslodex® by AstraZeneca, is currently the only FDA-approved SERD. While effective, fulvestrant is limited to its FDA-approved dosing regimen of two painful 5 mL concomitant monthly intramuscular injections, thus restricting the level of ER degradation that can be induced in patients, which we believe limits its efficacy. We have applied our expertise to design ZN-c5 as an oral potent and selective SERD with characteristics which we believe may result in a differentiated product profile. We believe ZN-c5, if approved, has the potential to be used as monotherapy and in combinations and could become the standard of care for hormonal therapy in the treatment of all lines of ER+/HER2- breast cancer.

We are currently conducting a Phase 1/2 clinical trial of ZN-c5 in patients with ER+/HER2- advanced or metastatic breast cancer. ER+/HER2-breast cancer affects approximately 70% of all breast cancer patients in the United States. We continue to enroll patients and collect data for ZN-c5 administered as monotherapy and in combination with palbociclib as part of a clinical research collaboration with Pfizer. Palbociclib, marketed as Ibrance®, is a CDK4/6 inhibitor that is FDA approved for the treatment of ER+/HER2- advanced or metastatic breast cancer in combination with hormonal therapies, such as fulvestrant. 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 CDK4/6 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 maintain full ownership of ZN-c5 in each collaboration.

We intend to initiate the Phase 2 monotherapy and combination portions of the Phase 1/2 trial in the first half of 2021. We are also currently dosing ZN-c5 in a Phase 1 Window of Opportunity study in patients with ER+/HER2- breast cancer scheduled to undergo surgical resection of the tumor or start neoadjuvant treatment. We expect to report topline results of the Window of Opportunity study in the first half of 2021. In addition, we 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.

#### **Background on Breast Cancer and Current Treatments**

Breast cancer is the most prevalent cancer in women, accounting for 30% of all female cancers and 13% of cancer-related deaths in the United States. The National Cancer Institute estimated that approximately 270,000 new cases of breast cancer would be diagnosed in the United States in 2019, and approximately 42,000 breast cancer patients would die of the disease.

Most breast cancer tumor growth is dependent on two main protein receptors: estrogen receptor and human epidermal growth factor receptor 2. Approximately 70% of breast cancers in the United States are ER+/HER2-, meaning that they express ER and not HER2, and therefore depend on estrogen signaling for tumor growth and survival. These ER+ tumors are sometimes referred to as hormone receptor positive, or HR+ tumors, and are currently treated using several approaches:

- by blocking receptor function with selective ER modulators, or SERMs;
- · by blocking the synthesis of these hormones with aromatase inhibitors, or AIs; or

by degrading, and thus potentially eliminating ER receptors with a drug in the SERD class.

AIs have demonstrated superior clinical benefit to SERMs, including tamoxifen, and SERDs have demonstrated superior clinical benefit to AIs.

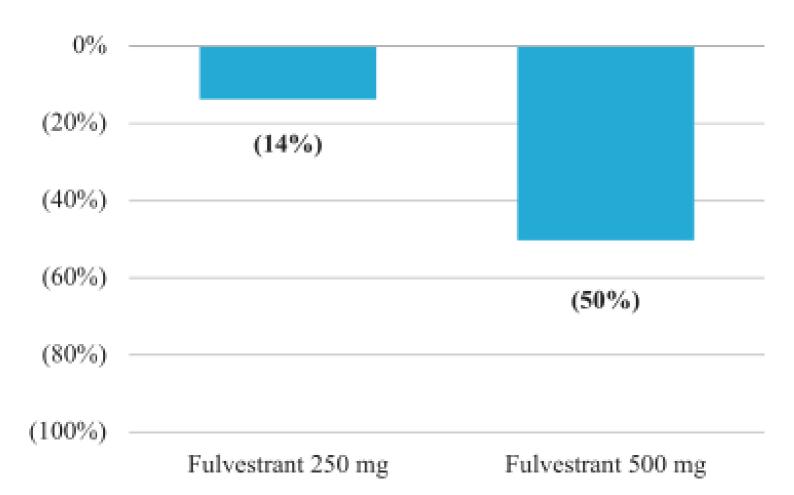
FDA-Approved SERD, Fulvestrant, and its Limitations

Currently, fulvestrant is the only FDA-approved SERD. Fulvestrant is FDA-approved for first and second-line treatment for women with HR+/HER2- advanced breast cancer both as monotherapy and as combination therapy with a number of other drug classes. Fulvestrant has demonstrated improved efficacy relative to AIs. In a randomized double-blind, placebo-controlled trial in treatment of naïve advanced and metastatic breast cancer patients, treatment with 500 mg of fulvestrant resulted in median progression free survival, or PFS, of 16.6 months versus 13.8 months for anastrozole, an FDA-approved oral AI marketed as Arimidex® by ANI Pharmaceuticals. However, fulvestrant has a number of pharmacological characteristics that require it to be delivered via two painful 5 mL concomitant monthly intramuscular injections, which we believe may limit its efficacy and tolerability. Despite these limitations, AstraZeneca reported worldwide sales of Faslodex® of over \$1.0 billion in 2018, the last year prior to generic competition.

We believe the following limitations associated with fulvestrant create an opportunity to develop a SERD with a superior product profile:

- **Route of administration**. Fulvestrant is highly insoluble and must be given via painful intramuscular injection. Fulvestrant is dosed monthly following two initial loading doses administered two weeks apart, and can only be delivered via two painful 5 mL concomitant monthly intramuscular injections.
- Capped efficacy in humans. Results of third-party clinical trials have shown that higher doses of fulvestrant increased ER degradation and efficacy. In a randomized Phase 2 clinical trial evaluating fulvestrant in 211 postmenopausal women with ER+ locally advanced or metastatic breast cancer, 250 mg and 500 mg of fulvestrant achieved a mean change of 14% and 50% of ER degradation, respectively, in each case measured at week 4 from dosing. In addition, in a Phase 3 clinical trial, the 500 mg dose arm achieved a median overall survival of 26.4 months as compared to 22.3 months achieved in the 250 mg dose arm.

#### Mean Change in ER Expression Levels (Week 4)



In preclinical mouse models, administration of 200 mg/kg of fulvestrant showed meaningful anti-tumor activity. However, based on recent published scientific literature, the human equivalent of the 200 mg/kg dose of fulvestrant results in exposure that is an estimated eight-fold higher than what is clinically

- achievable with the highest FDA-approved human dose (500 mg) of fulvestrant. Based on these clinical and preclinical data, we believe the overall efficacy that can be achieved with the administration of fulvestrant may be capped by the current FDA-approved dose.
- Convenience and resource utilization. The administration of fulvestrant as an intramuscular injection requires once monthly visits by patients to their health care providers, resulting in patient inconvenience and burden, such as time away from work. These injections also result in injection site pain, as well as bleeding complications in those patients with bleeding tendencies or anticoagulant use. In addition, significant injection related events such as sciatica, neuralgia, neuropathic pain, and peripheral neuropathy have been reported. Furthermore, we believe the combination of monthly intramuscular injections with a daily oral therapy, such as a CDK4/6 inhibitor, does not achieve optimal patient compliance.

#### SERD Use in Combination

Fulvestrant is FDA approved as a combination therapy with a number of other drug classes:

- *CDK4/6 inhibitors*. One common mechanism of resistance to fulvestrant is the activation of the CDK4/6 pathway. Fulvestrant administered in combination with oral CDK4/6 inhibitors has demonstrated improved clinical efficacy when compared with fulvestrant as monotherapy. In a randomized, double-blind clinical trial, treatment of HR+/HER2- advanced breast cancer patients with a combination of fulvestrant and palbociclib demonstrated a median PFS of 9.5 months compared to 4.6 months for those patients dosed with fulvestrant as a single agent. These patients had previously progressed on or after prior endocrine therapy. Worldwide sales of currently marketed CDK4/6 inhibitors, which are indicated for the treatment of breast cancer, were \$6.0 billion in 2019, and are expected to grow to \$14.4 billion in 2026. Worldwide sales of Ibrance® were \$5.0 billion in 2019 and are expected to grow to \$9.7 billion in 2026.
- Phosphoinositide 3-kinase, or PI3K, inhibitors. Another common mechanism of resistance to fulvestrant is the activation of the PI3K pathway, an important intracellular pathway that regulates cell growth and metabolism. Approximately one third of HR+ breast cancer tumors resistant to endocrine therapy harbor activating mutations of the catalytic subunit of PI3K, referred to as PIK3CA. Fulvestrant used in combination with alpelisib, an oral PI3K inhibitor marketed as Piqray® by Novartis approved by the FDA in May 2019, has demonstrated improved clinical efficacy in patients whose tumors had a PIK3CA mutation. In a randomized, double-blind clinical trial, treatment of HR+/HER2- advanced breast cancer patients with a PIK3CA mutation with a combination of fulvestrant and alpelisib led to a median PFS of 11.0 months compared to 5.7 months for those patients treated with fulvestrant as monotherapy. These patients had previously progressed on or after prior endocrine therapy. Worldwide sales of Piqray®, currently only FDA-approved for the treatment of breast cancer, were approximately \$116.0 million in 2019 and are expected to grow to \$1.4 billion in 2026.

Clinical data has also shown promising results from the use of fulvestrant with other targeted therapies:

• *Mammalian target of rapamycin, or mTOR, inhibitors.* Similar to CDK4/6 and PI3K, the mTOR pathway has also been identified as a mechanism of resistance to endocrine therapy. Everolimus is an mTOR inhibitor that is currently approved by the FDA for the treatment of HR+/HER2- advanced breast cancer in combination with exemestane, an AI. Everolimus has also shown clinical benefit in combination with fulvestrant. In a randomized, double-blind clinical trial, treatment of HR+/HER2- advanced breast cancer patients with a combination of fulvestrant and everolimus demonstrated a median PFS of 10.3 months compared to 5.1 months for those patients dosed with fulvestrant as monotherapy. These patients had previously progressed on or after prior AI therapy. Worldwide sales in breast cancer of everolimus, marketed as Afinitor® by Novartis and a leading mTOR inhibitor, were approximately \$831.0 million in 2019.

#### Our SERD Solution: ZN-c5

We believe a conveniently administered oral SERD with superior efficacy could be indicated for monotherapy or in combinations and could become the standard of care for hormonal therapy in the treatment of all lines of ER+/HER2- breast cancer.

ZN-c5 is our oral SERD product candidate, which we believe has the potential to overcome limitations of existing hormonal therapies in the treatment of ER+/HER2- breast cancer due to the following observed preclinical and clinical results:

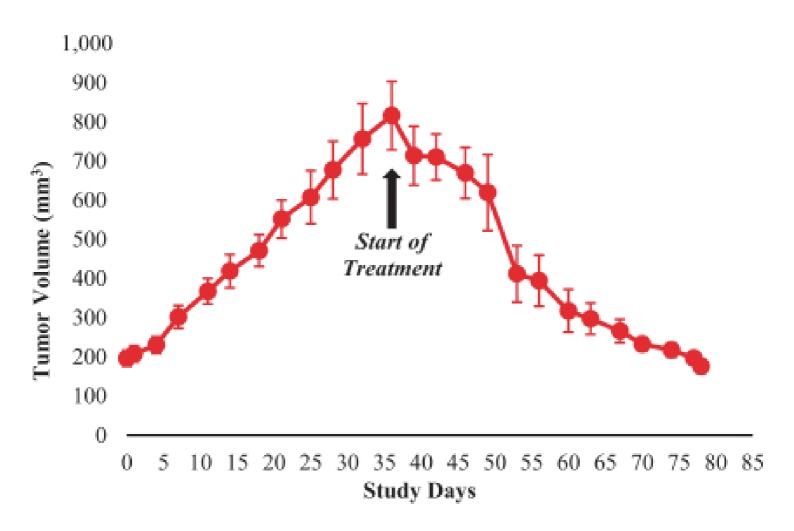
- **Potency and selectivity.** In our *in vitro* preclinical studies, we observed the potency of ZN-c5 as measured by proliferation inhibition and degradation of ERa, and that the combination of ZN-c5 and palbociclib was associated with meaningful shrinkage in MCF-7 tumors. In addition, ZN-c5 has exhibited no agonist activity in animal models which, if present, may compromise its anti-tumor activity.
- **Preclinical anti-tumor activity**. In preclinical studies, ZN-c5 demonstrated anti-tumor activity in multiple breast cancer cell lines, both as monotherapy and in combination with CDK4/6 inhibitors and PI3Ka inhibitors, as well as superior tumor growth inhibition when compared to fulvestrant. In addition, in preclinical studies ZN-c5 demonstrated increased anti-tumor activity when administered in combination with BCL-2 inhibitors, including our BCL-2 inhibitor product candidate, ZN-d5, as compared to ZN-c5 as monotherapy.
- **Preliminary Clinical Activity** As of the database cutoff date of June 30, 2020, one patient in the Phase 1, monotherapy dose expansion portion of the Phase 1/2 trial at the 150 mg/day dose level had met the definition of a confirmed partial response, or PR, per RECISTv1.1 criteria after four cycles of ZN-c5. In addition, as of such date, six of the 15 patients in the Phase 1, monotherapy dose escalation portion of the trial showed stable disease, or SD, for at least 24 weeks, leading to a clinical benefit rate, or CBR, of 40%.
- PK characteristics. In preclinical and clinical studies to date, oral dosing of ZN-c5 has shown high exposure levels.
- *Tolerability profile*. In preclinical studies, ZN-c5 was well tolerated in one-month repeat dose toxicology studies. In addition, based on results from our Phase 1/2 clinical trial as of the database cutoff date of June 30, 2020, no dose-limiting toxicities have been reported.
- *Safety profile*. In clinical studies to date, ZN-c5 has demonstrated a favorable tolerability profile, which we believe may be an important differentiating factor for patients who require longer term dosing, particularly patients with earlier stage disease.
- Convenience of administration. ZN-c5 was designed to be a once-daily oral drug. If approved, we believe this would provide patient convenience and the potential for an all oral dosing regimen as monotherapy and in combination with CDK4/6 inhibitors and other oral targeted therapies.

In our Phase 1/2 clinical trial, we are evaluating the potential of ZN-c5 as monotherapy and in combination with palbociclib, a CDK4/6 inhibitor, as part of a clinical development collaboration with Pfizer. In addition, we plan to initiate a Phase 1b clinical trial evaluating ZN-c5 in combination with abemaciclib as part of a clinical collaboration with Lilly in the second half of 2020, and a Phase 2/3 clinical trial evaluating ZN-c5 in earlier stage breast cancer patients in 2021. We also intend 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.

#### **Preclinical Results**

#### Potency of ZN-c5 in Combination Therapy in MCF-7 Breast Cancer Xenograft Model

We have assessed the potency of the combination of ZN-c5 and palbociclib in mice with MCF-7 tumors. In this study, the tumors were initially grown to a large size of over 800 mm3, at which point treatment began on day 36. We observed that the combination of ZN-c5 and palbociclib, both dosed orally, led to the meaningful shrinkage of these tumors to a mean size of less than 200 mm3 by day 78, as shown in the graph below.



#### **ER Degradation in MCF-7 Models**

We assessed the potency of ZN-c5 and third-party hormonal therapies, fulvestrant and RAD1901, in repeat preclinical studies using MCF-7 breast cancer cells. RAD1901 is a SERM/SERD being evaluated by a third party in an ongoing Phase 3 clinical trial. As shown in the table below, ZN-c5 was observed to have good anti-proliferative activity and ERa degradation activity.

COMPOUND	PROLIFERATION INHIBITION IC50(1)(2) MCF-7 (nM)	ERa DEGRADATION EC50(2)(3) MCF-7 (nM)
Fulvestrant <sup>(4)</sup>	0.73	0.2
RAD1901(4)	0.35	97
ZN-c5	0.45	0.19

IC50: the concentration of an inhibitor where the response or binding is reduced by half. Data based on a series of repeat preclinical studies using standard *in vitro* assay and uniform controls.

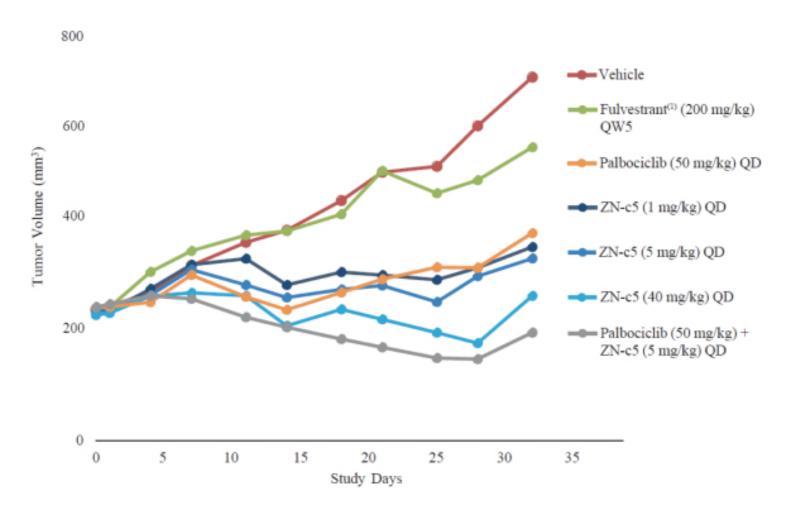
EC50: the concentration of a drug that gives half-maximal response.

Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than obtained from the pharmaceutical company commercializing or developing the respective hormonal therapy.

In preclinical studies, we observed no difference in agonist activity of ZN-c5 when compared to vehicle in a standard Uterine Wet Weight (UWW) animal model which, if present, may otherwise compromise anti-tumor activity.

#### Anti-tumor Activity in MCF-7 Breast Cancer Xenograft Models

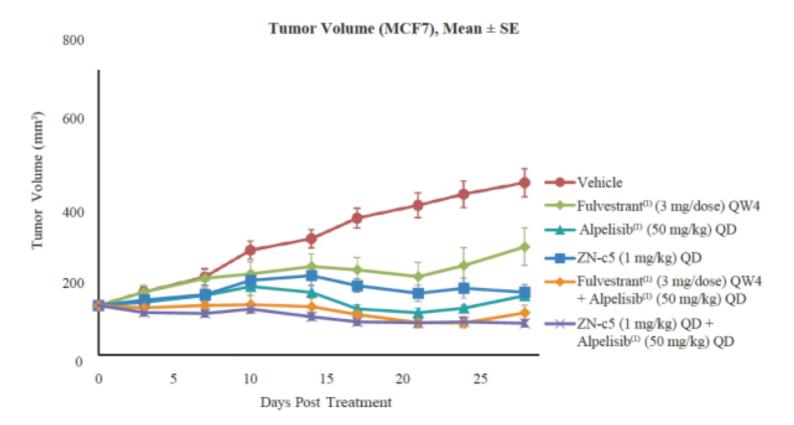
In a preclinical study, we assessed the anti-tumor activity of ZN-c5, alongside fulvestrant and palbociclib, in each case as monotherapy, in multiple breast cancer cell lines. ZN-c5 was also assessed in combination with palbociclib. As shown in the graph below, in a xenograft model using human MCF-7 breast cancer cells, we observed that ZN-c5 dosed at 1 mg/kg had more potent anti-tumor activity than 200 mg/kg of fulvestrant. Even greater anti-tumor activity was observed by either increasing the dose of ZN-c5 to 40 mg/kg or by combination therapy using 5 mg/kg of ZN-c5 and 50 mg/kg of palbociclib.



**Notes:** QW5: Once per week (5 doses in 5 weeks) QD: Once daily

Fulvestrant data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

We also assessed the anti-tumor activity of ZN-c5, alongside fulvestrant and alpelisib, in each case as monotherapy, in preclinical models. ZN-c5 and fulvestrant were also assessed in combination with alpelisib. As shown in the graph below, in a xenograft model using human MCF-7 breast cancer cells, we observed that ZN-c5 dosed once daily at 1 mg/kg had more potent anti-tumor activity than 3 mg/dose of fulvestrant administered once per week over four weeks. Even greater anti-tumor activity was observed with the combination of 1 mg/kg of ZN-c5 and 50 mg/kg of alpelisib. We also observed that the combination of ZN-c5 and alpelisib had more potent anti-tumor activity than the combination therapy using 3 mg/dose of fulvestrant and 50 mg/kg of alpelisib. In addition, the combination of ZN-c5 and alpelisib was associated with a body weight loss at the end of the study of 20.5% relative to baseline, compared to a body weight loss of 19% for alpelisib as monotherapy relative to baseline. The body weight loss at the end of the study for ZN-c5 as monotherapy was 7% relative to baseline.

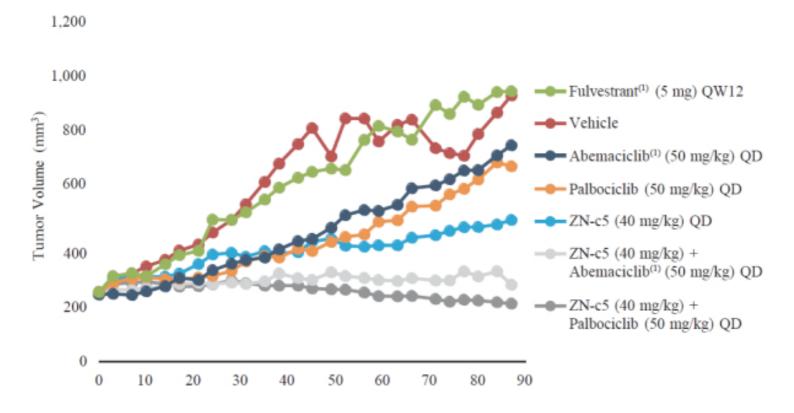


QW4: once per week (4 doses in 4 weeks) QD: once daily

<sup>(1)</sup> **Notes:** Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

#### Anti-Tumor Activity in Breast Cancer Resistance Model (ESR1)

In a preclinical study, we assessed anti-tumor activity of ZN-c5 as monotherapy and in combinations with palbociclib and abemaciclib in animal models using patient-derived tumors, referred to as PDX models. We also assessed the anti-tumor activity of palbociclib, abemaciclib and fulvestrant each as monotherapy in the same PDX models. In the WHIM20 model, tumors were established in mice from a tumor isolated from a patient with metastatic breast cancer. This tumor contained a mutation in the ESR1, the gene encoding the ER. These mutations are a common mechanism that drives resistance to therapy, with a prevalence of resistance that ranges from 11% to 39%. As shown in the graph below, ZN-c5 was observed to have anti-tumor activity at a concentration of 40 mg/kg as a single agent in this model. As monotherapy, ZN-c5 demonstrated improved anti-tumor activity compared with the fulvestrant dose that results in exposure that is an estimated eight-fold higher than what is clinically achievable with the highest FDA-approved human dose of fulvestrant. Further, tumor shrinkage was observed with doses of 40 mg/kg ZN-c5 in combination with 50 mg/kg palbociclib and in combination with 50 mg/kg abemaciclib.



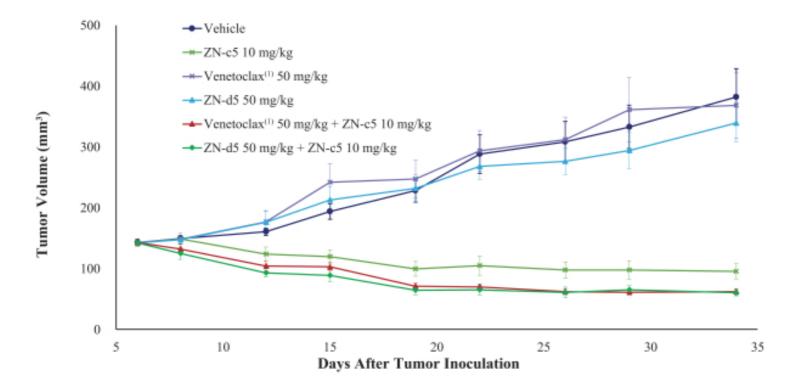
Days of Treatment

<sup>(1)</sup> Data based on evaluation of comparable proxy chemical compounds purchased from commercial sources rather than the pharmaceutical companies commercializing the compound. **Notes:** 

QD: once daily QW12: once per week (12 doses in 12 weeks)

#### Anti-Tumor Activity of ZN-c5 in Combination with BCL-2 Inhibitor in MCF-7 Breast Cancer Models

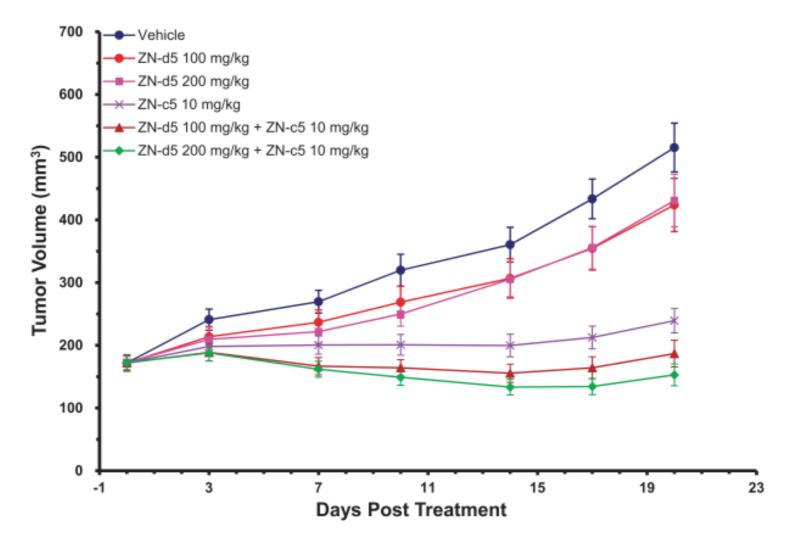
In preclinical studies, we assessed the anti-tumor activity of ZN-c5, both as monotherapy and in combination with ZN-d5, our BCL-2 inhibitor, as well as in combination with venetoclax. As shown in the graphs below, in MCF-7 breast cancer models, we observed that the combinations of ZN-c5 dosed at 10 mg/kg with venetoclax, dosed at 50 mg/kg, and ZN-d5, dosed at each of 50 mg/kg, 100 mg/kg and 200 mg/kg, had greater anti-tumor activity than 10 mg/kg of ZN-c5 as monotherapy.



Notes:

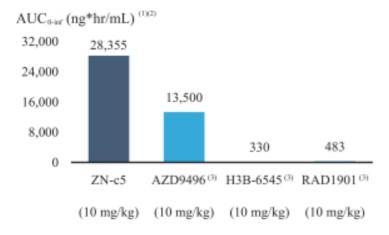
QD: once daily

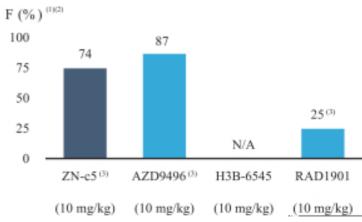
<sup>(1)</sup> Venetoclax data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.



#### PK Data Comparison in Mouse Model

We assessed the PK properties of ZN-c5 and select third-party hormonal therapies in clinical development in repeat preclinical mouse studies, as shown in the table below. Oral dosing of ZN-c5 resulted in peak concentrations, or Cmax, of 5,017 ng/mL. As shown below, ZN-c5 also had high overall drug exposure, or AUC, as measured by ng\*hr/mL, and good oral bioavailability (F), which is the fraction of an oral administered drug that reaches systemic circulation.





Based on oral administration.

Data based on a series of repeat preclinical studies using standard *in vitro* assay and uniform controls.

Other than H3B-6545, data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than obtained from the pharmaceutical company commercializing or developing the respective hormonal therapy. H3b-6545 data based on proxy chemical compound engineered based on published routes.

#### **Toxicology Results**

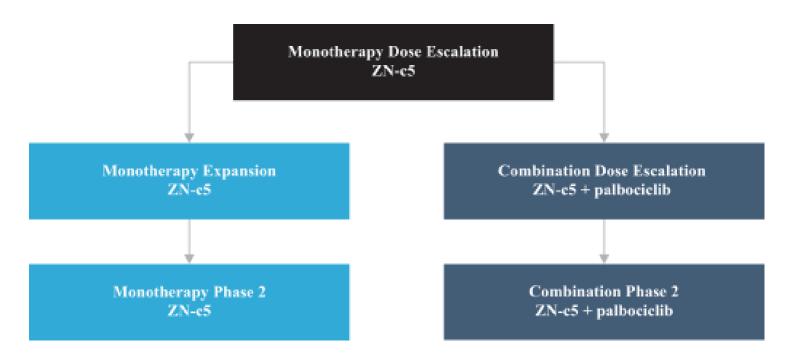
ZN-c5 was well tolerated in 28-day repeat dose toxicology studies and produced no evidence of diarrhea.

#### Phase 1/2 Clinical Trial of ZN-c5

Trial Design

In December 2018, we initiated enrollment in our Phase 1/2 open label, multi-center trial of ZN-c5 in patients with ER+/HER2- advanced or metastatic breast cancer, which we refer to as our ZN-c5-001 Trial, to assess the safety, tolerability, PK, pharmacodynamics and anti-tumor activity of ZN-c5 as monotherapy and in combination with palbociclib. We plan to enroll a total of approximately 286 patients in the trial, which will be conducted at multiple sites in the United States and Europe.

The Phase 1 portion of our ZN-c5-001 Trial consists of: a monotherapy dose escalation study, a monotherapy expansion study and a combination dose escalation study evaluating ZN-c5 in combination with palbociclib. The Phase 2 portion will evaluate preliminary anti-tumor efficacy of ZN-c5 as monotherapy and in combination with palbociclib.



#### Phase 1, Monotherapy Dose Escalation

The primary objective of the Phase 1, monotherapy dose escalation portion of this trial is to determine the maximum tolerated dose, or MTD, and recommended Phase 2 dose, or RP2D. The secondary objectives include, among others, to assess the PK, safety and tolerability as well as preliminary efficacy of ZN-c5. In addition, biomarkers will be assessed based on availability of patients' biopsies.

In the Phase 1, monotherapy dose escalation portion of this trial, ZN-c5 is being evaluated in up to 36 adult patients with ER+/HER2- advanced or metastatic breast cancer who are refractory to or intolerant of established cancer therapies, and who may have received up to two prior chemotherapy regimens for advanced/metastatic breast cancer. ZN-c5 is being orally administered, either once or twice daily continuously at sequentially escalating doses starting with 50 mg/day and up to 1,200 mg/day, using a 28-day cycle.

#### Phase 1, Monotherapy Expansion

During the Phase 1, monotherapy dose escalation portion of the trial, up to 45 additional patients with ER+/ HER2- advanced or metastatic breast cancer who have received up to two prior lines of endocrine therapy, and who have may have received at most one prior chemotherapy regimen for advanced/metastatic breast cancer, are expected to be enrolled onto one or more dose levels for the Phase 1, monotherapy expansion portion of this trial.

The primary objective of the Phase 1, monotherapy expansion portion of the trial will be to assess the safety and tolerability of ZN-c5 administered as monotherapy. Secondary objectives of the monotherapy expansion portion of this trial will include, among others, to assess the preliminary anti-tumor efficacy and characterize the PK of ZN-c5.

#### Phase 1, Combination Dose Escalation

We are also evaluating ZN-c5 in combination with palbociclib in the Phase 1, combination dose escalation portion of this trial in up to 18 adult patients with ER+/HER2- advanced or metastatic breast cancer who are refractory to or intolerant of established therapies known to provide clinical benefit for their malignancy, and who may have received at most one prior chemotherapy regimen for advanced metastatic breast cancer.

The primary objective of the Phase 1, combination dose escalation portion of the trial is to determine the MTD or RP2D for ZN-c5 when administered in combination with palbociclib. Secondary objectives include, among others, to assess the safety and tolerability of ZN-c5 in combination with palbociclib, to assess preliminary efficacy of ZN-c5 in combination with palbociclib and to characterize the individual PK of ZN-c5 and palbociclib when administered in combination.

The dose and schedule of palbociclib in the Phase 1, combination dose escalation portion of this trial will be the FDA-approved dose (125 mg/day), orally administered, once daily for 21 consecutive days, followed by seven days off treatment.

#### Phase 2

Once the MTD or RP2D have been determined for ZN-c5 as monotherapy and in combination with palbociclib, we plan to initiate enrollment in the Phase 2 portion of the trial to assess preliminary anti-tumor efficacy for ZN-c5 as monotherapy and in combination with palbociclib. We expect to initiate the Phase 2 monotherapy and combination portions of this Phase 1/2 trial in the first half of 2021.

The Phase 2 monotherapy portion of this trial will assess ZN-c5 at the RP2D in up to 75 adult patients with ER+/HER2- advanced breast cancer who have received one prior line of endocrine therapy, and no prior chemotherapy for advanced metastatic breast cancer.

The Phase 2 combination portion of this trial will evaluate ZN-c5 in combination with palbociclib in up to 112 adult patients with ER+/HER2-advanced or metastatic breast cancer and who have received up to one prior line of endocrine therapy, and at most one prior chemotherapy regimen for advanced metastatic breast cancer.

The primary objective of the Phase 2 portion of this trial will be to determine preliminary anti-tumor efficacy for ZN-c5 when administered as monotherapy and in combination with palbociclib. The secondary objectives will include, among others, to assess the safety and tolerability of ZN-c5 as monotherapy and in combination with palbociclib, and to characterize the PK of ZN-c5 as monotherapy and to characterize the individual PK of ZN-c5 and palbociclib when given in combination.

#### Clinical Results

As of June 30, 2020, we have enrolled 15 patients in the Phase 1, monotherapy dose escalation portion of this trial, three patients each at the dose levels of 50 mg, 75 mg, 100 mg, 150 mg and 300 mg. All patients were female, with a median age of 57 years (range 51 to 89 years) and an Eastern Cooperative Oncology Group, or ECOG, performance status, a measurement of a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability, of 0 (n = 9) or 1 (n = 6).

The median number of prior therapies for advanced disease was four (range two to eight). Twelve of the 15 patients received prior treatment with fulvestrant. Of these 15 patients, one is still on treatment and

14 discontinued due to disease progression (n = 13) or physician decision (n = 1). Enrollment in the Phase 1, monotherapy dose escalation portion of this trial is ongoing and a total of up to 36 patients may be enrolled.

As of June 30, 2020, 14 patients were enrolled in the Phase 1, monotherapy expansion portion of this trial, 12 patients at the 150 mg dose and two patients at the 300 mg dose. All patients were female, with a median age of 57 years (range 38 to 73 years) and an ECOG performance status of 0 (n = 3) or 1 (n = 11). The median number of prior therapies for advanced disease was one (range zero to three). Six of the 14 patients received prior treatment with fulvestrant. Of these 14 patients, five are still on treatment and nine discontinued due to disease progression. Enrollment in the Phase 1, monotherapy expansion portion of this trial is ongoing, and a total of up to 45 patients may be enrolled.

As of June 30, 2020, we have enrolled 15 patients in the Phase 1, combination dose escalation portion of this trial, three patients each at the ZN-c5 dose levels of 50 mg and 150 mg, and nine patients at 100 mg. 14 patients were female and one was male, with a median age of 65 years (range 51 to 79 years) and an ECOG performance status of 0 (n = 7), 1 (n = 7) or 2 (n = 1). The median number of prior therapies for advanced disease was one (range zero to six). Three of the 15 patients received prior treatments with fulvestrant. Of these 15 patients, nine are still on treatment and six discontinued due to disease progression (n = 5) and physician decision (n = 1). Enrollment in the Phase 1, combination dose escalation portion of this trial is ongoing.

#### Safety Results

#### Phase 1, Monotherapy Dose Escalation and Monotherapy Dose Expansion

Based on the results as of the database cutoff date of June 30, 2020 for the Phase 1, monotherapy dose escalation and monotherapy dose expansion portions of this trial, ZN-c5 has been observed to be well tolerated with no dose-limiting toxicities reported.

In the Phase 1 monotherapy dose escalation and monotherapy dose expansion portions of this trial, a total of 29 patients were enrolled and dosed, with data available in the electronic data capture system as of the June 30, 2020 database cutoff. Treatment-emergent adverse events, or TEAEs, occurred in 27 of the 29 patients. Nausea was observed in nine patients; hyperglycemia in eight patients; anemia, fatigue, hypertension and vomiting in six patients each; headache in five patients; cough, hot flush, hypokalemia, hypophosphatemia and lymphocyte count decreased in four patients each; alanine aminotransferase, or ALT increased, arthralgia, back pain, diarrhea, dyspnea, musculoskeletal pain and pyrexia in three patients each. and all other adverse events were observed in only one or two patients each. In addition, there have been no reports of bradycardia or any other cardiac abnormalities. TEAEs of Grade 3 severity were single cases of hypertension, hypercalcemia, back pain, arthralgia, pyrexia, COVID-19, device related infection, musculoskeletal chest pain and pain in extremity. None of the Grade 3 TEAEs were deemed related to ZN-c5. All other TEAEs were of Grade 1 or Grade 2 in severity. The Grade 3 TEAEs of arthralgia, device related infection and COVID-19 were also reported as serious adverse events, all deemed unrelated to treatment. There were no deaths reported.

Investigator assessed treatment-related adverse events occurred in 16 of 29 patients. These treatment-related adverse events included nausea, hot flush and fatigue (n = 3), ALT increased (n = 2) and other single adverse events. All were of Grade 1 or Grade 2 in severity.

Diarrhea, an adverse event of special interest, has been observed in three patients: one Grade 1 adverse event at 50 mg which was deemed treatment related; and one Grade 1 and one Grade 2 adverse event, each at 150 mg, neither of which was deemed treatment related.

The first patient with ALT increased had the first dose of 50 mg of ZN-c5 on December 19, 2018. The patient entered the study with a Grade 1 ALT increased, which subsequently worsened to a Grade 2 ALT

increased on February 13, 2019, 56 days after the first dose. On March 27, 2019, the patient was taken off treatment for disease progression, and at that time the Grade 2 ALT increased was still ongoing. The event was deemed related to ZN-c5. The second patient with ALT increased had the first dose of 300 mg of ZN-c5 on October 15, 2019. The patient developed Grade 1 ALT increased and Grade 1 aspartate aminotransferase, or AST, increased 84 days after the first dose, on January 6, 2020. Dosing was interrupted and the Grade 1 AST increased resolved on Day 91, and the Grade 1 ALT increased resolved on Day 98. The events were not deemed to be related to ZN-c5. The third patient with ALT increased had the first dose of 150 mg of ZN-c5 on December 18, 2019. The patient entered the study with Grade 1 ALT increased and AST increased, but AST increased normalized on Day 8 and ALT increased normalized on Day 15. The patient again developed Grade 1 ALT increased and Grade 1 AST increased 58 days after the first dose, on February 13, 2020. Dosing was not interrupted. The AST increased normalized on Day 83, but fluctuated again to Grade 1 on Day 162. On June 3, 2020, the patient was taken off treatment for disease progression, and at that time both the Grade 1 ALT increased and AST increased were still ongoing. The event was deemed to be related to ZN-c5.

Overall, in the Phase 1, monotherapy dose escalation and monotherapy dose expansion portions of the trial, there was no observed increase in incidence or in severity of adverse events with increasing dosing levels.

#### Phase 1, Combination Dose Escalation

As of the June 30, 2020 database cutoff date, ZN-c5 in combination with palbociclib was observed to be well tolerated with no dose-limiting toxicities reported. Based on these safety results, we are continuing to enroll patients ZN-c5 in combination with palbociclib.

TEAEs occurred in 14 of the 15 patients dosed. Adverse events occurring in three or more patients included: white blood cell count decreased (n = 11); neutrophil count decreased (n = 9); anemia (n = 5), hyperglycemia, hypophosphatemia and nausea (n = 4); arthralgia, dizziness, fatigue, headache and platelet count decreased (n = 3). All other adverse events were observed in one or two patients each. TEAEs of Grade 3 severity were neutrophil count decreased (n = 5), white blood cell count decreased (n = 3), arthralgia (n = 2) and single cases of each of hypophosphatemia, pneumothorax and pain in extremity. There was one serious adverse events of Grade 3 pneumothorax reported, deemed not related to ZN-c5 nor palbociclib. There were no deaths reported.

Investigator assessed treatment-related adverse events to either ZN-c5 or palbociclib occurred in 13 of 15 patients. These investigator assessed treatment-related adverse events included: white blood cell count decreased (n = 11), neutrophil count decreased (n = 9), anemia (n = 5), fatigue (n = 3), platelet count decreased (n = 3), lymphocyte count decreased (n = 2) and other single adverse events. Events of Grade 3 severity were neutrophil count decreased (n = 3) and white blood cell count decreased (n = 5). Of note, there has been no evidence of any TEAEs of diarrhea, bradycardia or visual disturbances.

Overall, as of the June 30, 2020 database cutoff date, there was no increase in incidence or in severity of adverse events observed with increasing dosing levels.

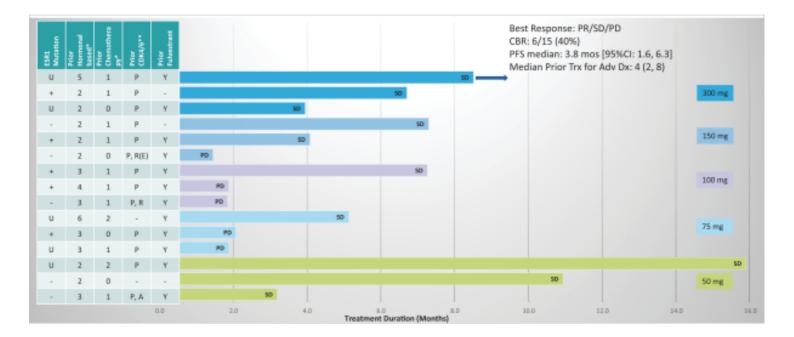
#### **Efficacy Results**

Clinical activity in the Phase 1 trial is determined by the CBR, which is the total number or percentage of patients who achieved a complete response, or CR, PR, or SD, for 24 weeks or longer per RECIST criteria.

While it is anticipated, based on the mechanism of action of ZN-c5 and advanced state of disease of the patients enrolled, that tumor regressions may not occur in this study phase, as of June 30, 2020, six of the 15 patients in the Phase 1, monotherapy dose escalation portion of this trial showed SD for at least 24 weeks, leading to a CBR, of 40%. Two of these patients were dosed at the low dose of 50 mg and showed SD for approximately 12 months.

Patients in the monotherapy expansion and the combination dose escalation portions of the trial have been on treatment for less than 24 weeks, an insufficient amount of time to establish the CBR. As of the database cutoff date of June 30, 2020, one patient in the Phase 1, monotherapy dose expansion portion of this trial at the 150 mg/day level has met the definition of a confirmed PR (reduction of 64%) per RECISTv1.1 criteria after four cycles of ZN-c5. Treatment of the patient is ongoing.

The following table illustrates treatment duration and best overall response for the Phase 1, monotherapy dose escalation portion of the trial as of the database cutoff date of June 30, 2020.



#### ZN-c5 Pharmacokinetics Results

As of the database cutoff date of June 30, 2020, the PK of ZN-c5 observed in the first 15 patients in the Phase 1, monotherapy dose escalation portion of our ZN-c5-001 Trial was characterized by fast absorption into the systemic circulation, as evidenced by median time to maximum concentration, or Tmax, of one to two hours. As shown in the table below, the exposures have generally increased with increased doses and was 124,000 ng\*hr/ml at the 300 mg dose. Additionally, we have not observed drug accumulation of ZN-c5 at steady state (day 15). The estimated mean elimination half-life ranged between 11 and 18 hours.

#### Preliminary Pharmacokinetic Data for ZN-c5

Dose		Day 1			Day 15/			
(mg) # of pts		Cmax (ng/mL)	Tmax (hr)	AUC0-24hr (ng*h/mL)	Cmax (ng/mL)	Tmax (hr)	AUC0-24hr (ng*h/mL)	Day 1 AUC Ratio
50 (n=3)	Mean	5,730	2	65,700	5,810	1	61,300	0.94
	SD	1,330	(1-2)	7,350	405	(1-2)	10,400	0.20
	CV(%)	23.3		11.2	6.97		17.0	21.4
75	Mean	6,700	2	77,300	6,700	2	64,400	1.1

Number of treatments reflect advanced or metastatic setting, not neo/adjuvant; also reflects combinations with targeted therapies CDK4/6, mTOR, PI3ka)

P-palbociclib, A-abemaciclib, R-ribociclib; (E-experimental treatment)

Stable Disease Progressive Disease Unknown PD:

(n=3)	SD	4,080	(1-4)	47,800	1,040	(1-2)	16,000	0.66
	CV(%)	60.8		61.9	15.6		24.8	59.8

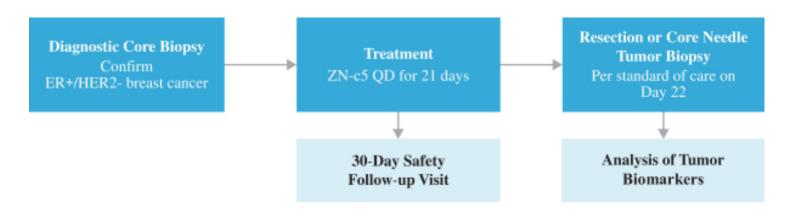
Dose			Day 1			Day 15		Day 15/
(mg) # of pts		Cmax (ng/mL)	Tmax (hr)	AUC0-24hr (ng*h/mL)	Cmax (ng/mL)	Tmax (hr)	AUC0-24hr (ng*h/mL)	Day 1 AUC Ratio
100	Mean	7,120	4	103,000	9,250	2	106,000	0.97
(n=3)	SD	2,550	(2-6)	42,100	5,350	(1-2)	74,500	0.30
(n-3)	CV(%)	35.9		40.7	57.8		70.2	31.6
150	Mean	8,120	2	115,000	9,210	2	94,800	0.83
(n=3)	SD	1,780	(2-4)	42,200	2,820	(1-2)	41,600	0.20
(n-3)	CV(%)	21.9		36.7	30.6		43.9	24.8
300 (n=3)	Mean	10,700	6	168,000	10,000	2	124,000	0.74
	SD	1,390	(2-6)	21,400	1,170	(2-6)	21,300	0.07
	CV(%)	13.0		12.7	11.7		17.2	9.15

Median(range) are listed for T<sub>max</sub> SD: standard deviation

ZN-c5 human drug exposure at all dose levels, ranging from 50 mg to 300 mg, exceeds the ZN-c5 effective concentration, 100%, or EC100, observed in our preclinical mouse studies at 10 mg/kg/day, the dose level associated with a 100% tumor growth inhibition in a MCF-7 mouse model. Based on the activity observed in mouse models, the exposures observed in human patients may translate into once daily, oral dosing.

#### Phase 1 Trial of ZN-c5 (Window of Opportunity study)

In January 2020, we dosed the first patient in our Phase 1 open label, multi-center, dose escalation trial of ZN-c5, which we refer to as our ZN-c5-002 Trial. The ZN-c5-002 Trial will be conducted at several sites in the United States, Europe and Asia-Pacific (Australia and Hong Kong), in patients with ER+/HER2- breast cancer scheduled to undergo surgical resection of the tumor or start neoadjuvant treatment. We plan to enroll approximately 36 patients in this trial.



This is a Window of Opportunity study, the objective of which is to assess the ER degradation ability of ZN-c5 as a monotherapy over a 21-day treatment period measured using paired biopsies. We intend to evaluate various tissue and functional imaging biomarkers in response to ZN-c5 exposure. These biomarkers will assess ER degradation, progesterone receptor degradation and Ki67, a proliferation marker, using paired biopsies. In addition, tumor tissue and plasma concentration of ZN-c5 will be assessed.

ZN-c5 will be evaluated at escalating doses starting at 50 mg, orally administered, once daily. Subsequent dose levels will be determined based on PK profile, safety and any additional biomarker data observed in our ZN-c5-001 Trial.

As of June 30, 2020, eight patients have been enrolled and treated: three patients at 50 mg/day, four patients at 150 mg/day and one patient at 300 mg/day.

We believe this trial will assist in determining the precise RP2D of ZN-c5 as a monotherapy, in conjunction with the safety, PK and pharmacodynamics, or PD, data from the ZN-c5-001 Trial. We expect to report topline results from this trial in the first half of 2021.

#### Phase 1b Trial of ZN-c5 in combination with abemaciclib

We plan to initiate a Phase 1b open label, multi-center trial of ZN-c5 in patients with ER+/HER2- advanced or metastatic breast cancer to assess the safety, tolerability, PK, pharmacodynamics and anti-tumor activity of ZN-c5 in combination with abemaciclib. We intend to initiate this trial in the second half of 2020.

#### ZN-c3, an Inhibitor of WEE1 for the Treatment of Solid Tumors and Other Cancers

#### Overview

We are developing ZN-c3, an oral, small molecule DNA damage response product candidate, targeting WEE1 in cancer. The inhibition of WEE1, a protein tyrosine kinase, aims to generate sufficient DNA damage in cancer cells to undergo apoptosis, thereby preventing tumor growth and potentially causing tumor regression. There is currently no FDA-approved WEE1 inhibitor, and AstraZeneca's AZD1775 is currently one of few other WEE1 inhibitors in clinical development of which we are aware. Despite the observed efficacy of AZD1775 in clinical trials, we believe its narrow therapeutic window is a potential limitation affecting its dosing in monotherapy and in combination. We have applied our expertise to design ZN-c3 to have such solubility, selectivity and PK properties that we believe may provide a broad therapeutic window and which, if ZN-c3 is approved, may constitute a differentiated product profile. We believe ZN-c3, if approved, may have broad applicability in a wide range of cancers both as monotherapy and in combination, including with chemotherapy agents, PARP inhibitors and other targeted therapies.

We have initiated a Phase 1/2 clinical trial of ZN-c3 in patients with advanced solid tumors. We expect to report results from the Phase 1, monotherapy dose escalation portion of the trial in 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 USC in 2021. 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.

#### Background on DNA Damage Repair and WEE1 Inhibitors

The underlying principle behind a number of cancer therapies is to generate sufficient DNA damage in cancer cells, many of which already have deficiencies in DNA damage response, to cause them to undergo apoptosis. Examples of these therapies include alkylating agents, DNA-binding drugs and the use of radiation. However, cancer cells have developed multiple mechanisms of resistance to these therapies, thereby potentially limiting their therapeutic efficacy.

The regulation of DNA damage response mechanisms in cancer cells may therefore play a crucial role in the induction of apoptosis and the ultimate efficacy of DNA damaging cancer therapies. This is particularly true in cancers with specific mutations in DNA repair proteins that prevent efficient DNA damage response and repair, rendering them particularly vulnerable to any agent that further inhibits the ability of cells to repair DNA damage.

Examples of such cancers are those with mutations in BRCA1 and BRCA2. Inhibitors of PARP, an independent DNA repair protein, work to prevent DNA damage repair, and are FDA approved for the treatment of multiple cancers, such as breast and ovarian cancers associated with BRCA1 and BCRA2 mutations. Sales of FDA-approved PARP inhibitors were approximately \$1.6 billion in 2019 and are expected to grow to \$6.9 billion in 2026.

Similar to PARP, WEE1 plays a role in cellular regulation and repair, allowing cells with DNA damage to repair and survive. WEE1 is a protein tyrosine kinase that mediates cell cycle arrest by regulating the phosphorylation of cyclin-dependent kinase 1, or CDK1. Inhibition of WEE1 causes dysregulation of DNA replication and inability of DNA response processes to act, leading to an increase in double-strand DNA breaks and subsequently inducing apoptosis. Based on these similar mechanisms of action, we believe the use of WEE1 and PARP, both DNA damage response agents, in combination can have a synergistic effect. In third-party preclinical studies, the combination of PARP and WEE1 has been observed to result in improved anti-tumor activity as compared to the use of each as monotherapy. However, both of these compounds have been associated with bone marrow toxicity, which may limit their concomitant administration.

#### WEE1 Inhibitor in Clinical Development and Limitations

One of few other WEE1 inhibitors currently in clinical development of which we are aware is AZD1775. AZD1775 has been the subject of many publications in the scientific literature and has been explored in numerous clinical trials across multiple tumor types. AZD1775 is currently being evaluated by third parties in Phase 1 and 2 clinical trials in ovarian cancer and a variety of other solid tumors, both as monotherapy and in combination with other cancer therapies. In earlier third-party clinical trials, multiple patients with advanced or metastatic tumors for whom no standard therapy was available achieved partial responses when dosed with AZD1775 in combination with chemotherapy agents. For example, in a Phase 2 clinical trial in 24 patients (21 of such patients were evaluable for efficacy) with relapsed ovarian cancer, the combination of AZD1775 and carboplatin, an FDA-approved chemotherapy, demonstrated an overall response rate of 43% and one patient exhibited a complete response lasting over 42 months.

In addition, in a recent Phase 2 clinical trial in patients with recurrent USC, an aggressive subtype of endometrial carcinoma characterized by TP53 mutations, AZD1775 administered as monotherapy demonstrated an overall response rate of 30%.

Further, in a recent Phase 1 clinical trial in patients with locally advanced pancreatic cancer, AZD1775 in combination with gemcitabine, an FDA-approved chemotherapy, and radiation resulted in a median overall survival of 21.7 months. This overall survival was substantially longer than the 11.9 to 13.6 months observed in a prior clinical trial with a similar population of patients combining gemcitabine with or without erlotinib with radiation.

Although AZD1775 has demonstrated promising efficacy in clinical trials, we believe AZD1775 has a narrow therapeutic window, a potential limitation affecting its dosing monotherapy and in combination. Furthermore, the use of AZD1775 in combination with PARP inhibitors in preclinical studies has demonstrated increased bone marrow toxicities, thereby potentially limiting its use in continuous dosing. We believe AZD1775 has a number of characteristics that could be improved upon, including selectivity, solubility, PK properties and tumor concentration.

#### Our WEE1 Solution: ZN-c3

ZN-c3 is our oral WEE1 inhibitor product candidate that we are currently evaluating for the treatment of advanced solid tumors in an ongoing Phase 1/2 clinical trial. We believe ZN-c3 has the potential to provide a wide therapeutic window due to the following observed clinical and preclinical results:

• **Potency, selectivity and solubility**. In our preclinical studies, ZN-c3 produced favorable absorption, distribution, metabolism and excretion, or ADME, results. In our *in vitro* preclinical studies, we observed ZN-c3's potency in inhibiting tumor growth and inducing apoptosis through DNA damage, and ZN-c3 has shown high selectivity for WEE1. In addition, in a series of repeat preclinical studies assessing the solubility of ZN-c3 and AZD1775 utilizing a standard *in vitro* assay and uniform controls, ZN-c3 demonstrated solubility of 2,132,000 nM, approximately 35 times greater than that of AZD1775, which we believe could reduce inter-patient drug exposure variability and limit the toxicity observed in clinical trials of AZD1775.

- Preclinical anti-tumor activity. In head-to-head preclinical studies, ZN-c3 showed anti-tumor activity across a number of cell lines, as well as superior tumor growth inhibition, DNA damage and apoptosis when compared to AZD1775. Anti-tumor activity was observed in both continuous and intermittent dosing, as well as in the shorter of the dosing periods evaluated.
- PK properties. In our preclinical studies, ZN-c3 showed PK properties that resulted in high drug exposure in animal models. We believe this level of drug exposure may contribute to the observed sustained and lengthy tumor growth inhibition, which may necessitate lower dose intensity thereby potentially affording a wide therapeutic window. In addition, we observed that ZN-c3 had favorable drug accumulation in tumors.
- Well tolerated in preclinical studies and clinical trials. In preclinical studies and clinical trials to date, ZN-c3 was observed to be well tolerated across varying dosage levels.

In addition to having a potentially wide therapeutic window, we believe the characteristics of ZN-c3 may allow patients with aggressive solid tumors to be treated with sequential therapy using mechanism of action synergistic multiple agents, including PARP inhibitors. In a third-party preclinical combination study with PARP inhibitors, sequential dosing resulted in favorable tolerability as compared to continuous dosing, while maintaining strong anti-tumor activity.

We have completed the first dose cohort level and started the second dose level cohort. We plan to report data from the Phase 1, monotherapy dose escalation portion of the trial in 2021.

#### **Preclinical Results**

#### **Potency Across Variety of Solid Tumor Cell Lines**

We assessed the potency of ZN-c3 and AZD1775 in repeat in vitro preclinical studies across a variety of solid tumor cell lines, as shown in the table below. We observed ZN-c3's potency in inhibiting tumor growth and inducing DNA damage and apoptosis in each of the solid tumor cell lines studied.

		CTG IC50 (nM)(1)							
	·								Squamous
	Non-S	mall Cell	Small	Cell Lung	Triple Ne	gative			Cell
	Lung	Cancer	C	ancer	Breast Ca	incer	Ovarian	Cancer	Carcinoma
COMPOUND	A-427	NCI-H23	DMS-53	NCI-H1048	MDA-MB-231	HCC1806	UWB.1.289	OVCAR3	SK-MES-1
AZD1775(2)	94	108	130	97	233	94	57	124	150
ZN-c3	88	124	118	92	190	95	54	69	83

Data based on a series of repeat preclinical studies using standard *in vitro* assay and uniform controls.

Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company developing the compound.

#### Selectivity of ZN-c3 in Kinase Screening Panel

In our head-to-head in vitro preclinical studies, we assessed the selectivity of ZN-c3, alongside AZD1775. The selectivity profile of each of ZN-c3 (right) and AZD1775 (left) was characterized against a broad kinase panel for WEE1 consisting of 485 mammalian serine/threonine and tyrosine, as depicted by the respective kinase dendograms below. ZN-c3 and AZD1775 were tested at a single concentration to determine the percentage inhibition at 1 mM. ZN-c3 was observed to have higher selectivity relative to that of AZD1775 as depicted by the overall fewer kinases being affected in the ZN-c3 dendogram.

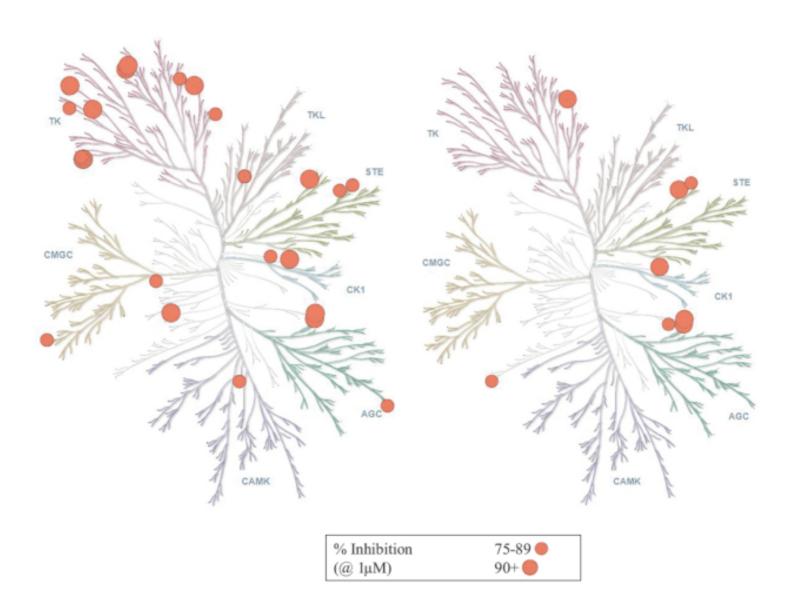


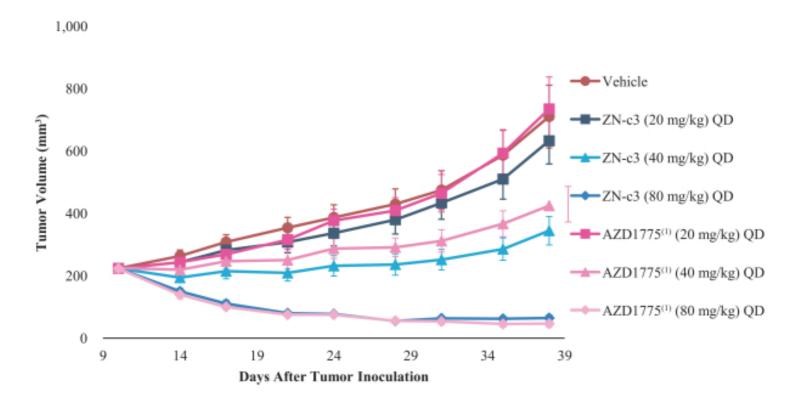
Illustration reproduced courtesy of Cell Signaling Technology, Inc. Each branch of the dendogram represents an individual human kinase. AZD1775 data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company developing the compound.

#### Solubility of ZN-c3

We assessed the relative ADME properties and solubility of ZN-c3 and a proxy chemical compound of AZD1775 in a series of repeat preclinical studies. ZN-c3 showed targeted ADME properties, and demonstrated solubility of 2,132  $\mu$ M, approximately 35 times greater than the 60  $\mu$ M observed with AZD1775 in repeat preclinical studies. We believe greater solubility may reduce interpatient variability, and in turn limit toxicities for ZN-c3.

#### **Anti-Tumor Activity in Human Lung Cancer Model**

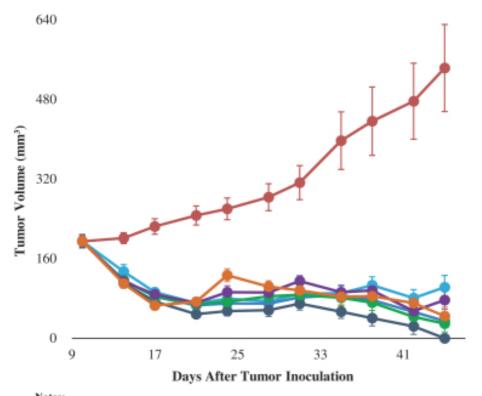
In a preclinical study, we assessed the anti-tumor potential of ZN-c3 alongside AZD1775, each as a monotherapy, in a lung cancer model using human A-427 cells that contained a KRAS mutation. In this model, doses of 40 mg/kg or 80 mg/kg of ZN-c3 demonstrated tumor shrinkage that was evident at the first post-treatment observation at four days and continued through the end of the experiment. Across dose levels there was no statistical difference between ZN-c3 and AZD1775 and each compound produced tumor regression. ZN-c3 was observed to be well tolerated across all doses.



<sup>(1)</sup> AZD1775 data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company developing the compound. **Notes:** QD: once daily

#### Anti-Tumor Activity in Lung Cancer Model Across Varying Dosage Levels and Intermittent Dosing Regimen

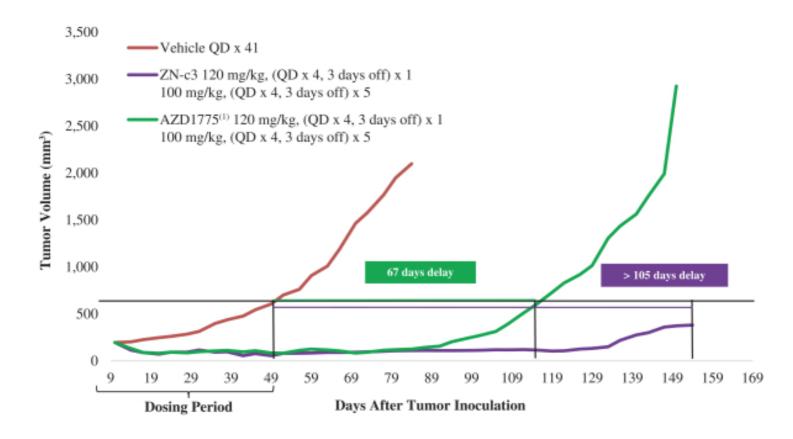
We have explored various dosing regimens of ZN-c3 in preclinical studies. A loading dose of 120 mg/kg daily for seven days followed by once-daily dosing of 100 mg/kg resulted in ten out of ten treated mice being tumor free after five weeks. We also explored the potential of shorter dosing periods or intermittent dosing of ZN-c3 in preclinical studies. A loading dose of 120 mg/kg for five days followed by two days off drug followed by five weeks of 100 mg/kg given five days on, two days off resulted in seven out of ten mice being tumor free as shown in the graph below. A loading dose of 120 mg/kg for seven days followed by seven days off drug followed by two cycles of seven days on 100 mg/kg drug and seven days off drug resulted in five out of ten mice being tumor free as shown in the graph below.



ZN-c3 DOSAGE (mg/kg), DOSING SCHEDULE	NO. OF TUMOR FREE ANIMALS
<ul><li>40, BID</li></ul>	1/10
<ul><li>80, QD</li></ul>	3/10
120, (QDx4d, 3d off)x1 100, (QDx4d, 3d off)x5	4/10
120, (QDx7d, 7d off)x1 100, (QDx7d, 7d off)x2	5/10
120, (QDx5d, 2d off)x1 100, (QDx5d, 2d off)x5	7/10
■ 120, QDx7, 100, QD	10/10

Notes: QD: Once daily BID: Twice daily

We also assessed the potential of utilizing an intermittent dosing regimen with ZN-c3 alongside that of AZD1775 in a preclinical study. Dosing of ZN-c3 by using a loading dose of 120 mg/kg for four days followed by three days off drug followed by five week of 100 mg/kg given four days on, three days off resulted in more prolonged tumor growth delay than that observed with AZD1775 at the same dosing regimen.



Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company developing the compound.

#### Notes:

QD: Once daily

#### **PK Data Comparison in Animal Models**

We assessed the PK properties of ZN-c3 and AZD1775 in repeat preclinical animal models, as shown in the table below. For each of the preclinical studies, we observed the respective  $C_{max}$ ,  $T_{max}$ , AUC and tumor concentration of each compound at doses of 20, 40 and 80 mg/kg/day. Administration of ZN-c3 was observed to result in high drug exposure in animal models and the selective accumulation of ZN-c3 to high levels in tumors. We believe this increased drug exposure may cause the inhibition of WEE1 at low doses, potentially affording a wide therapeutic window.

STUDY(1)	ZN-c3				AZD1775(2)	
Dose (mg/kg/day)	20	40	80	20	40	80
$C_{max}$ (ng/mL)	1,167	1,997	5,100	635	2,460	4,703
$T_{max}$ (hr)	1	1	1	1	1	1
AUC0-24hr (ng*hr/mL)	4,863	17,088	39,722	1,494	6,313	13,408
Tumor Concentration (ng/mL)	10.5	48.0	811	BQL	BQL	6.95

<sup>(1)</sup> Data based on a series of repeat preclinical studies using standard assay and uniform controls.

**Note**: BQL: Below Quantifiable Level

<sup>(2)</sup> Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than obtained from the pharmaceutical company developing the compound.

#### **Toxicology Results**

ZN-c3 was evaluated in 28-day repeat dose toxicology studies. Results of these studies showed many of the toxicities associated with other WEE1 inhibitors in development, including those reported for AZD1775.

#### Phase 1/2 Clinical Trial of ZN-c3

In November 2019, we initiated a Phase 1/2 open label, multi-center trial of ZN-c3 in patients with advanced solid tumors, which we refer to as our ZN-c3-001 Trial, to assess the safety, tolerability, efficacy, PK properties and pharmacodynamics of ZN-c3 as a single agent and in combination with a number of potential therapies, including PARP inhibitors. We plan to enroll up to 360 patients in this trial, which will be conducted at several sites in the United States. Our ZN-c3-001 Trial currently consists of a Phase 1, monotherapy dose escalation portion of the trial and a Phase 2 portion of the trial to evaluate ZN-c3 as monotherapy and in combination with relevant combination therapies.

The primary objective of the Phase 1, monotherapy dose escalation portion of the trial is to assess the safety and tolerability of ZN-c3 as a single agent and to determine the MTD or RP2D. The secondary objectives are to assess the PK properties and obtain preliminary assessments of anti-tumor efficacy of ZN-c3 as a single agent, as well as exploratory PD characteristics.

We plan to enroll up to 50 patients in the Phase 1, monotherapy dose escalation portion of the trial and the patient population will be limited to patients with solid tumors with advanced or metastatic disease who are refractory or ineligible to receive standard therapies, or for whom no standard therapy is available. We expect to report topline results from the Phase 1, monotherapy dose escalation portion of this trial in 2021.

The primary objective of the Phase 2 portion of the trial will be to assess the anti-tumor efficacy of ZN-c3 by objective response rate as well as the safety of ZN-c3 as monotherapy and in combination with relevant combination therapies. The secondary objectives of the Phase 2 portion of the trial will be to assess the anti-tumor efficacy of ZN-c3 by duration of response, clinical benefit rate and PFS as monotherapy and in combination with relevant combination therapies, and to assess the PK parameters of ZN-c3 and the relevant combination therapies when given in combination.

We expect to define the eligible patient population for the Phase 2 portion of the trial upon determination of the relevant combination therapies.

#### Phase 1b Clinical Trial of ZN-c3

We plan to initiate a Phase 1b, combination dose escalation clinical trial evaluating ZN-c3 in combination with chemotherapy in patients with advanced ovarian cancer in the second half of 2020.

The primary objective of this Phase 1b, combination dose escalation trial will be to determine the MTD or RP2D for ZN-c3 when administered in combination with chemotherapy.

#### **ZN-c3 Clinical Program**

# Phase 1

# Solid Tumors: Monotherapy Dose Escalation

Ovarian Cancer: Chemo Combination Phase 1b Study

> 2 Additional Combination Studies

## Phase 2

Solid Tumors: Combination Approaches (Chemo & PARPi)

Uterine Serous Carcinoma: Monotherapy Phase 2 Study

### Interim Clinical Results

Interim data is subject to change as more data on these patients and additional patients become available and are subject to audit and verification procedures that could result in material changes in the final data.

#### Safety Results

As of the June 19, 2020 database cutoff, in the Phase 1, monotherapy dose escalation portion of the ongoing ZN-c3-001 trial, a total of 22 patients were enrolled and dosed and had data available in the electronic data capture system: two patients each at the dose levels of 25 mg, 50 mg, 200 mg and 300 mg, four patients at 100 mg and ten patients at 75 mg/day. Enrollment in the Phase 1, monotherapy dose escalation portion of this trial is ongoing, and a total of up to 50 patients may be enrolled.

As of the June 19, 2020 database cutoff, no dose limiting toxicities were observed. TEAEs occurred in 21 of the 22 patients. Nausea was observed in seven patients; diarrhea in six patients; fatigue in five patients; anemia in four patients; and abdominal distention, decreased appetite, dyspnea, gamma-glutamyltransferase increased, pyrexia and vomiting in three patients each. All other adverse events were observed in one or two patients each. A single TEAE of Grade 4 severity (ALT increased) was observed. TEAEs of Grade 3 severity included two cases of gamma-glutamyltransferase increased, and single cases of anemia, hepatic enzyme increased, blood

bilirubin increased, hypertension, sepsis, and AST increased. All other TEAEs were of Grade 1 or Grade 2 in severity. The Grade 3 TEAEs of sepsis, anemia (n = 2) and hepatic enzyme increase also accounted for four of the six serious adverse events reported. The other two serious adverse events included Grade 2 transient ischemic attack and large intestinal obstruction. No serious adverse event was deemed related to ZN-c3. There were no deaths reported.

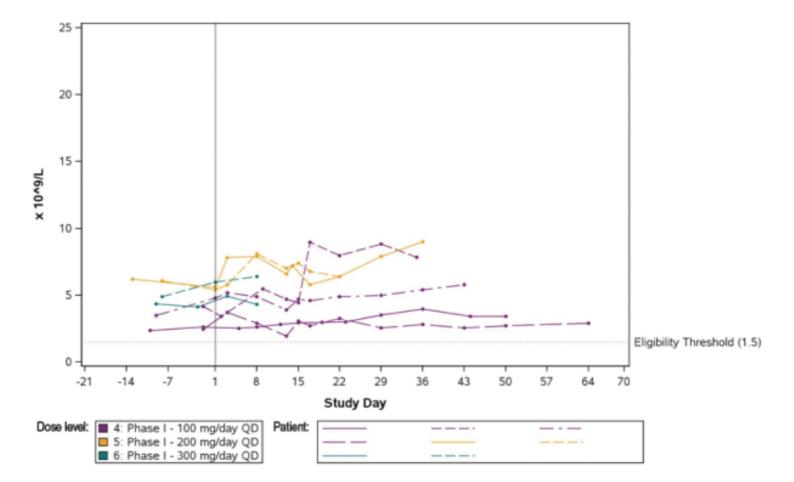
Investigator assessed treatment-related adverse events occurred in 14 of 22 patients. These treatment-related adverse events included diarrhea and nausea in three patients each, fatigue and vomiting in two patients each, and other single adverse events. A single treatment-related adverse event of Grade 4 severity (ALT increased) was observed. Grade 3 treatment-related adverse events reported included AST increased and hepatic enzyme increased. All others were of Grade 1 or Grade 2 in severity. None of the liver function test abnormalities were

indicative of drug-induced liver injury. Of the two patients with treatment-related hepatic enzyme increased, one had a history of ethanol use.

Overall, as of the June 19, 2020 database cutoff date, there was no increase in incidence or in severity of adverse events observed with increasing dosing levels.

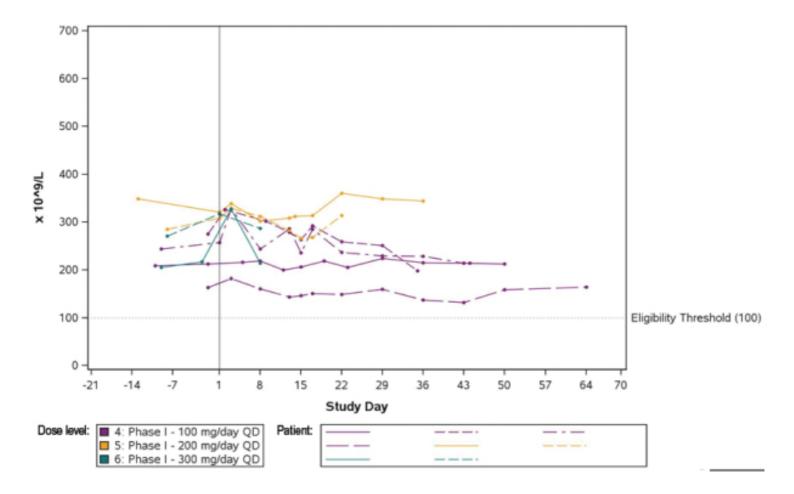
The following graphs show hematological parameters (neutrophilis, platelets or hemoglobin) on study for individual patients in each of the higher dose groups (100 mg/day, 200 mg/day and 300 mg/day). As of the June 19, 2020 database cutoff date, we have observed higher exposures with escalating doses of ZN-c3. Of note, these exposures have not led to a negative effect on hematological parameters (neutrophilis, platelets or hemoglobin).

# ZN-c3-001 - Hematology - Neutrophils



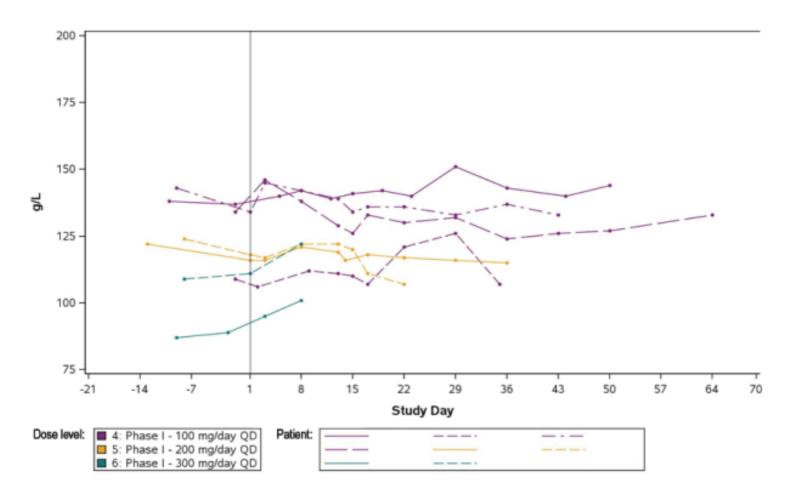
**Notes:** QD: once daily

# ZN-c3-001 – Hematology – Platelets



Notes: QD: once daily

# ZN-c3-001 - Hematology - Hemoglobin



Notes: QD: once daily

# **ZN-c3 Pharmacokinetics Results**

As of the June 19, 2020 database cutoff date, upon oral dosing at the dose levels of 25 mg to 200 mg, ZN-c3 was absorbed into the systemic circulation with the median  $T_{max}$  of one to four hours and the typical half-life was six to nine hours. As shown in the table below,  $C_{max}$  and AUC values of ZN-c3 increased in an approximately dose proportional manner on Day 1 and greater than dose proportionally on Day 15. Based on AUC, there was low to no ZN-c3 accumulation on Day 15 compared to Day 1, with accumulation ratios ranging between 0.72- and 2.38-fold.

# Preliminary Pharmacokinetic Data for ZN-c3

		Day 1			Day 15			
Dose (mg)		Cmax (ng/mL)	Tmax (hr)	AUClast (ng*h/mL)	Cmax (ng/mL)	Tmax (hr)	AUClast (ng*h/mL)	Accumulation by AUClast
25	Mean	14.3	2	87.2	9.14	2	62.7	~0.72
50	Mean	54.6	2.5	533	47.8	4	594	1.12
75	Mean	122	2	1,100	152	1	1,330	1.67
	SD	98. <i>7</i>	(1-4)	1,000	<i>70.</i> 5	0-24	<i>378</i>	0.75
	CV	80.8		90.6	46.3		28.5	44.8
100	Mean	124	1	1,120	199	3	1,620	1.56
	SD	118	(1-24)	827	285	(1-24)	1,750	0.78
	CV	95.2		74.0	144		108	50.0
200	Mean	353	2	2,870	712	2	6,160	2.38
	SD	327	(1-4)	1,950	464	(1-2)	3,250	0.53
	CV	92.6		68.1	65.2		52.8	22.4

Notes

Median (range) are listed for Tmax

25 and 50 mg: n=2; 75 mg: n=10 on Day 1 and n=8 on Day 15; 100 mg: n=4; 200 mg: n=3

Data regarding clinical activity are premature at this point. Pharmacodynamic data will be collected in subsequent patients and will be reported in the future.

# ZN-d5, an Inhibitor of BCL-2 for the Treatment of Hematologic Cancers

#### Overview

We are developing ZN-d5, an oral selective inhibitor of BCL-2, to promote apoptosis for the treatment of cancers, with an initial focus on hematologic malignancies. We have applied our expertise to design ZN-d5 as an oral BCL-2 inhibitor and to have optimized potency, selectivity and PK.

We submitted an IND to the FDA on March 30, 2020, which was accepted by the FDA in April 2020, and 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 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.

# Role of BCL-2 in Hematological Cancers

The BCL-2 family of protein is most notable for its critical role in the regulation of apoptosis at the mitochondrion. Based upon their functions, BCL-2 family proteins are classified into pro-apoptotic and anti-apoptotic members. The anti-apoptotic BCL-2 proteins include BCL-2, B-cell lymphoma extra-large, or BCL-xL, myeloid cell leukemia-1, or MCL-1, and BCL-2 related protein Al.

The overexpression of BCL-2 and/or BCL-xL proteins is frequently detected in many different types of cancers, including chronic lymphatic leukemia, or CLL, SLL, AML, non-Hodgkin's lymphoma, or NHL, follicular lymphoma, or FL, mantle-cell lymphoma, or MCL, Waldenström's macroglobulinemia, diffuse large B-cell lymphoma, or DLBCL, multiple myeloma, or MM, and small cell lung cancer, or SCLC. These overexpressed proteins prevent apoptosis of cancer cells. We believe the use of small molecule inhibitors to block the protein-protein interactions, or PPI, of BCL-2 and/or BCL-xL with their pro-apoptotic partners will restore the normal apoptosis process in cancer cells and has been pursued as a new cancer therapeutic strategy.

There have been many attempts to develop a new class of anticancer therapies that target BCL-2 and/or BCL-xL proteins. The intracellular localization of the BCL-2 family proteins on the mitochondrial membrane prevents the use of antibodies and other large molecules to target these antiapoptotic BCL-2 family proteins. The large surface area involved in BCL-2 PPIs also makes BCL-2 family proteins difficult targets for small molecule drugs. Currently, venetoclax is the only FDA-approved BCL-2 inhibitor and, to our knowledge, there are only a small number of additional agents in active clinical development.

# FDA-Approved BCL-2 Inhibitor, Venetoclax

Venetoclax, the only FDA-approved BCL-2 inhibitor (marketed by AbbVie and Genentech as Venclexta®), was initially developed to overcome unfavorable side effects of previously tested BCL-2 inhibitors resulting from BCL-xL inhibition. In third-party clinical trials, inhibition of BCL-xL has been shown to lead to thrombocytopenia, an adverse event observed in 29% of patients dosed with venetoclax. Venetoclax has demonstrated clinical efficacy across a range of hematological malignancies and was initially approved by the FDA in April 2016 to treat relapsed or refractory CLL. Venetoclax is now approved in the following indications:

- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, or CLL/SLL. Venetoclax was initially approved in April 2016 as a monotherapy in patients with CLL with 17p deletion who received at least one prior therapy based on overall response rate of 80% in an open-label, single-arm, multicenter clinical trial. Since then, venetoclax has demonstrated clinical efficacy and gained FDA approval in previously treated and untreated CLL/SLL patients in combination with anti-CD20 antibodies, rituximab and obinutuzumab. In a randomized clinical trial, treatment of CLL patients who had received at least one line of prior therapy with a combination of venetoclax and rituximab reduced the risk of disease progression or death as measured by median PFS by 81% compared to a commonly used standard of care regime of bendamustine, a chemotherapy agent, plus rituximab. Similarly, a randomized clinical trial demonstrated that the combination of venetoclax and obinutuzumab reduced the risk of disease progression or death for previously untreated CLL or SLL patients by 67% compared to a commonly used standard regime of chlorambucil, a chemotherapy agent, plus obinutuzumab.
- Acute Myeloid Leukemia, or AML. In November 2018, the FDA also approved venetoclax in combination with chemotherapy agents, azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly-diagnosed AML who are 75 years of age or older or have other medical conditions that prevent the use of standard chemotherapy. This approval was based on results from two open-label non-randomized trials showing complete remission rates ranging from 21% to 54%, depending on the combination agent.

Third-party trials have also reported promising antitumor activity in other hematologic cancers, often using higher doses of venetoclax than the FDA-approved dosage. A monotherapy trial of venetoclax investigating doses up to 1,200 mg reported that patients with MCL or follicular lymphoma responded well, including complete responses in some patients. Venetoclax is also being studied as monotherapy and in combination for the treatment of myelodysplastic syndrome and multiple myeloma.

Worldwide sales of Venclexta® were approximately \$792.0 million in 2019, and are expected to increase to \$4.3 billion by 2026.

# Emerging Role of BCL-2 in Solid Tumors

Although the development of venetoclax has to date been primarily limited to hematologic cancers, a study in a panel of cell lines derived from a variety of tumors demonstrated that BCL-2 expression and venetoclax sensitivity has been observed in multiple solid tumors. These include SCLC, bone, breast, and nervous system tumors. In a recent third-party Phase 1b clinical trial of venetoclax in combination with tamoxifen in patients with ER+/BCL-2+ metastatic breast cancer, it was observed that a dose of 800 mg venetoclax in combination

with 20 mg of tamoxifen was associated with an overall response rate of 54% and clinical benefit rate of 75%. Median PFS was 36 weeks in the overall trial. The authors of this third-party clinical trial cited the high pill burden associated with venetoclax as one reason why the highest dose was limited to 800 mg.

Additionally, the efficacy of venetoclax used in combination with fulvestrant versus fulvestrant administered as monotherapy is being evaluated in an ongoing third-party Phase 2 clinical trial in patients with ER+/HER2- breast cancer.

### Our BCL-2 Inhibitor: ZN-d5

ZN-d5 is our oral, small molecule BCL-2 inhibitor product candidate for the treatment of cancers, with the initial focus on hematologic malignancies. We have designed ZN-d5 to have the following characteristics:

- Potency. In our in vitro preclinical studies, ZN-d5 was observed to be potent across hematological malignancies cell lines.
- Selectivity. In our *in vitro* preclinical studies, ZN-d5 has been observed to have more than 600 times greater selectivity for BCL-2 than BCL-xL. The inhibition of BCL-xL in third-party clinical trials has been shown to lead to thrombocytopenia, an adverse event observed in 29% (20% Grade 3 or higher) of patients dosed with venetoclax and a cause of dose reductions and dosing interruptions. We believe this greater selectivity observed in our preclinical studies may support the use of ZN-d5 in combination with other drugs that have observed incidence in thrombocytopenia.
- Tolerability profile. In our in vivo preclinical studies, ZN-d5 has been observed to be well tolerated across various dosage levels.

We believe the observed properties of ZN-d5 make it an attractive candidate for evaluation as monotherapy and in combination with other therapies, initially for the treatment of hematological malignancies. We submitted an IND to the FDA on March 30, 2020, which was accepted by the FDA in April 2020, and intend to initiate a Phase 1 clinical trial of ZN-d5 as monotherapy in patients with AML or B-cell lymphoma in the first half of 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.

### **Preclinical Results**

### **Potency and Selectivity Across Hematological Malignancies**

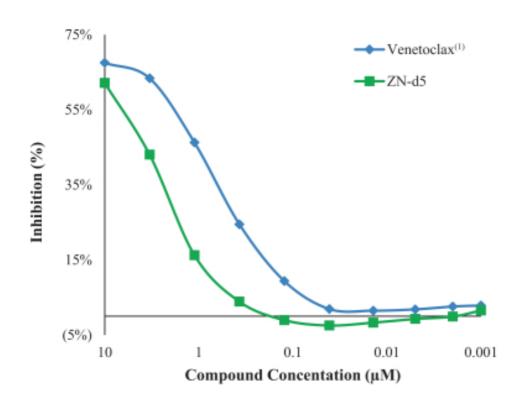
In an *in vitro* preclinical study, we assessed the selectivity and potency of ZN-d5 alongside venetoclax. As shown in the table below, we assessed the affinity of each agent as measured in nM in a biochemical assay. Based on these measurements, ZN-d5 showed 600 times greater selectivity for BCL-2 than BCL-xL, and we believe such selectivity may limit the incidence of thrombocytopenia observed in third-party clinical trials as a result of BCL-xL inhibition. We also observed that ZN-d5 was potent across hematological malignancy cell lines as measured by CellTiter-Glo, or CTG, a cell viability assay, shown in the table below.

	AFFINITY (nM)		ALL	MCL	DLBCL		AML		
	BCL-2	BCL-XL		GRANTA-				MOLM-	
COMPOUND	Kd	Kd	RS4;11	519	DOHH-2	TOLEDO	HL-60	13	MV4-11
Venetoclax(1)	0.41	28	2.9	161	43	191	26	18	3.8
ZN-d5	0.29	190	5.1	89	50	92	21	39	5.1

<sup>(1)</sup> Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

In a preclinical study, we also assessed the platelet toxicity of ZN-d5 against venetoclax, as measured by mM in a platelet viability assay. In each assay, ZN-d5 was observed to be less toxic to platelets than venetoclax, which we believe may limit the incidence of thrombocytopenia.

# ZN-d5 Toxicity Compared to Venetoclax In In Vitro Assay



	CTG IC <sub>50</sub> (μM)
Venetoclax <sup>(1)</sup>	0.6
ZN-d5	2.4

# **Potency for BCL-2 Mutations**

We believe genetic mutations in the BCL-2 gene may be responsible for a developed resistance to venetoclax observed in some CLL patients. In a third-party clinical trial, 16 of 29 patients acquired mutations in members of the BCL-2 family of proteins, 14 of which were a mutation in BCL-2. In nine of those 14 patients, the BCL-2 mutation was detected after 24 months on venetoclax. In an *in vitro* preclinical study, we assessed the affinity of ZN-d5 alongside venetoclax, to bind to such BCL-2 mutations, as measured in nM. In each assay, ZN-d5 was observed to bind with higher affinity to such BCL-2 mutants as compared to venetoclax.

COMPOUND	WT	G101V	F104L	D103Y
Venetoclax(1)	1.3	7.3	8.4	18.3
ZN-d5	1.4	3.7	1.4	5.0

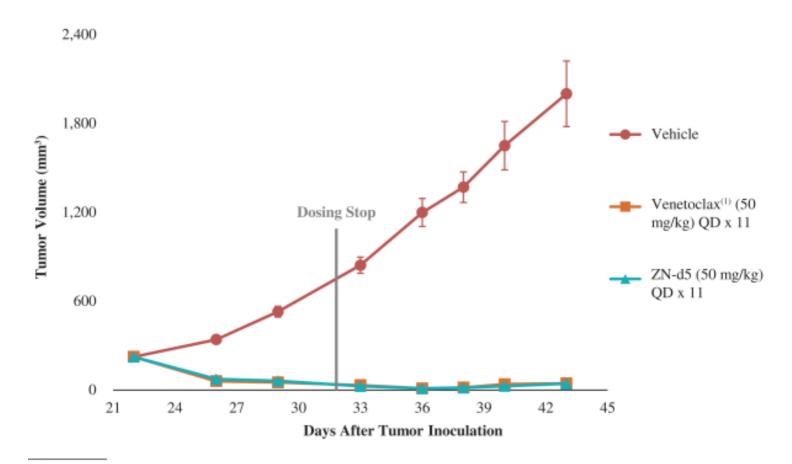
<sup>(1)</sup> Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

# Anti-Tumor Activity of ZN-d5 in Xenograft Leukemia Model

In a preclinical study, we assessed the anti-tumor activity of ZN-d5, alongside venetoclax. In a RS4;11 xenograft leukemia mouse model, ZN-d5, dosed at 50 mg/kg daily for a period of 11 days, showed potent anti-tumor activity with tumors shrinking upon treatment and yielding durable complete responses after cessation of

<sup>(1)</sup> Data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

dosing to the end of the study, as shown in the graphic below. We observed similar results with venetoclax in this model.



Venetoclax data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

# Notes:

QD: Once daily

# Toxicology

The IND enabling toxicology studies are currently ongoing.

### ZN-e4, an Inhibitor of EGFR for the Treatment of NSCLC

# Overview

We are developing ZN-e4, an irreversible inhibitor of mutant EGFR, a regulator of a number of cellular functions, including proliferation and survival, and a driver of tumorigenesis in certain cancers, including lung cancer. We have designed ZN-e4 to be highly selective against mutant EGFR, and we have observed in preclinical studies that the administration of ZN-e4 does not produce a metabolite potent for wild-type EGFR, the production of which is believed to be responsible for the development of a number of toxicities, including skin rash. We believe that eliminating the formation of such a metabolite will allow for a wide therapeutic window. In addition, we believe a more tolerable EGFR inhibitor would, if approved, allow for use in combination while limiting the toxicity associated with use in combination.

We are conducting a Phase 1/2 clinical trial of ZN-e4 in patients with advanced NSCLC with activating EGFR mutations, which we refer to as our ZN-e4-001 Trial. We are actively evaluating potential combination therapies for future clinical development of ZN-e4. We will evaluate whether to initiate the Phase 2 portion of this trial upon the completion of the Phase 1 portion and after considering trial design, patient population and combination strategies. We expect to report topline results from the Phase 1 portion of the trial in 2021.

### Role of EGFR Inhibition in NSCLC

Lung cancer is the leading cause of cancer death for both men and women, accounting for approximately 18% of all cancer deaths globally. There are an estimated 228,000 new cases of lung cancer diagnosed and 143,000 deaths in the United States annually. More than half of the people with lung cancer die within one year of being diagnosed. Non-small cell lung cancer, or NSCLC, accounts for approximately 80-85% of lung cancer cases. EGFR mutations are detected in approximately 10% to 15% and 30% to 40% of Caucasian and Asian patients, respectively, with NSCLC.

EGFR mutations lead to activation of EGFR signaling and oncogenic transformation both *in vitro* and *in vivo*. Cancers with EGFR mutations depend on EGFR signaling for growth and survival and are often sensitive to treatment with EGFR inhibitors. Two inhibitors of EGFR were approved in the early 2000s to treat patients with advanced NSCLC based on antitumor responses in a subset of patients. These first-generation drugs, erlotinib and gefitinib, were reversible EGFR inhibitors. Although most NSCLC patients with EGFR mutations displayed an initial pronounced response to these first-generation EGFR inhibitors, they acquired resistance to the drugs after approximately nine to 14 months of treatment. The T790M mutation of EGFR was the most common mechanism of such an acquired resistance, having been detected in over 50% of patients treated with EGFR inhibitors.

A second-generation of EGFR inhibitors was developed to address this treatment resistance and to improve upon the efficacy of the first-generation therapies. The second-generation of EGFR inhibitors, including afatinib, marketed as Gilotrif® by Boehringer Ingelheim, and dacomitib, marketed as Vizimpro® by Pfizer, are irreversible inhibitors which covalently bind to EGFR. As such, they are more potent, but are associated with increased toxicity. Further, T790M-mediated acquired resistance occurred at a similar frequency in patients receiving a second-generation therapy as those receiving first generation therapy. Third-generation therapies, such as osimertinib, specifically targeting the T790M mutation have been clinically shown to be a useful strategy in the treatment of NSCLC.

### FDA-Approved Third-Generation EGFR Inhibitor, Osimertinib

Osimertinib, which represents the third-generation of EGFR inhibitors, targets EGFR mutations and acquired resistance EGFR mutations such as T790M in order to improve upon the efficacy of previous generations of EGFR inhibitors. In a randomized Phase 3 clinical trial in patients with EGFR-mutated metastatic NSCLC, osimertinib demonstrated a median PFS period of 18.9 months versus 10.2 months for the control arm in which patients received gefitinib or erlotinib. Based on these results, osimertinib was approved by the FDA in November 2015. AstraZeneca reported sales of Tagrisso® of \$3.2 billion in 2019 and are expected to grow to \$9.5 billion in 2026.

Osimertinib was also designed to have reduced potency against non-mutated, or wild-type, EGFR found in healthy cells, thereby minimizing the toxicities associated with first and second-generation EGFR inhibitors. Despite its observed success in addressing the T790M-mediated acquired resistance and improved efficacy, osimertinib has a similar adverse event profile to first and second-generation EGFR inhibitors. As demonstrated by third-party clinical data, approximately 60% of patients dosed with osimertinib reported rashes compared to 80% of those dosed with gefitinib or erlotinib and a range of 70% to 90% for the second-generation EGFR inhibitor, afatinib. In addition, similar levels of gastrointestinal disorders such as diarrhea were observed in each of the patient populations. Osimertinib also has warnings and precautions regarding interstitial lung disease, QT prolongation, a surrogate marker for the risk of developing tachycardias, cardiomyopathy, keratitis and Stevens-Johnson Syndrome.

We believe one of the major metabolites of osimertinib, AZ5104, which accounts for approximately 9% to 10% of the total drug concentration at clinical doses, may be contributing to these toxicities. In addition, the off-target toxicities are exacerbated by the long half-life of osimertinib.

#### Our EGFR Solution: ZN-e4

ZN-e4 is our irreversible EGFR inhibitor product candidate which we have designed to potently inhibit mutant EGFR, including the T790M resistance mutation. We have designed ZN-e4 to be highly selective against mutant EGFR and have observed in preclinical studies that the administration of ZN-e4 does not produce a metabolite potent for wild-type EGFR. We have also designed ZN-e4 with improved physical-chemical characteristics, including improved solubility. In a head-to-head preclinical study, ZN-e4 showed greater than 450-fold solubility within 48 hours when compared to osimertinib.

We are evaluating ZN-e4 in our Phase 1/2 clinical trial in patients with advanced NSCLC. We believe ZN-e4, if approved, has the potential to be used as monotherapy and in combination with a number of therapies, including ZN-c3, our WEE1 inhibitor product candidate, if approved, tyrosine-protein kinase Met, or c-Met, inhibitors, mitogen-activated protein kinase, or MEK, inhibitors, and c-ros oncogene1 receptor tyrosine kinase, or ROS1, inhibitors. Results of various third-party preclinical studies and clinical trials support such combinations across a number of oncology indications and we continue to actively evaluate the potential of combinations for future clinical development with ZN-e4.

#### **Preclinical Results**

### **Selectivity Across EGFR Cell Lines**

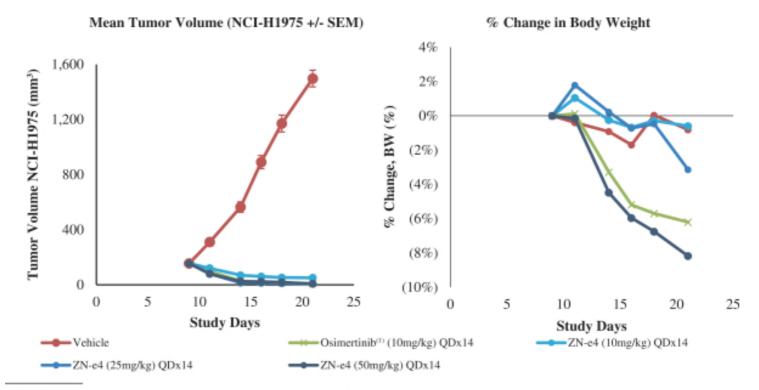
In a preclinical study, we evaluated the potency of ZN-e4 alongside osimertnib against three types of EGFR cell lines –double mutant (DM cell), single mutant (AM cell) and wild-type (WT cell). As shown in the table below, we observed similar potency in the DM and AM cell lines and three times greater selectivity than osimertinib based on the wild-type binding. In addition, we also observed that the administration of ZN-e4 did not produce a metabolite potent for wild type EGFR.

	DOUBLE MUTANT CELL	SINGLE MUTANT CELL	WILD-TYPE CELL
	IC50 (nM)	IC50 (nM)	IC50 (nM)
Osimertinib(1): Core Drug	15	29	294
ZN-e4: Core Drug	20	38	839

Osimertinib data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

# Anti-tumor Activity, Tolerability and Solubility of ZN-e4

In a preclinical study, we evaluated the anti-tumor activity of ZN-e4 alongside that of osimertinib. In a NCI-H1975 NSCLC tumor model in which there is a double mutation in EGFR, T790M and L858R, oral dosing of ZN-e4 for 14 days at the dose tested, 10 mg/kg, induced complete tumor regression, as did 10 mg/kg osimertinib dosed orally. In addition, ZN-e4 at this dose was well tolerated in these models with no apparent loss in body weight throughout the study. In contrast, the 10 mg/kg dose of osimertinib led to a loss of greater than 8% of total body weight. We observed a similar loss of body weight with ZN-e4 when we increased the dose to 50 mg/kg, roughly five times the dose we found to reduce tumor volumes.



 Osimertinib data based on evaluation of comparable proxy chemical compound purchased from commercial sources rather than the pharmaceutical company commercializing the compound.

# Note:

QD: Once daily

We also assessed the relative solubility of ZN-c3, alongside a proxy chemical compound of osimertinib, using a standard *in vitro* assay. The solubility of ZN-e4 was observed to be 1,614,000 nM, greater than 450 fold the solubility that of osimertinib which was observed at 3,500 nM. In addition, we did not observe confirmed cardiac toxicity as measured by the standard electrophysiological hERG safety assay.

# Phase 1/2 Clinical Trial of ZN-e4

In April 2018, we initiated dosing in a Phase 1/2 open label, multi-center trial of ZN-e4 in patients with advanced NSCLC with activating EGFR mutations who have progressed following therapy with an EGFR tyrosine kinase inhibitor, which we refer to as our ZN-e4-001 Trial, to assess the safety, tolerability, PK and anti-tumor activity of ZN-e4. We plan to enroll a total of up to 186 patients in this trial, which is currently being conducted across multiple sites in the United States. Our ZN-e4-001 Trial consists of a Phase 1, monotherapy 3+3 dose escalation portion of this trial and a Phase 2 portion of this trial.

The primary objective of the Phase 1 portion of this trial is to determine the MTD or RP2D of ZN-e4. The secondary objectives include assessing the safety and tolerability, determining a RP2D and characterizing the PK, of ZN-e4 as an oral monotherapy.

As of February 5, 2020, 19 patients had been enrolled in this trial in seven dose level cohorts. We expect to report topline results from the Phase 1 portion of this trial in 2021. We will evaluate whether to initiate the Phase 2 portion of this trial upon the completion of the Phase 1 portion and after considering trial design, patient population and combination strategies.

# Interim and Preliminary Clinical Results

As of the February 5, 2020 database cutoff date, we completed dosing in six of our dose escalation cohorts and have enrolled two patients in cohort seven. Nineteen patients have been enrolled and treated with doses of ZN-e4 ranging from 20 mg to 480 mg, once daily. At baseline, the mean age of the enrolled population was 63.9 years (range 38 to 86 years) and consisted of 47% females and 53% males. Of the enrolled patients, six (31.6%)

are continuing treatment and 13 (68.4%) have discontinued treatment, nine of which were due to disease progression.

Enrolled patients have received the following prior lines of cancer treatment: EGFR tyrosine kinase inhibitors (16 of 19 patients), chemotherapy (12 of 19 patients), osimertinib (11 of 19 patients), immunotherapy (five of 19 patients), investigational EGFR tyrosine kinase inhibitors (two of 19 patients) and EGFR monoclonal antibodies (two of 19 patients). Of the enrolled patients, 12 of the 19 had one to three prior systemic cancer regimens, and seven of the 19 had four or more.

The interim and preliminary data described herein are subject to change as more data on these patients and additional patients become available and are subject to authorization and verification procedures that could result in material changes in the final data.

# Interim ZN-e4 Preliminary Safety Results

As of the February 5, 2020 database cutoff date, ZN-e4 was generally well tolerated. One patient reported a dose-limiting toxicity at the 320 mg dose level. The trial is currently ongoing at a dose level of 480 mg.

TEAEs occurred in 18 of 19 patients. No serious adverse events were reported. Two deaths occurred during the safety reporting time period of the study, each due to progression of disease and determined to not be related to treatment.

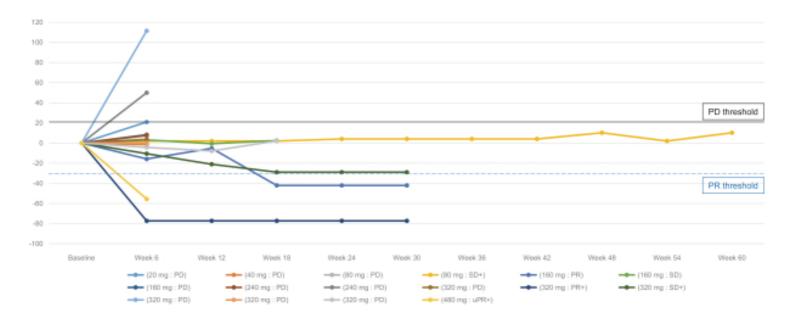
The most frequent of these TEAEs observed were diarrhea (11 of 19 patients), nausea (six of 19 patients), fatigue (six of 19 patients), back pain (five of 19 patients), cough (five of 19 patients), dyspnea (four of 19 patients) and vomiting (four of 19 patients). All cases of diarrhea were Grade 1 except for one which was Grade 2. Rash of Grade 1 severity was only reported in one patient.

Investigator-assessed, treatment-related adverse events occurred in 11 of 19 patients. Of these treatment-related adverse events, nine of 19 patients reported treatment-related adverse events of Grade 1 or Grade 2 severity and two of 19 patients reported treatment-related adverse events of Grade 3 in severity; one case of dysphagia and two cases of fatigue.

As of the February 5, 2020 database cutoff date, there was no apparent increase of incidence or severity of adverse events with increased dose.

# **Interim and Preliminary Efficacy Results**

As of the February 5, 2020 database cutoff date, we observed that two patients, each of which was osimertinib naïve and one of which had the T790M mutation, had confirmed PR by RECIST criteria as showing their best overall response, one dosed at 160 mg and one at 320 mg. One patient dosed at 480 mg showed an unconfirmed PR as of the cutoff date. One other patient currently with stable disease had a reduction in target lesion size of approximately 29%.

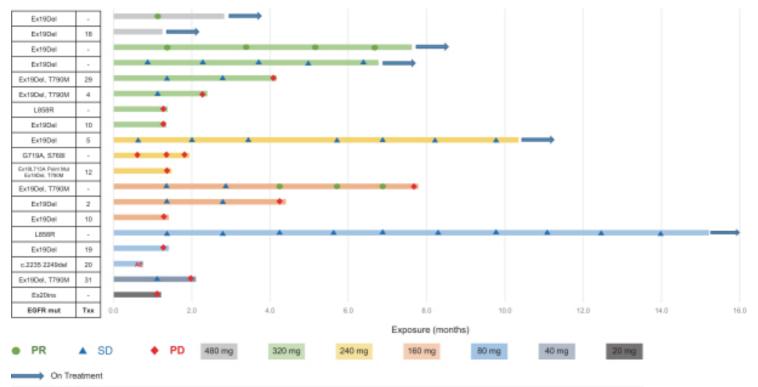


### Notes

Includes data for the 16 evaluable patients as of the February 5, 2020 database cutoff date. (zz mg:rr) indicates: (dose: best response, + if ongoing)

As of the database cutoff date, one patient had a treatment duration of 15.2 months and another patient had a treatment duration of 10.3 months.

The following table illustrates response, duration of remission and re-dosing of ZN-e4 in this trial as of the database cutoff date.



Notes:

Txx: prior Tagrisso® use and duration in months

PR: Partial Response

SD: Stable Disease

PD: Progressive Disease

# **Drug Pharmacokinetics**

As of the February 5, 2020 database cutoff date, PK results were available for the first 17 patients dosed in our ZN-e4 Trial. The PK results from such patients showed rapid absorption into the systemic circulation, with typical median  $T_{max}$  values of two to four hours. The exposures were observed to be dose dependent. Little to no ZN-e4 accumulation at steady state on day 15 of once daily dosing was observed with mean day 15 to day one AUC ratios of 1.0-1.8.

		DAY 15 (STEADY STATE)				
DOSE (mg)		Cmax (ng/mL)	Tmax (hr)(1)	AUC0-8hr (ng*h/mL)		
20 (n=1)	Mean	55.9	8	376		
40 (n=1)	Mean	36.9	8	179		
80	<b>Mean</b>	<b>144</b>	<b>4</b>	<b>945</b>		
(n=1)	SD	65.3	(2-4)	48 <i>7</i>		
160	<b>Mean</b>	<b>382</b>	<b>4</b> (2-4)	<b>2,440</b>		
(n=3)	SD	274		1,630		
240	<b>Mean</b>	<b>532</b>	<b>4</b>	<b>3,730</b>		
(n=3)	SD	117	(4-6)	926		
320	<b>Mean</b>	<b>388</b>	<b>4</b> (2-4)	<b>2,550</b>		
(n=5)	SD	203		1,410		

<sup>(1)</sup> Median (range) are listed for Tmax

### **Manufacturing**

We currently do not own or operate any manufacturing facilities. We rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We require that our CMOs produce bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations. We maintain agreements with our manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We have engaged CMOs to manufacture and package ZN-c5, ZN-c3, ZN-d5 and ZN-e4 for preclinical and clinical use. Additional CMOs are used to label and distribute ZN-c5, ZN-c3 and ZN-e4 for clinical use. We obtain our supplies from these CMOs on a purchase order basis and do not have long-term supply arrangements in place. Although we do not currently have contractual arrangements in place for redundant supply for all of these product candidates, it is our goal to identify and contract with at least two manufacturers for active pharmaceutical ingredient and two manufacturers for drug product. More broadly, for each of our product candidates, we intend to identify and qualify additional manufacturers to provide the active pharmaceutical ingredient and fill-and-finish services prior to seeking regulatory approval.

### Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or less expensive than any medicines we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market. We believe that the key competitive factors affecting the success of any of our product candidates, if approved, will include efficacy, combinability, safety profile, convenience, cost, level of promotional activity devoted to them and intellectual property protection.

If the product candidates for our priority programs are approved for the indications we are currently targeting, they will compete with the drugs discussed below. Furthermore, it is possible that other companies are also engaged in discovery or preclinical development of drug candidates for the same indications. These competitors, if successful in clinical development, may achieve regulatory approval and market adoption in advance of our product candidates, constraining our ability to gain significant market share for such product candidates. In addition, our product candidates, if approved, will complete with multiple approved drugs or drugs that may be approved for future indications for which we develop such product candidate.

# **Intellectual Property**

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

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

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biopharmaceuticals has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued licensed-in patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued licensed-in patents may be challenged, invalidated, deemed unenforceable or circumvented, which could limit our ability to stop competitors from

marketing-related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued in-licensed patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent directed to such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

# **In-licensed Patents and Patent Applications**

Recurium IP Holdings, LLC or Zeno Management, Inc., are currently the listed owner/assignee, or retained the exclusive license to 48 families of patent applications directed to our technology across our pipeline. As of July 8, 2020, our in-licensed portfolio consists of twelve U.S. patents and eleven foreign patents in six jurisdictions, Europe, Hong Kong, India, Japan, Singapore and Taiwan.

As of July 8, 2020, 20 of the 48 families have a single application pending, and 27 of 48 families have multiple applications pending. The 48 families include 60 U.S. applications (including pending U.S. provisional patent applications and pending U.S. non-provisional patent applications), 9 PCT applications and 188 international applications in approximately 17 countries, including major markets in North America, Europe and Asia, each having a nominal expiration date ranging from 2034 to 2040. The nominal expiration of our patents and patent applications does not account for any applicable patent term adjustments or extensions.

U.S. Patent No. 10,513,509, or the '509 Patent, includes claims directed to composition of matter, including ZN-e4, a pharmaceutical composition, a method for inhibiting replication of a malignant growth or a tumor, a method for ameliorating or treating a cancer and a method for inhibiting the activity of EGFR. The '509 Patent has an expected expiration date in May 2037. However, we believe the '509 Patent may be eligible for a patent term extension under the Hatch-Waxman Act.

One of the aforementioned pending U.S. and PCT patent applications includes claims directed to ZN-c5, ZN-c3 or ZN-d5, and has an expected expiration in 2037 (ZN-c5) and 2039 (ZN-c3 and ZN-d5). However, there can be no assurance that any of our pending in-licensed patent applications will issue. Furthermore, there can be no assurance that we will benefit from any patent term extension or favorable adjustments to the term of any of our in-licensed issued patents or patents that are issued in the future. The applicable authorities, including the FDA in the United States, may not agree with our assessment of whether such patent term extensions should be granted, and, if granted, they may grant more limited extensions than we request.

#### **Trademarks**

As of July 8, 2020, our trademark portfolio contains the following trademarks applications or registrations. U.S. trademark applications are pending for each of the marks ZENTALIS and the stylized "Z" mark. The mark ZENO has a registered U.S. trademark. Applications to register the marks ZENO and ZENTALIS have been filed internationally. The portfolio has an International Madrid Trademark Application designating Australia, Europe, Israel, Japan, Mexico, New Zealand, the Russian Federation, the United Kingdom and Singapore for the mark ZENO. The portfolio also has pending applications for registration and/or a registration has issued for one or more classes in Argentina, Brazil, Canada, Hong Kong and Taiwan for the mark ZENO. The portfolio also has an International Madrid Trademark Application designating Australia, Brazil, Canada, China, Europe, the United Kingdom, Israel, India, Japan, Korea, Mexico, New Zealand, the Russian Federation and Singapore for the mark ZENTALIS. The portfolio also has pending applications for registration in Argentina, Hong Kong, and Taiwan for the mark ZENTALIS.

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

# Licensing Agreements and Strategic Collaborations

### 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 preventions of disease, other than for pain. 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 the Company. 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 the Company 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 IPO, Recurium Equity, LLC's ownership interest in us was 11.6%, 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. Upon the closing of this offering, based on our issuance and sale of 3,750,000 shares in this offering, Recurium Equity, LLC's ownership interest us would be 10.5%, 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.

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. The Recurium Agreement will expire on the later of on a

country-by-country basis the expiration of royalty term for all licensed products in such country and December 21, 2032. The Recurium Agreement may be terminated in its entirety either by Recurium or by us in the event of an uncured material breach by the other party, in the event the other party is subject to specified bankruptcy, insolvency or similar circumstances, or in the event of a force majeure event under certain circumstances.

Upon termination of the Recurium Agreement for any reason, all rights and licenses granted to us under the agreement will terminate and revert to Recurium, and in the event of certain termination events, we would grant Recurium worldwide, royalty-bearing rights to our licensed products and transfer to Recurium any regulatory filings and data for such 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 to related 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 February 29, 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 prospectus, 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, 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 to 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 up-front 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. 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 license

Following the December 2016 amendment to the SciClone Agreement, SciClone retains the exclusive license to develop our EGFR inhibitor product candidate, ZN-e4, in the SciClone Territory and the exclusive option to obtain an exclusive license to up to two specified compounds under the SciClone Agreement for which we submit an IND by providing notice and paying \$5 million to us. The SciClone Agreement will expire at the later of on a country-by-country basis the expiration of royalty term for all licensed products in such country and 15 years after the effective date of such agreement. The SciClone Agreement may be terminated in its entirety or on a country-by-country basis by SciClone upon 180 days' notice or either by SciClone or by us in its entirety in the event of an uncurred material breach by the other party, in the event the other party is subject to specified bankruptcy, insolvency or similar circumstances, or in the event of a force majeure event under certain circumstances.

# 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 ZN-c5-001 Trial, at no cost to us. We are required to provide to Pfizer clinical data and other reports upon completion of the ZN-c5-001 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 Pfizer will expire upon completion of all obligations of the parties thereunder or upon termination by either party. We and Pfizer 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. Pfizer also has the right to terminate this agreement if it notifies us in writing that it reasonably and in good faith believes that palbociclib is being used in an unsafe manner, and we fail to incorporate changes to address such issue, and the joint development committee is unable to resolve the issue following elevation to appropriate parties.

### 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 ZN-c5 in combination with their CDK 4/6 inhibitor, abemaciclib, in a planned 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. We and Lilly will each designate a project manager that will meet no less than twice yearly and will be responsible for implementing and coordinating activities, and facilitating the exchange of information, with respect to the study. 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.

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 Percentages"). 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 less than 10%, 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 1

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 continue with respect to each region within the Collaboration Territory and each Collaboration Product until the later of (i) the date on which such Collaboration Product is no longer covered by a licensed patent, and (ii) the 15th anniversary of the first commercial sale of such Collaboration Product in such region. Each Zentera Sublicense will expire on a region-by-region basis at the expiration of the royalty term for the Collaboration Product in such region.

Each Zentera Sublicense may be terminated in its entirety either by Zentera or by us in the event of an uncured material breach by the other party, in the event the other party is subject to bankruptcy, insolvency or similar circumstances, or in the event of a force majeure event under certain circumstances. In addition, Zentera may terminate each Zentera Sublicense upon 180 days' notice to us after the first regulatory approval of the licensed compound in the People's Republic of China, or if the applicable licensed compound does not achieve regulatory approval in the People's Republic of China within the timeframe set forth in the initial regional development plan or as otherwise agreed by the parties. We may terminate each Zentera Sublicense if Zentera fails to meet certain diligence obligations under such Zentera Sublicense.

Upon termination of each Zentera Sublicense for any reason, all rights and licenses granted to Zentera under the agreement will terminate and revert to us. In the event of termination, Zentera would assign to us certain intellectual property related to the applicable Collaboration Products and transfer to Zentera any regulatory filings and data for such Collaboration Products, and, in the event of termination by Zentera for convenience, due to a breach by us, or due to our insolvency, we would pay Zentera royalties at a mid-single digit percentage on net sales in the Zentera Collaboration Territory of any Collaboration Product for which clinical trial data was generated by Zentera until certain of Zentera's development, manufacturing and certain commercialization costs accrued, if any, have been reimbursed.

### **Government Regulation and Product Approval**

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

### **U.S. Drug Development Process**

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

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

 completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;

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

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30- day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

• Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption,

metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

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

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

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

### U.S. Review and Approval Process

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

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

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

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have

continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

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

### **Expedited Development and Review Programs**

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the

FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

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

### **Post-approval Requirements**

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;

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

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

### **Marketing Exclusivity**

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

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA.

However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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

### Other Healthcare Laws

Pharmaceutical and medical device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal antikickback, fraud and abuse, false claims, consumer fraud, pricing reporting, data privacy and security, and transparency laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities or that require the registration of pharmaceutical sales representatives; and state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing 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. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

### Coverage and Reimbursement

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

companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

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

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

### Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. 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, several bills affecting the implementation of certain taxes under the ACA have passed. For example, in 2017, Congress enacted the Tax Act, which eliminated 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. On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. 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.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2030 absent additional congressional action, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020 implemented under the Coronavirus Aid, Relief, and Economic Security Act, which was signed into law on March 27, 2020. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical 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 other 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 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. 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. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

# FDA Approval and Regulation of Companion Diagnostics

If safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has

adequate performance characteristics in the intended population. The review of in vitro companion diagnostics in conjunction with the review of our therapeutic treatments for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

Under the FDCA, in vitro diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval.

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

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

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

# **Employees**

As of June 30, 2020, we had 75 full-time employees, including 29 employees with M.D. or Ph.D. degrees. Of these full-time employees, 55 employees are engaged in research and development activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

# **Facilities**

Our principal executive office is located at 530 Seventh Avenue, Suite 2201, New York, New York, 10018, where we lease approximately 4,800 square feet of office space under a lease that terminates on June 30, 2023. We also occupy approximately 11,100 square feet of office and laboratory space and approximately 2,300 square feet of office and laboratory space, in each case, in San Diego, California, under leases that expire June 21, 2022 and February 28, 2022, respectively. In January 2020, we entered into a lease for approximately 37,000 feet of office and laboratory space in San Diego, California. In July 2020, such lease was terminated in accordance with its terms prior to our occupation of the leased premises. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

# **Legal Proceedings**

We are not subject to any material legal proceedings.

#### MANAGEMENT

### **Executive Officers and Directors**

The following table sets forth the name, age and position of the individuals who serve as our directors and executive officers as of the date of this prospectus. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of our directors and executive officers as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers		
Anthony Y. Sun, M.D.	48	President, Chief Executive Officer and Executive Chairman
Melissa B. Epperly	43	Chief Financial Officer
Kevin D. Bunker, Ph.D.	48	Chief Operating Officer
Dimitris Voliotis, M.D.	57	Senior Vice President, Clinical Development
Non-Employee Directors		
Cam S. Gallagher	51	Director
Kimberly Blackwell, M.D.(1)(3)	51	Director
Karan S. Takhar(1)(2)(3)	29	Director
David M. Johnson(1)(2)(3)	55	Director

- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee.

# **Executive Officers**

Anthony Y. Sun, M.D., has served as our President and Chief Executive Officer and a member of our board of directors since 2014. From 2002 to 2015, Dr. Sun served in a variety of positions, including at Perseus-Soros BioPharmaceutical Fund and most recently as partner at Aisling Capital, a private equity firm dedicated to investing in life sciences companies. Dr. Sun currently serves on the board of directors of Immusoft Corporation, a pre-clinical gene therapy company, and Eyenovia, a public ophthalmic biopharmaceutical company. Dr. Sun received a B.S. in Electrical Engineering from Cornell University, an M.D. from Temple University School of Medicine, an M.B.A from The Wharton School at the University of Pennsylvania. Dr. Sun trained in internal medicine at the Hospital of the University of Pennsylvania and was board certified in Internal Medicine. We believe Dr. Sun's extensive experience in the life sciences industry and extensive understanding of our business, operations and strategy qualify him to serve on our board of directors.

Melissa B. Epperly has served as our Chief Financial Officer since September 2019. From June 2018 to August 2019, Ms. Epperly served as Chief Financial Officer at PsiOxus Therapeutics, a clinical-stage gene therapy cancer company, where she led the company's financial operations. Prior to joining PsiOxus, Ms. Epperly served as Chief Financial Officer and head of Business Development at R-Pharm US, a commercial-stage oncology company, from October 2015 to June 2018, where she led the company's financial operations and business development. From 2012 to 2015, Ms. Epperly served as a Director at Anchorage Capital Group, a credit-focused hedge fund. Previously, Ms. Epperly was a Vice President at Goldman Sachs in equity research in New York and London, a management consultant with Bain & Company, and a healthcare investment banker at Morgan Stanley. Ms. Epperly received an M.B.A. from Harvard Business School and a B.A. in Biochemistry and Economics from the University of Virginia.

Kevin Bunker, Ph.D., has served as our Chief Operating Officer since 2015. Dr. Bunker also currently serves as Chief Scientific/Operations Officer of Kalyra Pharmaceuticals, Inc., or Kalyra, a small-molecule drug discovery and development company, a position he has held since founding the company in 2011. Dr. Bunker also currently serves as a member of the board of directors of Kalyra. Prior to founding Kalyra, from 2006 to 2011, Dr. Bunker was part of the medicinal chemistry department at Pfizer, including as a Senior Scientist, where he made meaningful contributions to Pfizer's drug discovery research group in La Jolla, California. Dr. Bunker received his B.S. in chemistry from Arizona State University and his PhD in organic chemistry from the University of California, San Diego. He also held a post-doctorate position as a research associate at The Scripps Research Institute under the direction of Professor Dale Boger.

**Dimitris Voliotis, M.D.,** has served as our Senior Vice President of Clinical Development since March 2020. Prior to joining us, Dr. Voliotis was Chief Development Officer at CureVac AG, a biopharmaceutical company that develops therapies based on messenger RNA, a position he held beginning in January 2019. At CureVac AG, Dr. Voliotis oversaw preclinical and clinical development activities for prophylactic vaccines, rare diseases/molecular therapies and oncology. From January 2016 to January 2019, Dr. Voliotis served as Senior Vice President and Head of Global Clinical Development in the Oncology Business Group at Eisai US, a pharmaceutical company focused on therapeutic areas of oncology and neurology. At Eisai, Dr. Voliotis had previously served as Vice President, Therapeutic Area Head and Head of Global Clinical Research Oncology from 2014 to 2016. Prior to joining Eisai, Dr. Voliotis served in various leadership positions at Bayer Healthcare from 2001 to 2014, including most recently as Vice President and Head of Global Development Specialty Medicine/Oncology. Dr. Voliotis received his M.D. from the University of Cologne Medical School and is board certified in Medical Oncology & Hematology and Internal Medicine.

### Non-Employee Directors

Cam S. Gallagher has served as a member of our board of directors since December 2014. Mr. Gallagher currently serves as the Chief Business Officer at Immusoft Corporation, a pre-clinical gene therapy company, a position he has held since April 2018. From 2016 to 2019 Mr. Gallagher served as the Head of Corporate Development at Oncternal Therapeutics, Inc., a clinical-stage oncology biotechnology company, and from 2014 to 2016 Mr. Gallagher served as Chief Business Officer at Retrosense Therapeutics, LLC, a gene therapy company. Mr. Gallagher served on the board of directors of Sorrento Therapeutics, Inc., a clinical stage biopharmaceutical company developing therapies to treat malignant cancers, from September 2012 to August 2014, and on the board of directors of Oncternal Therapeutics, Inc., a clinical- stage oncology biotechnology company, from October 2016 to June 2019. Mr. Gallagher received his M.B.A. from the University of San Diego and a B.S. in Business Administration from Ohio University. We believe Mr. Gallagher's extensive experience in the life sciences industry qualifies him to serve on our board of directors.

**Kimberly Blackwell** has served as a member of our board of directors since July 2020. Dr. Blackwell currently serves as the Chief Medical Officer of Tempus Labs, a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare, a position she has held since March 2020. From 2018 to 2020, Dr. Blackwell served as the Vice President of Early Stage Oncology and Immuno-oncology at Eli Lilly, where she led clinical teams advancing early phase therapeutics. From 2000 to 2018, Dr. Blackwell was a professor at Duke University where she oversaw the women's cancer program. Dr. Blackwell received her M.D. from Mayo Clinic Medical School and a B.S. in Bioethics from Duke University. We believe Dr. Blackwell's extensive experience in the life sciences industry qualifies her to serve on our board of directors.

**Karan S. Takhar** has served as a member of our board of directors since December 2017. Since 2013, Mr. Takhar has served in a variety of positions, most recently as Managing Director and head of Life Sciences investing, at Matrix Capital Management Company, L.P., an investment fund focused on technology and life sciences. Mr. Takhar currently serves on the board of Kalyra. Mr. Takhar received a B.S. in Economics and Mathematics from the Massachusetts Institute of Technology. We believe Mr. Takhar's extensive experience in the life sciences industry qualifies him to serve on our board of directors.

**David M. Johnson** has served as a member of our board of directors since January 2020. Mr. Johnson is Chief Executive Officer of VelosBio, a clinical stage, venture backed biopharmaceutical company, a position he has held since co-founding the company in 2017. From 2013 to 2016, Mr. Johnson was with Acerta Pharma, an oncology focused pharmaceutical company, where he rose to Chief Executive Officer leading the company through the required growth to advance acalabrutinib from early to late-stage global clinical development. His tenure at Acerta culminated in the execution of a strategic transaction with AstraZeneca valued at up to \$7 billion. Prior to joining Acerta Pharma, he held various roles with increasing responsibilities within clinical development, medical affairs, pipeline development and commercial at a number of biopharmaceutical and healthcare companies including Calistoga Pharmaceuticals, Gloucester Pharmaceuticals, Millennium Pharmaceuticals, Immunex and Hoffman-La Roche. Mr. Johnson earned his bachelor's degree in economics from Indiana University. We believe Mr. Johnson's extensive experience in the life sciences industry qualifies him to serve on our board of directors.

# **Family Relationships**

There are no family relationships among any of our directors or executive officers.

### **Board Composition and Election of Directors**

Our board of directors currently consists of five members. Prior to the Corporation Conversion in connection with our IPO, our Second Amended and Restated LLC Agreement, or the LLC Agreement, and Second Amended and Restated Voting Agreement, or the Voting Agreement provided for:

- one director designated by Matrix Capital Management Master Fund, L.P., for which Karan Takhar had been designated;
- one director designated by Matrix Capital Management Master Fund, L.P., and reasonably acceptable to holders of at least 70% of the outstanding Series B convertible preferred units, voting as a separate class, for which David Goel, who resigned from our board of directors effective June 26, 2020, had been designated;
- one director designated by the holders of a majority of the outstanding Series C convertible preferred units, for which David Johnson had been designated; and
- two directors designated by the holders of a majority of outstanding Class A common units, for which Cam Gallagher and Anthony Sun had been designated.

Each of the LLC Agreement and Voting Agreement are no longer in effect as of the closing of the IPO, and none of our stockholders have any special rights regarding the election or designation of members of our board of directors. See "Certain Relationships and Related Party Transactions—Voting Agreement." As a result of the Corporate Conversion, our directors will now be elected by the vote of our common stockholders. Under our bylaws, the number of directors will be determined from time to time by our board of directors.

# Director Independence

Our board of directors has determined that, of our five directors, Dr. Blackwell and Messrs. Johnson and Takhar do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of The Nasdaq Stock Market LLC, or the Nasdaq rules. There are no family relationships among any of our directors or executive officers.

# **Classified Board of Directors**

In accordance with our certificate of incorporation and bylaws, our board of directors is divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors

whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- the Class I director is Dr. Blackwell and her term will expire at our first annual meeting of stockholders following this offering;
- the Class II directors are Mr. Takhar and Mr. Gallagher, and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors are Dr. Sun and Mr. Johnson, and their terms will expire at the third annual meeting of stockholders following this offering.

Our certificate of incorporation and bylaws provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

## **Board Leadership Structure**

Our board of directors is currently chaired by our chief executive officer, Anthony Y. Sun, M.D. Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director's responsibilities would include, but would not be not limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

# Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

# **Board Committees**

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a written charter. A copy of each of the audit committee, compensation committee and nominating and corporate governance committee charters is available under the

Corporate Governance section of our website at *www.zentalis.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

# **Audit Committee**

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- · overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code
  of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

The members of our audit committee are Dr. Blackwell and Messrs. Johnson and Takhar. Mr. Johnson serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable Nasdaq rules. Our board of directors has determined that Dr. Blackwell and Messrs. Johnson, and Takhar meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq rules. Our board of directors has determined that each of Dr. Blackwell and Messrs. Johnson and Takhar is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules.

#### **Compensation Committee**

The compensation committee's responsibilities include:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our Chief Executive Officer and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- · reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual compensation committee report required by SEC rules, to the extent required.

The members of our compensation committee are Messrs. Johnson and Takhar. Mr. Takhar serves as the chairperson of the committee. Our board of directors has determined that each of Messrs. Johnson and Takhar is independent under the applicable Nasdaq rules, including the Nasdaq rules specific to membership on the compensation committee, and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

# Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become board members;
- recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- developing and recommending to our board of directors corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time; and
- overseeing a periodic evaluation of our board of directors.

The members of our nominating and corporate governance committee are Dr. Blackwell and Messrs. Johnson and Takhar. Mr. Johnson serves as the chairperson of the committee. Our board of directors has determined that Dr. Blackwell, Mr. Johnson and Mr. Takhar are independent under the applicable Nasdaq rules.

# **Compensation Committee Interlocks and Insider Participation**

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our compensation committee during the last completed fiscal year.

#### **Code of Ethics and Code of Conduct**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our code of business conduct and ethics is available under the Corporate Governance section of our website at <a href="https://www.zentalis.com">www.zentalis.com</a>. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

#### EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below, whom we refer to as our "NEOs."

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

#### **Summary Compensation Table**

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our NEOs for services rendered during the year ended December 31, 2019.

		Salary	Bonus	Stock awards	Option awards	Non-equity incentive plan compensation	All other	
Name and principal position	Year	(\$)	(\$)	(\$)	(\$)(1)	(\$)	(\$)	Total (\$)
Anthony Sun, M.D.	2019	455,091	_		918,000	204,791	_	1,577,882
President and Chief Executive Officer								
Kevin Bunker, Ph.D.	2019	360,024	_	_	275,400	144,010	_	779,434
Chief Operating Officer								
Robert Winkler, M.D	2019	461,725	_	_	_	184,690	_	646,415
Former Chief								
Medical Officer								

<sup>(1)</sup> Represents the grant date fair value of Class B common units issued as "profits interests" in Zentalis Pharmaceuticals, LLC computed in accordance with FASB ASC 718. See Note 8 to the audited consolidated financial statements for the fiscal year ended December 31, 2019 included elsewhere in this prospectus for a description of the assumptions used in valuing our Class B common units. These Class B common units were intended to constitute profits interests for U.S. federal income tax purposes. Despite the fact that the Class B common units do not require the payment of an exercise price, for purposes of this table we believe they are most similar economically to stock options and are properly classified as "options" under the definition provided in Item 402(a)(6)(i) of Regulation S-K as an instrument with an "option-like feature."

#### **Narrative Disclosure to Compensation Tables**

The primary elements of compensation for our NEOs are base salary, annual performance bonuses and equity awards. The NEOs also participate in employee benefit plans and programs that we offer to our other employees, as described below.

# **Annual Base Salary**

We pay our NEOs a base salary to compensate them for the satisfactory performance of services rendered to us. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries for our NEOs have generally been set at levels deemed necessary to attract and retain individuals with superior talent.

Effective January 1, 2019, our board of directors approved a base salary increase for Dr. Bunker from \$300,800 to \$360,024. Upon the closing of Zentalis Pharmaceuticals, LLC's Series C financing in September 2019, Dr. Sun received a base salary increase from \$437,091 to \$455,091, with retroactive effect as of January 1, 2019. Dr. Winkler's base salary was increased from \$460,000 to \$461,725 effective January 1, 2019.

On February 25, 2020, our board of directors determined to increase the base salaries for Dr. Sun and Dr. Bunker to \$550,000 and \$420,000, respectively, subject to the consummation of our IPO, with such increase to have retroactive effect as of January 1, 2020.

# **Bonus Compensation**

From time to time our board of directors or compensation committee may approve bonuses for our NEOs based on individual performance, company performance or as otherwise determined appropriate.

For 2019, annual bonuses were based on such factors as the board and the compensation committee deemed appropriate, including clinical developments and achievements and corporate operational objectives and each individual NEO's performance as it relates to his or her area of responsibility.

Pursuant to their respective employment agreements, each NEO has an established target annual bonus amount. The 2019 target annual bonus amounts for each NEO, expressed as a percentage of his annual base salary, were 45% for Dr. Sun, 40% for Dr. Bunker and 40% for Dr. Winkler.

For 2019, our board of directors determined that Dr. Sun, Dr. Bunker and Dr. Winkler earned annual bonuses equal to 100% of their respective target amounts, resulting in payouts of \$204,791, \$144,010 and \$184,690, respectively. On February 25, 2020, our board of directors approved increases to the target annual bonus amounts for Dr. Sun and Dr. Bunker to 55% and 45% of each NEO's base salary, respectively, with respect to 2020.

#### **Equity-Based Incentive Awards**

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officers. The board of directors is responsible for approving equity grants.

Prior to the IPO, since the formation of Zentalis Pharmaceuticals, LLC, we had granted equity awards in the form of Class B common unit awards pursuant to the Zentalis Pharmaceuticals, LLC Profits Interest Plan, or Profits Interest Plan, and a profits interest award agreement issued thereunder. These Class B common unit awards were intended to qualify as "profits interests" for U.S. federal income tax purposes entitling the holder to participate in our future appreciation from and after the date of grant of the applicable Class B common units. Following our IPO, we grant equity incentive awards under the terms of our 2020 equity incentive plan, or the 2020 Plan. The terms of our equity plans are described below under "—Incentive Award Plans."

On December 3, 2019, we granted awards to Drs. Sun and Bunker of 300,000 and 90,000 Class B common units, respectively.

The Class B common units granted to our NEOs were typically subject to time-based vesting conditions and may be subject to accelerated vesting in certain circumstances, including as described below in the Outstanding Equity Awards Table and the sections titled "—Profits Interest Plan and Class B Common Unit Agreements" and "—Termination or Change in Control Benefits."

# **Employment Agreements with our NEOs**

Below are written descriptions of our employment agreements with each of our NEOs. Each of our NEOs' employment is "at will" and may be terminated at any time.

#### **Employment Agreement with Dr. Sun**

Effective February 1, 2018, Zeno Management, Inc., or Zeno Management, entered into an employment agreement with Dr. Sun setting forth the terms of his employment as our Chief Executive Officer. We amended

and restated the employment agreement with Dr. Sun effective February 1, 2019. Pursuant to his amended and restated employment agreement, Dr. Sun was entitled to an annual base salary of \$437,091, which annual base salary rate automatically increased to \$455,091 upon the consummation of Zentalis Pharmaceuticals, LLC's series C financing in September 2019. Such increase was effective as of January 1, 2019 and Dr. Sun received a lump sum cash payment in the amount of the incremental base salary that would have been paid to him as if such increased rate had actually been in effect since January 1, 2019. On February 25, 2020, Dr. Sun's employment agreement was amended to provide for a base salary of \$550,000, subject to the consummation of our IPO, with such increase to have retroactive effect as of January 1, 2020. Dr. Sun's base salary is subject to annual review by and at the sole discretion of our board of directors or its designee.

Dr. Sun's employment agreement provides that he may be eligible to earn an annual performance-based bonus with a target amount equal to 45% of his annual base salary (which target bonus was increased to 55% for 2020 pursuant to the February 25, 2020 amendment to his employment agreement).

Pursuant to his employment agreement, if we terminate Dr. Sun's employment other than for cause (as defined below) or Dr. Sun terminates his employment for good reason (as defined below), he is entitled to the following payments and benefits, subject to his timely execution and non-revocation of a general release of claims in favor of the company and his continued compliance with the restrictive covenants set forth in his employment agreement: (1) his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled; (2) a payment equal to 12 months of his then-current base salary, payable in a lump sum payment 60 days following the termination date; (3) a payment equal to his prorated target annual bonus for the year in which the termination date occurs, payable in a lump sum payment 60 days following the termination date (provided that if such termination occurs within 12 months after a change in control (as defined in our 2020 Plan), such target annual bonus will not be subject to proration); and (4) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the expiration of 12 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment.

In the event we terminate Dr. Sun's employment for cause, he terminates his employment without good reason, or upon his death or permanent disability, he is entitled to receive only his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled.

#### **Employment Agreement with Dr. Bunker**

Effective February 1, 2019, Zeno Management entered into an employment agreement with Dr. Bunker setting forth the terms of his employment as our Chief Operations Officer. Pursuant to the agreement, Dr. Bunker is entitled to an annual base salary of \$360,024, which amount is subject to annual review by and at the sole discretion of our board of directors or its designee. On February 25, 2020, Dr. Bunker's employment agreement was amended to provide for a base salary of \$420,000, subject to the consummation of our IPO, with such increase to have retroactive effect as of January 1, 2020.

Dr. Bunker's employment agreement provides that he may be eligible to earn an annual performance-based bonus with a target amount equal to 40% of his annual base salary (which target bonus was increased to 45% for 2020 pursuant to the February 25, 2020 amendment to his employment agreement).

Pursuant to his employment agreement, if we terminate Dr. Bunker's employment other than for cause (as defined below) or Dr. Bunker terminates his employment for good reason (as defined below), he is entitled to the following payments and benefits, subject to his timely execution and non-revocation of a general release of claims in favor of the company and his continued compliance with the restrictive covenants set forth in his employment agreement: (1) his fully earned but unpaid base salary and accrued and unused paid time off through

the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled; (2) a payment equal to 12 months of his then-current base salary, payable in a lump sum payment 60 days following the termination date; (3) a payment equal to his prorated target annual bonus for the year in which the termination date occurs, payable in a lump sum payment 60 days following the termination date (provided that if such termination occurs within 12 months after a change in control, such target annual bonus will not be subject to proration); and (4) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the expiration of 12 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment.

In the event we terminate Dr. Bunker's employment for cause, he terminates his employment without good reason, or upon his death or permanent disability, he is entitled to receive only his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled.

# Employment Agreement with Dr. Winkler

On February 1, 2019, Zeno Management entered into an employment agreement with Dr. Winkler setting forth the terms of his employment as our Chief Medical Officer. Pursuant to the agreement, Dr. Winkler is entitled to an annual base salary of \$461,725, which amount is subject to annual review by and at the sole discretion of our board of directors or its designee.

Dr. Winkler's employment agreement provides that he may be eligible to earn an annual performance-based bonus with a target amount equal to 40% of his annual base salary.

Pursuant to his employment agreement, if we terminate Dr. Winkler's employment other than for cause (as defined below) or Dr. Winkler terminates his employment for good reason (as defined below), he is entitled to the following payments and benefits, subject to his timely execution and non-revocation of a general release of claims in favor of the company and his continued compliance with the restrictive covenants set forth in his employment agreement: (1) his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled; (2) a payment equal to 9 months of his then-current base salary, payable in a lump sum payment 60 days following the termination date; and (3) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the expiration of 9 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment.

In the event we terminate Dr. Winkler's employment for cause, he terminates his employment without good reason, or upon his death or permanent disability, he is entitled to receive only his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled.

Effective March 19, 2020, Dr. Winkler's employment terminated and he ceased serving as our Chief Medical Officer. In connection with Dr. Winkler's termination of employment, we entered into a separation agreement with Dr. Winkler whereby he received (1) his fully earned but unpaid base salary and accrued and unused paid time off through the date of termination at the rate then in effect, plus all other amounts under any compensation plan or practice to which he is entitled; (2) a payment equal to 12 months of his then-current base salary, payable in a lump sum payment 60 days following the termination date; and (3) payment of the COBRA premiums for him and his eligible dependents until the earliest of (a) the expiration of 12 months following his termination date, (b) expiration of his eligibility for continuation coverage under COBRA, or (c) the date he becomes eligible for health insurance coverage in connection with his new employment, subject to his timely execution and non-revocation of a general release of claims in favor of the company and his continued compliance with the restrictive covenants set forth in his employment agreement.

#### Defined Terms Applicable To NEO Employment Agreements

For purposes of the employment agreements with Drs. Sun, Bunker and Winkler, "cause" means any of the following: (1) the unauthorized use or disclosure of confidential information or trade secrets of the company or its affiliates or any material breach of a written agreement between the executive and the company or any affiliate, including without limitation a material breach of any employment, confidentiality, non-compete, non-solicit or similar agreement; (2) the commission of, indictment for or the entry of a please of guilty or nolo contendere to a felony under the laws of the United States or any state thereof or any crime involving dishonesty or moral turpitude (or any similar crime in any jurisdiction outside the United States); (3) gross negligence or willful misconduct or willful or repeated failure or refusal to substantially perform assigned duties; (4) any act of fraud, embezzlement, material misappropriation or dishonesty committed by the executive against the company or its affiliates; or (5) any acts, omissions or statements which the company reasonably determines to be materially detrimental or damaging to the reputation, operations, prospects or business relations of the company or its affiliates.

For purposes of the employment agreements with Drs. Sun, Bunker and Winkler, "good reason" means the occurrence of any of the following without the executive's written consent: (1) a change in position or responsibilities that represents a substantial reduction in position or responsibilities as in effect immediately prior thereto; the assignment of any duties or responsibilities that are materially inconsistent with such position or responsibilities; or any removal from or failure to reappoint or reelect the executive to any of such positions, including, for Dr. Sun, his position as a member of our board of directors or the board of directors of Zeno Management, except in connection with the termination of the executive's services for cause, as a result of his permanent disability (as defined in the applicable employment agreement) or death, or by the executive other than for good reason; provided, however, that neither a change in reporting relationship as a result of a change in control nor the fact that his reporting relationship is altered following a change in control because the company or its successor is a wholly-owned subsidiary of another entity following such change in control shall alone constitute good reason; (2) a material reduction in annual base salary; (3) the requirement that the executive be based at any place outside a ten (10)-mile radius of his then-current place of employment with the company prior to any such relocation, except for reasonably required travel on the company business; or (4) any material breach by the company or any affiliate of its obligations to him under any applicable employment or services agreement between the executive and the company or such affiliate.

#### Restrictive Covenant Obligations

Pursuant to their employment agreements, each of our NEOs is subject to one-year post-termination non-solicitation of employees and consultants covenants and a perpetual non-disparagement covenant, in addition to his obligations under the Company's standard proprietary information and inventions assignment agreement.

#### **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information with respect to outstanding Class B common unit awards for each of our NEOs as of December 31, 2019. For the Class B common units, the table reflects both vested and unvested units. Class B common units are subject to time-based vesting and to an additional requirement that a minimum valuation threshold be met before the holder of the Class B common units is entitled to a distribution in respect of such award.

In connection with the Corporate Conversion, outstanding Class B common units of our NEOs were converted into shares of common stock. The number of shares of common stock issued to each such NEO in respect of his or her Class B common units was determined as described above under "Corporate Conversion" and below under "Profits Interest Plan and Class B Common Unit Agreements; Effect of the Corporate Conversion and our IPO on Class B Common Units Held by our Employees and Service Providers." The vesting

provisions applicable to the Class B common units prior to the Corporate Conversion continue to apply in substantially the same manner, to the common stock issued in respect of such Class B common units in the Corporate Conversion.

			Option awards		
	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Anthony Sun, M.D.	02/13/18	103,125(2)	121,875	(1)	
	12/03/19	(2)	300,000	(1)	_
Kevin Bunker, Ph.D.	12/21/17	212,500(3)	_	(1)	_
	03/01/18	41,250(2)	48,750	(1)	_
	12/03/19	(2)	90,000	(1)	_
Robert Winkler, M.D.	12/04/18	52,212(2)	140,572	(1)	_

- (1) These Class B common units were issued as "profits interests" for U.S. federal income tax purposes and did not require the payment of an exercise price, but rather entitled the holder to participate in our future appreciation from and after the date of grant of the applicable Class B common units. Despite this, for purposes of this table we believe they are most similar economically to stock options and are properly classified as "options" under the definition provided in Item 402(a)(6)(i) of Regulation S-K as an instrument with an "option-like feature." Each Class B common unit was granted with a threshold value applicable to such Class B common unit. The threshold amount represented the cumulative distributions that were required to have been made by us pursuant to the Zentalis Pharmaceuticals, LLC limited liability company agreement before a grantee would have been entitled to receive any distributions or payments in respect of such grantee's Class B common units. The threshold amount for Dr. Bunker's grant of Class B common units granted on December 21, 2017 was \$134,000,027, the threshold for Drs. Sun and Bunker's grants of Class B common units granted on December 4, 2018 was \$143,800,075; and the threshold amount for Drs. Sun and Bunker's grants of Class B common units granted on December 3, 2019 was \$309,824,355.
- (2) The awards vest as to 25% of such grant on the one year anniversary of the vesting commencement date (February 13, 2018 for Dr. Sun's February 13, 2018 grant and Dr. Bunker's March 1, 2018 grant, November 19, 2018 for Dr. Winkler's grant and September 6, 2019 for Drs. Sun and Bunker's December 3, 2019 grants) and monthly thereafter in equal installments until fully vested at the fourth anniversary of the vesting commencement date, subject to accelerated vesting in certain circumstances as described below under "—Profits Interest Plan and Class B Common Unit Agreements" as well as the executive's continued employment or service through the applicable vesting dates. Dr. Winkler's unvested Class B common units were forfeited upon his termination of employment on March 19, 2020.
- (3) The award was vested as to 85% of such grant on the grant date, with the remainder of the award scheduled to vest monthly in equal installments until fully vested as of the fourth anniversary of April 9, 2015. Such award was fully vested as of December 31, 2019.

### Other Elements of Compensation

# Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on generally the same basis as all of our other employees. We provide a 401(k) plan to our employees, including our current named executive officers, as discussed in the section below titled "—401(k) plan."

We do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

# 401(k) plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The 401(k) plan provides that each participant may make pre-tax deferrals from his or her compensation up to the statutory limit, which is \$19,500 for calendar year 2020, and other testing limits. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2020 may be up to an additional \$6,500 above the statutory limit. Although the 401(k) plan provides for discretionary matching and profit sharing contributions, we currently do not make either type of contribution to the 401(k) plan. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

#### **Nonqualified Deferred Compensation**

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

# Termination or Change in Control Benefits

Our executive officers may become entitled to certain benefits or enhanced benefits in connection with a change in control of our company. Each of our executive officers' employment agreements entitles them to certain benefits, upon a qualifying termination and in connection with a change in control of our company. In addition, the award agreements evidencing the common stock issued upon conversion of the Class B common units in the Corporate Conversion, stock options and restricted stock unit awards granted in connection with the IPO, provide for accelerated vesting under certain circumstances. For additional discussion, please see "—Employment Agreements with our NEOs" above and "—Profits Interest Plan and Class B Common Unit Agreements" and "—IPO-Related Equity Awards" below.

# Profits Interest Plan and Class B Common Unit Agreements; Effect of the Corporate Conversion and our IPO on Class B Common Units Held by our Employees and Service Providers

Prior to our IPO, we granted awards of Class B common units pursuant to the Profits Interest Plan, subject to the terms of the LLC Agreement. These Class B common unit awards were intended to constitute profits interests for U.S. federal income tax purposes to our employees (including our NEOs), non-employee consultants and non-employee directors and those of our affiliates. Under the Profits Interest Plan, our board of directors (or its designee) was delegated the authority to administer the Profits Interest Plan in order to enhance our ability to attract and retain individuals of exceptional talent to contribute to the sustained progress, growth and profitability of our company and our affiliates.

In addition to the discretion to grant Class B common units under the Profits Interest Plan, our board of directors set the vesting terms for awards pursuant to a Class B common unit award agreement. Each award of Class B common units was issued with an applicable minimum valuation threshold, or threshold amount, that must be achieved before the interest was entitled to receive any distributions under the LLC Agreement.

As of December 31, 2019, there were 2,670,668 issued and outstanding Class B common units, of which 1,008,479 were vested.

In connection with our IPO, the Class B common units were converted into shares of our common stock pursuant to the Corporate Conversion. All outstanding unvested Class B common units, including those held by our NEOs, were converted into unvested shares of our restricted common stock on the basis of an exchange ratio that took into account the number of Class B common units held, the applicable threshold value applicable to such Class B common units and the value of the distributions that the holder would have been entitled to receive had Zentalis Pharmaceuticals, LLC been liquidated on the date of such conversion in accordance with the terms of the distribution "waterfall" set forth in the LLC Agreement. Vested Class B common units were similarly converted into shares of our common stock based on the same considerations. The unvested restricted shares of our common stock the NEOs received upon conversion of unvested Class B common units will continue to vest in accordance with the same vesting schedule applicable to the Class B common units and are collectively referred to herein as the "Conversion Restricted Stock Awards." The Conversion Restricted Stock Awards are evidenced by individual restricted stock agreements and were not issued under the 2020 Plan.

The number of shares of vested and unvested common stock issued upon conversion of the Class B common units pursuant to the Corporate Conversion to each of our NEOs and our current executive officers based on the vested and unvested awards as of April 2, 2020, was as follows: Dr. Sun, 119,749 vested shares of common stock, and 305,372 restricted shares; Dr. Bunker, 342,774 vested shares of common stock and 102,630 restricted shares; Ms. Epperly, no vested shares of common stock, and 130,135 restricted shares; Dr. Winkler, 61,663 vested shares of common stock, and no restricted shares. Dr. Voliotis did not hold any Class B common units.

Dr. Sun's unvested restricted shares will vest as follows: 110,171 of the restricted shares were issued to him in respect of the conversion of his Class B common unit award granted on February 13, 2018, which was scheduled to vest over four years commencing on such date, with 25% vesting on February 13, 2019 and the remainder vesting in equal monthly installments over the three years thereafter, which restricted shares will be fully vested on February 13, 2022; and 195,201 of the restricted shares were issued to him in respect of the conversion of his Class B common unit award granted on December 3, 2019, which was scheduled to vest as to 25% of such award on September 6, 2020, and the remainder vesting in equal monthly installments over the three years thereafter, which restricted shares will be fully vested on September 6, 2023. The restricted shares are subject to accelerated vesting in the event of Dr. Sun's termination by us without cause following a change in control.

Dr. Bunker's unvested restricted shares will vest as follows: 44,069 of the restricted shares were issued to him in respect of the conversion of his Class B common unit award granted on March 1, 2018, which was scheduled to vest over four years commencing on such date, with 25% vesting on February 13, 2019 and the remainder vesting in equal monthly installments over the three years thereafter, which restricted shares will be fully vested on February 13, 2022; and 58,561 of the restricted shares were issued to him in respect of the conversion of his Class B common unit award granted on December 3, 2019, which was scheduled to vest as to 25% of such award on September 6, 2020, and the remainder vesting in equal monthly installments over the three years thereafter, which restricted shares will be fully vested on September 6, 2023. The restricted shares are subject to accelerated vesting in the event of Dr. Bunker's termination by us without cause following a change in control.

The restricted shares were issued to Ms. Epperly in respect of the conversion of her Class B common unit award granted on September 10, 2019, which was scheduled to vest over a period of four years commencing on September 5, 2019, with 25% of such restricted shares vesting on September 5, 2020, and the remainder vesting in equal monthly installments over the three years thereafter, which restricted shares will be fully vested on September 5, 2023. The restricted shares are subject to accelerated vesting in the event of Ms. Epperly's termination by us without cause following a change in control.

For more information about the treatment of the Class B common units in the Corporate Conversion, see the section titled "Corporate Conversion". The Profits Interest Plan terminated effective upon the Corporate Conversion.

# **IPO-Related Equity Grants**

# Restricted Stock Unit Awards

In connection with the Corporate Conversion, including the conversion of vested and unvested Class B common units into vested and unvested shares of our common stock, respectively, our board of directors approved the issuance of restricted stock units to each holder of our Class B common units that remained employed by or providing services to us on the date of the Corporate Conversion, including our executive officers and non-employee directors (the "Eligible RSU Recipients"). Each Eligible RSU recipient received a number of restricted stock units equal to the difference between the number of Class B common units held by them immediately prior to the Corporate Conversion and the resulting number of shares of common stock that was issued to them in connection with the Corporate Conversion. The restricted stock units were granted effective on April 7, 2020. The restricted stock units were granted under the 2020 Plan, and each restricted stock represents the right to receive, upon vesting, one share of our common stock.

The restricted stock units granted to the Eligible RSU Recipients vest based on one of two vesting schedules, depending on the remaining vesting schedules of the Class B common units held by the individual at the time of the Corporate Conversion. For those individuals who held any unvested Class B common units granted prior to June 2018, the restricted stock units granted to such individuals vest as follows: 50% of the restricted stock units shall vest on the date that is 8 months following the date the effectiveness of the registration statement of which this prospectus forms a part (the date of such effectiveness, the "RSU Vesting Start Date"), or December 2, 2020, 25% of the restricted stock units shall vest on the date that is 12 months following the RSU Vesting Start Date, or April 2, 2021, and 25% of the restricted stock unit shall vest on the date that is 15 months following the RSU Vesting Start Date, or July 2, 2021, subject to the individual's continued employment or service through the applicable vesting dates (the "First RSU Vesting Schedule").

For those restricted stock units held by all other individuals, the restricted stock units shall vest as follows: 25% of the restricted stock units shall vest on the date that is 8 months following the RSU Vesting Start Date, or December 2, 2020, 25% of the restricted stock units shall vest on the date that is 12 months following the RSU Vesting Start Date, or April 2, 2021, and 25% of the restricted stock unit shall vest on the date that is 18 months following the RSU Vesting Start Date, or October 2, 2021, and 25% of the restricted stock unit shall vest on the date that is 24 months following the RSU Vesting Start Date, or April 2, 2022, subject to the individual's continued employment or service through the applicable vesting dates (the "Second RSU Vesting Schedule"). All of the restricted stock units are subject to accelerated vesting upon a termination of the individual by the Company without "cause", resignation for "good reason", or upon a termination due to death or "disability", each as defined in the 2020 Plan, subject to the individual's continued employment or service through the applicable vesting dates.

Our executive officers received the following restricted stock unit awards in connection with our IPO: Dr. Sun, 303,392; Dr. Bunker, 99,246; and Ms. Epperly, 147,394. Neither Dr. Winkler nor Dr. Voliotis received any restricted stock units. The restricted stock units granted to Drs. Sun and Bunker vest in accordance with the First RSU Vesting Schedule and the restricted stock units granted to Ms. Epperly vest in accordance with the Second RSU Vesting Schedule.

# Stock Option Awards

Our board of directors approved grants of stock options pursuant to the 2020 Plan to certain of our employees and service providers, including our executive officers, in connection with our IPO, which became effective as of immediately following the determination of the initial public offering price per share of our common stock in our IPO as follows: Dr. Sun, options to purchase 500,000 shares of common stock; Dr. Bunker, options to purchase 250,000 shares of common stock; Ms. Epperly, options to purchase 100,000 shares of common stock; and Dr. Voliotis, options to purchase 154,949 shares of common stock. The options being granted to Dr. Voliotis are in connection with his commencement of employment with us. An aggregate of

options to purchase 1,970,671 shares of common stock were granted to all employees and service providers in connection with our IPO, including the executive options listed above and the options to be granted to our non-employee directors (including Mr. Gallagher) described below under "—Director Compensation." These stock options have an exercise price per share equal to \$18.00, which is the initial public offering price per share of our common stock. Other than the options granted to our non-employee directors described below, the stock options will vest as to 25% of the shares underlying the option on the one-year anniversary of the grant date and monthly thereafter in equal installments until fully vested at the fourth anniversary of the grant date, subject to the recipient's continued service through the applicable vesting dates. The stock options are subject to accelerated vesting upon the holder's involuntary termination following a change in control.

#### **Incentive Award Plans**

#### 2020 Incentive Award Plan

In connection with our IPO, our board and stockholders approved the 2020 Plan. Under the 2020 Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2020 Plan are summarized below.

#### **Eligibility and Administration**

Our employees, consultants and directors, and employees and consultants of our subsidiaries, are eligible to receive awards under the 2020 Plan. The 2020 Plan is generally administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2020 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2020 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2020 Plan, including any vesting and vesting acceleration conditions.

#### Limitation on Awards and Shares Available

An aggregate of 5,600,000 shares of our common stock are initially available for issuance under awards granted pursuant to the 2020 Plan, plus any shares subject to the Conversion Restricted Stock Awards that are forfeited or repurchased by us following the effectiveness of the 2020 Plan (provided that no more than 1,250,000 shares may become available for issuance under the 2020 Plan upon the forfeiture or repurchase of Conversion Restricted Stock Awards). The number of shares initially available for issuance will be increased by an annual increase on January 1 of each calendar year beginning in 2021 and ending in 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. No more than 60,000,000 shares of common stock may be issued upon the exercise of incentive stock options, or ISOs, under the 2020 Plan. Shares issued under the 2020 Plan may be authorized but unissued shares, shares purchased in the open market or treasury shares.

If an award under the 2020 Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, or any shares subject to a Conversion Restricted Stock Award are forfeited or repurchased by us following the effectiveness of the 2020 Plan, shares subject to such award or Conversion Restricted Stock Award will, as applicable, become or again be available for new grants under the 2020 Plan. Awards granted under the 2020 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2020 Plan.

#### Awards

The 2020 Plan provides for the grant of stock options, including ISOs, and nonqualified stock options, or NSOs, restricted stock, dividend equivalents, restricted stock units, or RSUs, stock appreciation rights, or SARs, and other stock or cash-based awards. Certain awards under the 2020 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Internal Revenue Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2020 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

Stock options. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Internal Revenue Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.

SARs. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

Restricted stock and RSUs. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

Other stock or cash-based awards. Other stock or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

# Performance Awards

Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include: net earnings or losses (either before or after one or more of

interest, taxes, depreciation, amortization and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to our performance or the performance of a subsidiary, division, bu

# Provisions of the 2020 Plan Relating to Director Compensation

The 2020 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2020 Plan's limitations. In connection with our IPO, our stockholders approved the initial terms of our non-employee director compensation program, which is described below under the heading "—Director compensation." Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that, commencing with 2021, the sum of any cash compensation or other compensation and the grant date fair value (as determined in accordance with ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a non-employee director during any calendar year may not exceed \$750,000, increased to \$1,000,000, in the fiscal year of a non-employee director's initial service as a non-employee director (which limits will not apply to any non-employee director that serves in any additional capacity with the company for which he or she receives compensation or any compensation paid to any non-employee director during 2020). The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion.

#### **Certain Transactions**

In connection with certain transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2020 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant's rights under the vested portion of such award, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property or terminating awards under the 2020 Plan. In the event of a change in control where the acquirer does not assume awards granted under the 2020 Plan, awards issued under the 2020 Plan shall be subject to accelerated vesting such that 100% of the awards will become vested and

exercisable or payable, as applicable. In addition, in the event of certain non-reciprocal transactions with our stockholders, or an "equity restructuring," the plan administrator will make equitable adjustments to the 2020 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

#### Foreign Participants, Claw-back Provisions, Transferability and Participant Payments

With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/ or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2020 Plan are generally non-transferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2020 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2020 Plan, the plan administrator may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable or any combination of the foregoing.

#### Plan Amendment and Termination

Our board of directors may amend or terminate the 2020 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2020 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its price per share. No award may be granted pursuant to the 2020 Plan after the tenth anniversary of the date on which our board of directors adopted the 2020 Plan.

#### Securities Laws

The 2020 Plan is intended to conform to all provisions of the Securities Act, and the Exchange Act and any and all regulations and rules promulgated by the SEC thereunder, including, without limitation, Rule 16b-3. The 2020 Plan will be administered, and awards will be granted and may be exercised, only in such a manner as to conform to such laws, rules and regulations.

#### Federal Income Tax Consequences

The material federal income tax consequences of the 2020 Plan under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the 2020 Plan. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

Stock options and SARs. A 2020 Plan participant generally will not recognize taxable income and we generally will not be entitled to a tax deduction upon the grant of a stock option or SAR. The tax consequences of exercising a stock option and the subsequent disposition of the shares received upon exercise will depend upon whether the option qualifies as an ISO or an NSO. Upon exercising an NSO when the fair market value of our stock is higher than the exercise price of the option, a 2020 Plan participant generally will recognize taxable income at ordinary income tax rates equal to the excess of the fair market value of the stock on the date of exercise over the purchase price, and we (or our subsidiaries, if any) generally will be entitled to a corresponding tax deduction for compensation expense, in the amount equal to the amount by which the fair market value of the shares purchased exceeds the purchase price for the shares. Upon a subsequent sale or other disposition of the option shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

Upon exercising an ISO, a 2020 Plan participant generally will not recognize taxable income, and we will not be entitled to a tax deduction for compensation expense. However, upon exercise, the amount by which the fair market value of the shares purchased exceeds the purchase price will be an item of adjustment for alternative minimum tax purposes. The participant will recognize taxable income upon a sale or other taxable disposition of the option shares. For federal income tax purposes, dispositions are divided into two categories: qualifying and disqualifying. A qualifying disposition generally occurs if the sale or other disposition is made more than two years after the date the option was granted and more than one year after the date the shares are transferred upon exercise. If the sale or disposition occurs before these two periods are satisfied, then a disqualifying disposition generally will result.

Upon a qualifying disposition of ISO shares, the participant will recognize long-term capital gain in an amount equal to the excess of the amount realized upon the sale or other disposition of the shares over their purchase price. If there is a disqualifying disposition of the shares, then the excess of the fair market value of the shares on the exercise date (or, if less, the price at which the shares are sold) over their purchase price will be taxable as ordinary income to the participant. If there is a disqualifying disposition in the same year of exercise, it eliminates the item of adjustment for alternative minimum tax purposes. Any additional gain or loss recognized upon the disposition will be recognized as a capital gain or loss by the participant.

We will not be entitled to any tax deduction if the participant makes a qualifying disposition of ISO shares. If the participant makes a disqualifying disposition of the shares, we should be entitled to a tax deduction for compensation expense in the amount of the ordinary income recognized by the participant.

Upon exercising or settling an SAR, a 2020 Plan participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid or value of the shares issued upon exercise or settlement. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

Restricted stock and RSUs. A 2020 Plan participant generally will not recognize taxable income at ordinary income tax rates and we generally will not be entitled to a tax deduction upon the grant of restricted stock or RSUs. Upon the termination of restrictions on restricted stock or the payment of RSUs, the participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid to the participant or the amount by which the then fair market value of the shares received by the participant exceeds the amount, if any, paid for them. Upon the subsequent disposition of any shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares. However, a 2020 Plan participant granted restricted stock that is subject to forfeiture or repurchase through a vesting schedule such that it is subject to a "risk of forfeiture" (as defined in Section 83 of the Code) may make an election under Section 83(b) of the Code to recognize taxable income at ordinary income tax rates, at the time of the grant, in an amount equal to the fair market value of the shares of common stock on the date of grant, less the amount paid, if any, for such shares. We will be entitled to a corresponding tax deduction for compensation, in the amount recognized as taxable income by the participant. If a timely Section 83(b) election is made, the participant will not recognize any additional ordinary income on the termination of restrictions on restricted stock, and we will not be entitled to any additional tax deduction.

Other stock or cash-based awards. A 2020 Plan participant will not recognize taxable income and we will not be entitled to a tax deduction upon the grant of other stock or cash-based awards until cash or shares are paid or distributed to the participant. At that time, any cash payments or the fair market value of shares that the participant receives will be taxable to the participant at ordinary income tax rates and we should be entitled to a corresponding tax deduction for compensation expense. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares, the participant

will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant's tax basis in the shares.

# 2020 Employee Stock Purchase Plan

In connection with our IPO, we adopted the ESPP, which became effective in connection with our IPO. The material terms of the ESPP are summarized below. Offering periods under the ESPP will commence when determined by the plan administrator.

Shares available; administration. A total of 450,000 shares of our common stock are initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2021 and ending in 2030, by an amount equal to the least of: (a) 1% of the shares outstanding on the final day of the immediately preceding calendar year, (b) 1,500,000 shares and (c) such smaller number of shares as is determined by our board of directors. In no event will more than 15,450,000 shares of our common stock be available for issuance under the ESPP.

Our board of directors or its committee will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP.

*Eligibility.* Our employees are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under our ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

*Grant of rights.* The ESPP is intended to qualify under Section 423 of the Internal Revenue Code and stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during each offering period will be established by the plan administrator prior to the commencement of each offering period. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation, which includes a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period, which, in the absence of a contrary designation, will be 100,000 shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period. Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such shorter or longer period specified by the plan administrator), and will be paid their

accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided under the ESPP.

Certain Transactions. In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the 2020 Plan.

Plan amendment; Termination. The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP will be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. The ESPP will continue until terminated by our board.

Securities Laws. The ESPP has been designed to comply with various securities laws in the same manner as described above in the description of the 2020 Plan.

Federal Income Taxes. The material federal income tax consequences of the ESPP under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the ESPP. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

The ESPP, and the right of participants to make purchases thereunder, is intended to qualify under the provisions of Section 423 of the Code. Under the applicable Code provisions, no income will be taxable to a participant until the sale or other disposition of the shares purchased under the ESPP. This means that an eligible employee will not recognize taxable income on the date the employee is granted an option under the ESPP (i.e., the first day of the offering period). In addition, the employee will not recognize taxable income upon the purchase of shares. Upon such sale or disposition, the participant will generally be subject to tax in an amount that depends upon the length of time such shares are held by the participant prior to disposing of them. If the shares are sold or disposed of more than two years from the first day of the offering period during which the shares were purchased and more than one year from the date of purchase, or if the participant dies while holding the shares, the participant (or his or her estate) will recognize ordinary income measured as the lesser of: (1) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price; or (2) an amount equal to 15% of the fair market value of the shares as of the first day of the offering period. Any additional gain will be treated as long-term capital gain. If the shares are held for the holding periods described above but are sold for a price that is less than the purchase price, there is no ordinary income and the participating employee has a long-term capital loss for the difference between the sale price and the purchase price.

If the shares are sold or otherwise disposed of before the expiration of the holding periods described above, the participant will recognize ordinary income generally measured as the excess of the fair market value of the shares on the date the shares are purchased over the purchase price and we will be entitled to a tax deduction for compensation expense in the amount of ordinary income recognized by the employee. Any additional gain or loss on such sale or disposition will be long-term or short-term capital gain or loss, depending on how long the shares were held following the date they were purchased by the participant prior to disposing of them. If the shares are sold or otherwise disposed of before the expiration of the holding periods described above but are sold for a price that is less than the purchase price, the participant will recognize ordinary income equal to the excess of the fair market value of the shares on the date of purchase over the purchase price (and we will be entitled to a corresponding deduction), but the participant generally will be able to report a capital loss equal to the difference between the sales price of the shares and the fair market value of the shares on the date of purchase.

# **Director Compensation**

#### **Director Compensation Table**

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our non-employee directors for services rendered during the year ended December 31, 2019.

Name and principal postion	Option awards (\$)(1)(2)	Non-equity incentive plan compensation (\$)	All other compensation (\$)(3)	Total (\$)
Cam S. Gallagher	\$183,600	81,580	144,464	409,644
David E. Goel <sup>(4)</sup>	_	_	_	_
Karan S. Takhar	_	_	_	
David M. Johnson	<del></del>	_	_	_

- (1) Represents the grant date fair value of Class B common units issued as "profits interests" in Zentalis Pharmaceuticals, LLC computed in accordance with FASB ASC 718. See Note 8 to the audited consolidated financial statements for the fiscal year ended December 31, 2019 included elsewhere in this prospectus for a description of the assumptions used in valuing our Class B common units. These Class B common units were intended to constitute profits interests for U.S. federal income tax purposes. Despite the fact that the Class B common units did not require the payment of an exercise price, for purposes of this table we believe they are most similar economically to stock options and are properly classified as "options" under the definition provided in Item 402(a)(6)(i) of Regulation S-K as an instrument with an "option-like feature."
- (2) As of December 31, 2019, Mr. Gallagher held 140,000 outstanding Class B common units, of which 103,333 were unvested. None of our other non-employee directors held any unvested equity awards as of December 31, 2019.
- (3) Represents consulting fees paid by us to Mr. Gallagher with respect to 2019.
- (4) Mr. Goel resigned from our board of directors effective June 26, 2020.

# **Gallagher Consulting Agreement**

Effective February 25, 2020, Zeno Management entered into an amended consulting agreement with Mr. Gallagher setting forth the terms of his engagement as our Executive Director. Pursuant to the agreement, Mr. Gallagher is entitled to an annual retainer of \$203,950, which amount is subject to annual review by and at the sole discretion of our board of directors or its designee. Subject to the consummation of our IPO, Mr. Gallagher's cash retainer will increase to \$25,000 per month, with such increase to have retroactive effect as of January 1, 2020.

Mr. Gallagher's consulting agreement provides that he may be eligible to earn an annual performance-based bonus with a target amount equal to 40% of his annual retainer.

Pursuant to his consulting agreement, either party must give 12 months' prior written notice for termination of the agreement. Mr. Gallagher will be required to continue to provide services as required under the agreement, and will continue to receive his compensation thereunder, during any such notice period.

In the event we terminate Mr. Gallagher's service for cause, or upon his death or permanent disability, he is entitled to receive only his fully earned but unpaid retainer, plus all other amounts under any compensation plan or practice to which he is entitled.

Pursuant to his consulting agreement, Mr. Gallagher is subject to a non-competition covenant during the term of his service with the Company, as well as one-year post-termination non-solicitation of employees and consultants covenants and a perpetual non-disparagement covenant, in addition to his obligations under the company's standard proprietary information and inventions assignment agreement.

For purposes of Mr. Gallagher's consulting agreement, "cause" generally has the same meaning as set forth in the NEOs' employment agreements and as described above.

#### Non-Employee Director Compensation Program and Initial Awards in Connection with our IPO

During 2019, none of our non-employee directors received any cash or equity compensation other than Mr. Gallagher, who serves as a consultant to the company. Dr. Sun, who also serves as both executive officer and director, did not receive any additional compensation for his service on our board of directors.

In connection with our IPO, we implemented our non-employee director compensation program, the material terms of which are summarized below.

The non-employee director compensation program provides for annual retainer fees and/or long-term equity awards for our non-employee directors. Each non-employee director will receive an annual retainer of \$40,000. A non-employee director serving as chairman of the board or lead independent director will receive an additional annual retainer of \$15,000. Non-employee directors serving as the chairs of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of \$20,000, \$15,000 and \$10,000, respectively. Non-employee directors serving as members of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of \$10,000, \$7,500 and \$5,000, respectively. The non-employee directors will also receive initial grants of options to purchase 40,000 shares of our common stock, vesting over three years, upon initial election to the board of directors (however, our board of directors approved an initial award of 42,000 options to Dr. Blackwell in connection with her appointment to our board of directors on July 1, 2020). On the date of each annual meeting of our stockholders following the completion of our IPO, each non-employee director will receive an annual grant of options to purchase 20,000 shares of our common stock (30,000 shares of our common stock for any non-employee director serving as chairman of the board or lead independent director), vesting on the first to occur of (1) the first anniversary of the grant date or (2) the next occurring annual meeting of our stockholders.

In addition, pursuant to the director compensation program, each of Mr. Johnson and Mr. Gallagher received a grant of stock options pursuant to the 2020 Plan in connection with our IPO (30,000 shares of our common stock for Mr. Johnson and 20,000 shares of our common stock for Mr. Gallagher, effective as of immediately following the determination of the initial public offering price per share of our common stock. These stock options have an exercise price per share equal to \$18.00, and will vest in twelve equal monthly installments following the date of grant.

Our board of directors approved an additional grant of stock options to purchase 75,000 shares of our common stock pursuant to the 2020 Plan to Mr. Gallagher in connection with our IPO in connection with his service as our Executive Director, effective as of immediately following the determination of the initial public offering price per share of our common stock. These stock options have an exercise price per share equal to the

initial public offering price per share of our common stock in our IPO, or \$18.00. The stock options granted to Mr. Gallagher will vest as to 25% of the shares underlying the option on the one-year anniversary of the grant date and monthly thereafter in equal installments until fully vested at the fourth anniversary of the grant date, subject to his continued service through the applicable vesting dates. The stock options are subject to accelerated vesting upon the termination of Mr. Gallagher's consulting relationship by the company without cause, or notice of non- renewal of the consulting agreement by the company without cause, in either case following a change in control.

In connection with our IPO, our stockholders approved the initial terms of our non-employee director compensation program.

Compensation under our non-employee director compensation policy will be subject to the annual limits on non-employee director compensation set forth in the 2020 Plan, as described above, but such limits will not apply prior to 2021. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on non-employee director compensation set forth in the 2020 Plan. As provided in the 2020 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors or its authorized committee may determine in its discretion.

## Effect of Corporate Conversion on Class B Common Units Held by Non-Employee Directors; Restricted Stock Unit Awards

Cam Gallagher and David Johnson are the only non-employee directors who held Class B common units at the time of the Corporate Conversion. The number of shares of vested and unvested common stock issued to Messrs. Gallagher and Johnson upon conversion of their Class B common units based on the vested and unvested awards as of April 2, 2020, was as follows: Mr. Gallagher, 42,577 vested shares of common stock and 78,214 restricted shares; and Mr. Johnson, 1,897 vested shares of common stock and 43,651 restricted shares.

Mr. Gallagher's unvested restricted shares will vest as follows: 39,173 of the restricted shares were issued to him in respect of the conversion of his Class B common unit award granted on March 2, 2018, which was scheduled to vest in equal monthly installments over a period of four years commencing on February 13, 2018, which restricted shares will be fully vested on February 13, 2022; and 39,041 of the restricted shares were issued to him in respect of the conversion of his Class B common unit award granted on December 3, 2019, which was scheduled to vest as to 25% of such award on September 6, 2020, and the remainder in equal monthly installments over the remaining vesting period, which restricted shares will be fully vested on September 6, 2023. The restricted shares are subject to accelerated vesting in the event of Mr. Gallagher's termination by us without cause following a change in control.

The restricted shares were issued to Mr. Johnson in respect of the conversion of his Class B common unit award granted on January 6, 2020, which was scheduled to vest in 48 equal monthly installments over a period of four years commencing on January 6, 2020, which restricted shares will be fully vested on January 6, 2024. The restricted shares are subject to accelerated vesting in the event of Mr. Johnson's removal from the board without cause on or after January 6, 2021 and upon a change in control.

In connection with the Corporate Conversion, our board of directors approved the issuance of 73,478 and 51,587 restricted stock units to Messrs. Gallagher and Johnson, respectively. The number of restricted stock units was equal to the difference between the number of Class B common units held by them immediately prior to the Corporate Conversion and the resulting number of shares of common stock issued to them in connection with the Corporate Conversion, as detailed in the table above. Mr. Gallagher's restricted stock units will vest in accordance with the First RSU Vesting Schedule and Mr. Johnson's restricted stock units will vest in accordance

with the Second RSU Vesting Schedule. Mr. Gallagher's restricted stock units are also subject to accelerated vesting in the event of his termination by us without cause, our termination of his consulting agreement without cause, and upon his death or disability. Mr. Johnson's restricted stock units are subject to accelerated vesting in the event of Mr. Johnson's removal from the board without cause on or after January 6, 2021, upon his death or disability and upon a change in control.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2017 to which we have been a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock, or 5% Security Holders, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

# Participation in our Initial Public Offering

In connection with our IPO, certain of our existing stockholders purchased shares of our common stock from the underwriters at the initial public offering price of \$18.00 per share, and on the same terms as other investors in our IPO. The following table summarizes purchases of shares of our common stock in our IPO by holders of more than 5% of our capital stock. Additional details regarding holders of more than 5% of our capital stock, certain members of our board of directors and entities affiliated with members of our board of directors are provided in this prospectus under the caption "Principal Stockholders."

<u>Participants</u>	Shares Purchased	00 0	Aggregate Purchase Price (in thousands)	
Greater than 5% Stockholders <sup>(1)</sup>				
Tybourne Capital Management (HK) Limited(2)	1,475,000	\$	25,550	
Citadel, LLC(3)	1,350,000	\$	24,300	
Viking Global Opportunities Illiquid Investments Sub-Master LP(4)	725,000	\$	13,050	

- (1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal Stockholders."
- (2) Based solely on a Schedule 13G filed with the SEC on May 29, 2020.
- (3) Based solely on a Schedule 13G filed with the SEC on April 9, 2020.
- (4) Based solely on a Schedule 13G filed with the SEC on April 15, 2020.

#### **Equity Financings**

# Series B Convertible Preferred Units

In December 2017, we issued and sold to investors in a private placement an aggregate of 2,735,320 Series B convertible preferred units at a purchase price of \$12.43 per unit, for aggregate consideration of approximately \$34.0 million. In a subsequent closing in January 2018, we issued and sold an additional 764,281 Series B convertible preferred units for an aggregate consideration of approximately \$9.5 million. In a second subsequent closing in July 2018, we issued and sold an additional 24,138 Series B convertible preferred units for an aggregate consideration of \$0.3 million.

The following table sets forth the aggregate number of Series B convertible preferred units acquired by 5% Security Holders in the financing transactions described above.

Participants Participants	Series B Convertible Preferred Units	Purchase Price housands)
Greater than 5% Stockholders(1)		
Matrix Capital Management Master Fund, LP(2)	2,011,264	\$ 25,000
Viking Global Opportunities Illiquid Investments Sub-Master LP	643,605	\$ 8,000

<sup>(1)</sup> Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal Stockholders."

(2) Mr. Karan Takhar, a member of our board of directors, is affiliated with Matrix Capital Management Master Fund, LP.

# Series C Convertible Preferred Units

In September 2019, we issued and sold to investors in a private placement an aggregate of 4,847,106

Series C convertible preferred units at a purchase price of \$17.50 per unit, for aggregate consideration of approximately \$84.8 million.

The following table sets forth the aggregate number of Series C convertible preferred units acquired by 5% Security Holders in the financing transactions described above.

<u>Participants</u>	Series C Convertible Preferred Units	Aggregate Purchase Price (in thousands)	
Greater than 5% Stockholders(1)			
Matrix Capital Management Master Fund, LP(2)	742,858	\$	13,000
Viking Global Opportunities Illiquid Investments Sub-Master LP	742,858	\$	13,000

<sup>(1)</sup> Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal Stockholders."

# **Investors' Rights Agreement**

In September 2019, we entered into an amended and restated investors' rights agreement, which we refer to as our Investors' Rights Agreement, with certain of our investors, including Matrix Capital Management Master Fund, LP and Viking Global Opportunities Illiquid Investments Sub-Master LP, two of our 5% Security Holders. The Investors' Rights Agreement imposes certain affirmative obligations on us and also grants certain rights to holders, including certain registration rights with respect to the securities held by them, certain information and observer rights, and certain additional rights. Certain provisions of the Investors' Rights Agreement will terminate in connection with this offering. See "Description of Capital Stock—Registration Rights" for additional information.

# **Corporate Conversion**

Prior to the IPO, we operated as a Delaware limited liability company under the name Zentalis Pharmaceuticals, LLC. In connection with the IPO, we converted from a Delaware limited liability company to a Delaware corporation pursuant to a statutory conversion and changed our name to Zentalis Pharmaceuticals, Inc. Existing holders at the time of our IPO, including certain 5% Security Holders, executive officers and directors, of our class A common units, class B common units, series A convertible preferred units, series B convertible preferred units and series C convertible preferred units, received shares of our common stock as a result of the Corporate Conversion.

# Transactions with Kalyra Pharmaceuticals, Inc.

In December 2017, we acquired 17,307,692 shares of Series B convertible preferred stock of Kalyra Pharmaceuticals, Inc., or Kalyra, for a price per share of \$0.26 or approximately \$4,500,000. We have determined that Kalyra is a variable interest entity, of which we are the primary beneficiary. Anthony Y. Sun, M.D., our Chief Executive Officer and a member of our board of directors, currently serves as chairman of the board of directors of Kalyra. Karan Takhar, a member of our board of directors, currently serves as a member of the board of directors of Kalyra. Kevin Bunker, our Chief Operating Officer, currently serves as a member of the

<sup>(2)</sup> Mr. Karan Takhar, a members of our board of directors, is affiliated with Matrix Capital Management Master Fund, LP.

board of directors of Kalyra and as its Chief Scientific Operations Officer. Mr. Bunker previously served as the Chief Executive Officer of Kalyra from 2013 to December 2017. Cam Gallagher, a member of our board of directors, currently serves as the Chief Business Officer of Kalyra. Each of Messrs. Sun, Bunker and Gallagher maintains an ownership interest in Kalyra.

We entered into an intercompany services agreement, or ISA, 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 the year ended December 31, 2019, we provided \$650,316 of research and development services to Kalyra. As of December 31, 2019, \$238,656 was due from Kalyra under the ISA.

# Transactions with Recurium IP Holdings, LLC

In December 2014, and as amended and restated in December 2017 and September 2019 and as amended in May 2020, we entered into the Recurium Agreement with Recurium IP under which we were granted an exclusive worldwide license to certain intellectual property rights owned or controlled by Recurium IP. See the section titled "Business—Licensing Agreements and Strategic Collaborations—Recurium IP Holdings, LLC" for more information. Kevin Bunker, our Chief Operating Officer, and Cam Gallagher, a member of our board of directors, currently serve as managing members of Recurium IP. Each of Messrs. Bunker and Gallagher maintain an ownership interest in Recurium IP.

# Transactions with Tybourne Capital Management (HK) Limited

In May 2020, we entered into a collaboration and license agreement with our majority-owned joint venture, Zentera Therapeutics (Cayman), Ltd., or Zentera, through our subsidiaries Zeno Alpha, Inc., K-Group Alpha, Inc. and K-Group beta, Inc., pursuant to which we collaborate with Zentera on the development and commercialization of ZN-c5, ZN-d5 and ZN-c3 for the treatment or preventions of disease, other than for pain, in select Asian countries (including China). See "Business—Licensing Agreements and Strategic Collaborations—Zentera Therapeutics." In May 2020, Zentera issued and sold to investors in a private placement Series A Preference Shares, \$0.0001 par value per share, at a purchase price of \$1.00 per share, for aggregate consideration of approximately \$20 million. The following table sets forth the aggregate number of Series A Preference Shares of our majority-owned joint venture, Zentera, acquired by 5% Security Holders in the financing transaction described above.

<u>Participants</u>	Series A Preference Shares of Zentera	00	gate Purchase Price in thousands)
Greater than 5% Stockholders(1)			
Tybourne Capital Management (HK) Limited	10,000,000	\$	10,000,000

<sup>(1)</sup> Additional details regarding this stockholder and its equity holdings are provided in this prospectus under the caption "Principal Stockholders."

# **Employment Agreements**

We have entered into employment agreements or consulting agreements with each of our executive officers. See "Executive Compensation—Employment Agreements with our NEOs" for a further discussion of these arrangements.

# **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer. For further information, see "Executive and Director Compensation—Limitations of Liability and Indemnification."

#### **Policies and Procedures for Related Person Transactions**

Our board of directors has adopted a written related person transaction policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth information as of June 30, 2020 with respect to the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock
- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group;

The number of shares beneficially owned by each stockholder is determined in accordance with the rules issued by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any community property laws.

Percentage ownership of our common stock before this offering is based on 35,878,108 shares of our common stock outstanding as of June 30, 2020. Percentage ownership of our common stock after this offering without giving effect to the underwriters' option to purchase additional shares is based on 39,628,108 shares of common stock as of June 30, 2020, after giving pro forma effect to our issuance of 3,750,000 shares of our common stock in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of June 30, 2020 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 530 Seventh Avenue, Suite 2201, New York, New York 10018.

The table below does not give effect to potential purchases by the existing stockholders below in this offering.

	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After to Offering	
Name of Beneficial Owner	Number	Percentage	Number	Percentage
5% or Greater Stockholders				
Recurium Equity, LLC(1)	4,162,930	11.6%	4,162,930	10.5%
Matrix Capital Management Master Fund, LP <sup>(2)</sup>	3,821,739	10.7	3,821,739	9.6
Viking Global Opportunities Illiquid Investments Sub-Master LP(3)	4,443,284	12.4	4,443,284	11.2
Citadel, LLC(4)	2,142,940	6.0	2,142,940	5.4
Tybourne Capital Management (HK) Limited(5)	2,664,409	7.4	2,664,409	6.7
Named Executive Officers and Directors				
Anthony Y. Sun, M.D.(6)	2,817,478	7.9	2,817,478	7.1
Kevin Bunker, Ph.D.(7)	4,608,684	12.8	4,608,684	11.6
Robert Winkler, M.D	61,663	*	61,663	*
Cam Gallagher(8)	4,585,262	12.8	4,585,262	11.6
Kimberly Blackwell, M.D(9)	1,167	*	1,167	*
Karan Takhar <sup>(10)</sup>	3,821,739	10.7	3,821,739	9.6
David Johnson(11)	73,061	*	73,061	*
All executive officers and directors as a group (9 persons)	11,956,259	33.3	11,956,259	30.2

- \* Represents beneficial ownership of less than 1%.
- (1) Consists of 4,162,930 shares of common stock held by Recurium Equity, LLC, or Recurium. Cam Gallagher, a member of our board of directors, Kevin Bunker, our Chief Operating Officer, Ned Israelsen and Cam Garner are the managing members of Recurium and may be deemed to share voting and dispositive power over the shares held by Recurium. The mailing address for Recurium is 10835 Road to the Cure, #205, San Diego, California 92121.
- (2) Consists of 3,821,739 shares held by Matrix Capital Management Master Fund, LP, or Matrix. Karan Takhar, a member of our board of directors, is a managing director of Matrix and may be deemed to have voting and dispositive power over the shares held by Matrix. The mailing address for Matrix is 1000 Winter Street, Suite 4500, Waltham, Massachusetts 02451.
- (3) Based solely on a Schedule 13G filed with the SEC on April 15, 2020. Consists of 3,718,284 shares held by Viking Global Opportunities Illiquid Investments Sub-Master LP, or Opportunities Fund and (ii) 725,000 shares held by Viking Global Investors. Opportunities Fund has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Portfolio GP LLC, or Opportunities GP, and by Viking Global Investors LP, or VGI, which provides managerial services to Opportunities Fund. O. Andreas Halvorsen, David C. Ott and Rose Shabet, as Executive Committee members of Viking Global Partners LLC (the general partner of VGI) and Opportunities GP, have shared authority to direct the voting and disposition of investments beneficially owned by VGI and Opportunities GP. The business address of the Opportunities Fund is c/o Viking Global Investors LP, 55 Railroad Avenue, Greenwich, Connecticut 06830.
- (4) Based solely on a Schedule 13G filed with the SEC on April 9, 2020. Consists of (i) 792,940 shares held by Citadel Multi-Strategy Equities Master Fund Ltd. and (ii) 1,350,000 shares purchased in our IPO.
- (5) Based solely on a Schedule 13G filed with the SEC on May 29, 2020. Consists of (i) 1,189,409 held by Aquila Investments VI and (ii) 1,475,000 held by Tybourne Capital Management.
- (6) Consists of (i) 1,843,176 shares of common stock held by Dr. Sun and (ii) 974,302 shares of common stock held by Essex Group International, LLC for which Dr. Sun is a managing member.
- (7) Consists of (i) 445,754 shares of common stock held by Dr. Bunker and (ii) 4,162,930 shares of common stock held by Recurium, which shares Dr. Bunker may be deemed to beneficially own. See footnote (1) above.
- (8) Consists of (i) 415,665 shares of common stock held by Mr. Gallagher, (ii) 6,667 shares of common stock subject to options held by Mr. Gallagher that are exercisable within 60 days of June 30, 2020 and (iii) 4,162,930 shares of common stock held by Recurium, which shares Mr. Gallagher may be deemed to beneficially own. See footnote (1) above.
- (9) Consists of 1,167 shares of common stock subject to options held by Dr. Blackwell that are exercisable within 60 days of June 30, 2020.
- (10) Consists of 3,821,739 shares held by Matrix, which shares Mr. Takhar may be deemed to beneficially own. See footnote (2) above.
- (11) Consists of (i) 63,061 shares of common stock held by Mr. Johnson and (ii) 10,000 shares of common stock subject to options held by Mr. Johnson that are exercisable within 60 days of June 30, 2020.

#### DESCRIPTION OF CAPITAL STOCK

The following description summarizes important terms of our capital stock and certain provisions of our certificate of incorporation and bylaws, which are included as exhibits to the registration to which this prospectus forms a part. We urge you to read these documents before making any decision to purchase shares of our common stock.

#### General

Our authorized capital stock consists of 250,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share.

As of June 30, 2020, there were 35,878,108 shares of our common stock, held by approximately 78 stockholders of record. No shares of our preferred stock are designated, issued or outstanding.

#### Common Stock

#### Voting

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our certificate of incorporation and bylaws provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions."

#### Dividends

Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

#### Liquidation

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

# Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking funds provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of share of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

#### **Preferred Stock**

As of June 30, 2020, there were no shares of preferred stock outstanding.

Under the terms of our certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

# **Registration Rights**

Under our Investors' Rights Agreement, holders of approximately 8,743,379 shares of our common stock are entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act, until the rights otherwise terminate pursuant to the terms of the Investors' Rights Agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

#### Form S-1 Registration Rights

If at any time beginning 180 days after the closing date of our IPO the holders of registrable securities request in writing that we effect a registration with respect to all or part of such registrable securities then outstanding and having an anticipated aggregate offering price that would exceed \$10,000,000, net of expenses, we may be required to register their shares. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

# **Piggyback Registration Rights**

If we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

# Form S-3 Registration Rights

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of the registrable securities request in writing that we effect a registration

with respect to registrable securities at an aggregate price to the public in the offering of at least \$1,000,000, we will be required to effect such registration; provided, however, that we will not be required to effect such a registration if, within any twelve month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

#### **Expenses and Indemnification**

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders and blue sky fees and expenses. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact in any registration statement or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

# **Termination of Registration Rights**

The registration rights terminate upon the earliest of, with respect to a particular holder, (i) such time as that holder and its affiliates may sell all of their shares of common stock pursuant to Rule 144 under the Securities Act or similar exemption during a three-month period without registration, (ii) five years after the effective date of the registration statement of which this prospectus forms a part, and (ii) the closing of a deemed liquidation event, as defined in the Investors' Rights Agreement.

#### **Anti-Takeover Provisions**

Some provisions of Delaware law and our certificate of incorporation and our bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interests or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

# **Undesignated Preferred Stock**

The ability of our board of directors, without action by our stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to effect a change in control of our company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

# **Stockholder Meetings**

Our bylaws provide that a special meeting of stockholders may be called only by the chairman of our board of directors, our chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

#### Requirements for Advance Notification of Stockholder Nominations and Proposals

Our bylaws contain advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors of a committee of our board of directors.

# **Elimination of Stockholder Action by Written Consent**

Our certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

## Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve a three-year term, with one class being elected each year by our stockholders. For more information on our classified board, see "Management—Board Composition and Election of Directors." This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

#### **Removal of Directors**

Our certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

#### **Stockholders Not Entitled to Cumulative Voting**

Our certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors will be able to elect all of the directors standing for election, if they choose, other than any directors that holders of our convertible preferred stock may be entitled to elect.

#### **Choice of Forum**

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws, or (5) any action asserting a claim governed by the internal affairs doctrine. Under our certificate of incorporation, this exclusive form provision does not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or the rules and regulations thereunder. This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Our certificate of incorporation also provides that any person or entity holding, purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

#### Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, requires approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, and our certificate of incorporation and bylaws, could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

# Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors.

# **Limitations on Liability and Indemnification Matters**

Our certificate of incorporation limits our directors' liability to the fullest extent permitted under Delaware law, which prohibits our certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify our directors and officers to the fullest extent permitted under Delaware law and that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether we would have the power to indemnify such person against such expense, liability or loss under the DGCL.

We have also entered into separate indemnification agreements with each of our directors and executive officers, in addition to indemnification provided for in our bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by such persons in any action or proceeding arising out of this person's services as a director or

executive officer or at our request. We believe that these provisions in our certificate of incorporation and bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the limitation of liability and indemnification provisions of our certificate of incorporation, our bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which will be filed as an exhibit to this registration statement to which this prospectus forms a part.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

#### Listing

Our common stock is listed on The Nasdaq Global Market under the symbol "ZNTL."

# **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust, LLC.

# MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder's particular circumstances, including the impact of the alternative minimum tax or the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities or currencies;
- persons that hold more than 5% of our common stock, directly or indirectly;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- corporations organized outside of the United States, any state thereof or the District of Columbia that are nonetheless treated as U.S. taxpayers for U.S. federal income tax purposes;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons for whom our common stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement; and
- tax-qualified retirement plans.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS LEGAL OR TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

## Definition of a Non-U.S. Holder

For purposes of this discussion, a "non-U.S. holder" is any beneficial owner of our common stock that is neither a "U.S. person," nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and which has one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) who have the authority to control all substantial decisions of the trust, or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

#### Distributions

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Disposition of Common Stock."

Subject to the discussion below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders will be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock in connection with the conduct of a trade or business within the United States and dividends being effectively connected with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax

under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. If a non-U.S. holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

## Sale or Other Disposition of Common Stock

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitute U.S. real property interests, or USRPIs, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits, as adjusted for certain items, which will include such effectively connected gain.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we would be a USRPHC if our USRPIs comprise (by fair market value) at least half of our business assets. We believe we are not currently and do not anticipate becoming

a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if our common stock are "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

# Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding with respect to distributions on our common stock we make to the non-U.S. holder, provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a U.S. person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on our common stock to the non-U.S. holder, regardless of whether such distributions constitute a dividend or whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale or other taxable disposition of our common stock within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale or other taxable disposition of our common stock outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or W-8BEN-E, or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

## Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code, such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends paid on our common stock, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code) (including, in some cases, when such foreign financial institution or non-financial foreign entity is acting as an intermediary), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an

agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends paid on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock, proposed Treasury Regulations, if finalized in their present form, would eliminate FATCA withholding on payments of gross proceeds from a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of FATCA.

#### UNDERWRITERS

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, Jefferies LLC and SVB Leerink LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<u>Underwriter</u>	Number of Shares
Morgan Stanley & Co. LLC	
Jefferies LLC	
SVB Leerink LLC	
Guggenheim Securities, LLC	
Total:	3,750,000

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ per share under the public offering price.

After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representative.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 562,500 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 562,500 shares of common stock.

		Tota	<u> 11</u>
			Full
	Per Share	No Exercise	Exercise
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$750,000. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$35,000.

Our common stock is listed on The Nasdaq Global Market under the trading symbol "ZNTL".

We and all directors and officers and certain stockholders have agreed that, without the prior written consent of Morgan Stanley & Co. LLC, Jefferies LLC and SVB Leerink LLC on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus (the "restricted period"):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock beneficially owned (as such term is used in Rule 13d-3 of the Exchange Act) or any other securities so owned convertible into or exercisable or exchangeable for common stock, or make any public announcement of an intention to do any of the foregoing;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock,

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph do not apply to our directors, officers and securityholders with respect to:

- transactions of shares of common stock or any other securities acquired in this offer or in open market transactions after the completion of the offering, provided that no filing under Section 16(a) of the Exchange Act is required or voluntarily made in connection with subsequent sales of our common stock or other securities acquired in this offering or in such open market transactions;
- transfers of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift or charitable contribution, (ii) by will or intestacy or to any immediate family of such person or to a trust whose beneficiaries consist exclusively of one or more of such person and/or any immediate family, (iii) to limited partners, members, stockholders or holders of similar equity interests of such person or (iv) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of such person, or to any investment fund or other entity controlled or managed by such person or affiliates of such person; provided that (A) each transferee, donee or distributee shall sign and deliver a lock-up letter and (B) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period;
- transfers of common stock or any security convertible into or exercisable or exchangeable for common stock by operation of law pursuant to a qualified domestic order or other court order or in connection with a divorce settlement; provided that (i) any filing under Section 16(a) of the Exchange Act made during the restricted period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described herein and (B) no securities were sold by such person and (ii) such person does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;
- the receipt by such person from the company of shares of common stock upon the transfer or disposition of shares of common stock or any securities convertible into common stock to the company

upon a vesting or settlement event of the company's securities or upon the exercise of options to purchase the company's securities on a "cashless" or "net exercise" basis, in each case pursuant to any equity incentive plan of the company described herein and to the extent permitted by the instruments representing such options outstanding as of the date of the hereof (and solely to cover withholding tax obligations in connection with such transaction and any transfer to the company for the payment of taxes as a result of such transaction), provided that (i) the shares received upon exercise or settlement of the option are subject to the terms of a lock-up letter, (ii) no public disclosure or filing under Section 16(a) of the Exchange Act shall be voluntarily made during the restricted period and (iii) to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers described herein, it shall (A) clearly indicate that the filing relates to the circumstances described herein, including that the securities remain subject to the terms of a lock-up letter and (B) no securities were sold by such person other than as contemplated hereby;

- transfers to the company in connection with the repurchase of common stock in connection with the termination of such person's employment with the company pursuant to contractual agreements with the company as in effect as of the date of this prospectus, provided that no public disclosure or filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the restricted period;
- the conversion of the outstanding common units or preferred units of the company described herein into shares of common stock of the company, provided that such shares of common stock remain subject to the terms of this letter;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of such person or the company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period; or
- transfers pursuant to a bona fide third-party tender offer for all outstanding common stock of the company, merger, consolidation or other similar transaction approved by the company's board of directors and made to all holders of the company's securities involving a change of control of the company; provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by such person shall remain subject to the provisions of the lock-up letter.

The restrictions on transfers or other dispositions by us described above do not apply to:

- the shares to be sold in this offering;
- the issuance by us of shares of common stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- grants of options, restricted stock or other equity awards and the issuance of common stock or securities convertible into or exercisable for common stock pursuant to the terms of a plan in effect on the date of this prospectus and described herein;
- the filing of a registration statement on Form S-8 to register common stock issuable pursuant to any employee benefit plans, qualified stock option plans or other employee compensation plans;
- common stock or any securities convertible into, or exercisable or exchangeable for, common stock, or the entrance into an agreement to issue common stock or any securities convertible into, or exercisable or exchangeable for, common stock, in connection with any merger, joint venture, strategic alliances, commercial or other collaborative transaction or the acquisition or license of the business, property,

technology or other assets of another individual or entity or the assumption of an employee benefit plan in connection with a merger or acquisition; provided that the aggregate number of common stock or any securities convertible into, or exercisable or exchangeable for, common stock that the Company may issue or agree to issue shall not exceed 5.0% of the total outstanding shares of common stock of the company immediately following the completion of this offering; and provided further that the recipients thereof sign a lock-up letter; or

• the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

Morgan Stanley & Co. LLC, Jefferies LLC and SVB Leerink LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In connection with our initial public offering, we and all of our directors and executive officers and substantially all of our stockholders agreed to 180 day lock-up agreements on substantially the same terms as the 90 day lock-up agreements for this offering. Morgan Stanley & Co. LLC, Jefferies LLC and SVB Leerink LLC have waived the lock-up agreement from our initial public offering to the extent necessary to permit us to sell shares of our common stock in this offering.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory,

investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses. For example, certain of the underwriters also served as underwriters in our initial public offering in April 2020.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

# **Selling Restrictions**

#### Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Regulation, or each, a Relevant Member State, an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Regulation, if they have been implemented in that Relevant Member State:

- (i) to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

# **United Kingdom**

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 ("FSMA") received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

#### Hong Kong

Shares of our common stock may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to shares of our common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

## Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (the "FIEL") has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

# For Qualified Institutional Investors ("QII")

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "QII only private placement" or a "QII only secondary distribution" (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

#### For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "small number private placement" or a "small number private secondary distribution" (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

# Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where shares of our common stock are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired shares of our common stock under Section 275 except: (a) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (b) where no consideration is given for the transfer; or (c) by operation of law.

#### LEGAL MATTERS

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Latham & Watkins LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Cooley LLP, New York, New York. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm collectively own less than 1% of our common stock.

#### **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2018 and 2019 and for the years then ended, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We are subject to the informational requirements of the Exchange Act, and in accordance with the Exchange Act, we are required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission. You may read and copy this information at the Public Reference Room of the Securities and Exchange Commission, 100 F Street, N.E., Room 1580, Washington, District of Columbia. 20549. You may obtain information on the operation of the public reference rooms by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is www.sec.gov.

# ZENTALIS PHARMACEUTICALS, LLC

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# Report of Independent Registered Public Accounting Firm

The Members and Board of Directors of Zentalis Pharmaceuticals, LLC

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Zentalis Pharmaceuticals, LLC (the Company) as of December 31, 2018 and 2019, the related consolidated statements of operations, changes in convertible preferred units and members' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

#### **Basis for Opinion**

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

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

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

/s/ Ernst & Young LLP

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

San Diego, California March 6, 2020

# Zentalis Pharmaceuticals, LLC

# FINANCIAL STATEMENTS

# Consolidated Balance Sheets (In thousands, except unit amounts)

		<u>1ber 31</u> 2019
ASSETS		2015
Current assets		
Cash and cash equivalents	\$ 25,154	\$ 67,246
Accounts receivable from government grants, net	917	140
Prepaid expenses and other current assets	606	1,505
Total current assets	26,677	68,891
Property and equipment, net	260	501
Operating lease right-of-use assets	_	2,335
Prepaid expenses and other assets	1,525	2,134
Deferred financing costs	_	841
Goodwill	3,736	3,736
In-process research and development	8,800	8,800
Restricted cash	_	243
Total assets	\$ 40,998	\$ 87,481
LIABILITIES, CONVERTIBLE PREFERRED UNITS AND EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable	\$ 3,431	\$ 4,289
Accrued expenses	2,554	10,608
Deferred grant proceeds	223	_
Total current liabilities	6,208	14,897
Deferred tax liability	2,463	2,463
Other long-term liabilities	21	1,700
Total liabilities	8,692	19,060
Commitments and contingencies	-,	2,722
Convertible preferred units; Redemption value of \$146,944 at December 31, 2019	_	141,706
EQUITY		,
Convertible preferred units; Redemption value of \$62,120 at December 31, 2018	59,830	_
Class A common units; 15,000,000 and 20,000,000 units authorized at December 31, 2018 and 2019, respectively; 5,594,385 and 5,601,478	ĺ	
units issued and outstanding at December 31, 2018 and 2019, respectively	672	709
Class B common units, 2,154,816 and 3,458,522 units authorized at December 31, 2018 and 2019, respectively; 1,612,311 and 2,670,668		
units issued and outstanding at December 31, 2018 and 2019, respectively	1,598	2,178
Common Stock, \$0.001 par value per share; no shares authorized, issued and outstanding at December 31, 2018 and 2019, respectively;		
250,000,000 shares authorized, 25,321,524 shares issued and 24,147,270 shares outstanding, pro forma (unaudited)	_	_
Preferred stock, \$0.001 par value per share; no shares authorized, issued and outstanding at December 31, 2018 and 2019, respectively;		
10,000,000 shares authorized, no shares issued and outstanding, pro forma (unaudited).	_	_
Additional paid-in capital		
Accumulated deficit	(37,330)	(82,993)
Total Zentalis Pharmaceuticals, LLC members' equity (deficit), Pro forma stockholders' equity	24,770	(80,106)
Noncontrolling interests	7,536	6,821
Total equity (deficit)	32,306	(73,285)
Total liabilities, convertible preferred units and equity (deficit)	\$ 40,998	\$ 87,481

# Zentalis Pharmaceuticals, LLC

# Consolidated Statements of Operations (In thousands, except per unit amounts)

		Ended lber 31,
	2018	2019
Revenue	\$ 14	\$ —
Operating Expenses		
Research and development	18,921	38,386
General and administrative	4,876	8,459
Total operating expenses	23,797	46,845
Operating loss	(23,783)	(46,845)
Other Income		
Interest income	355	498
Other expense		(16)
Net loss before income taxes	(23,428)	(46,363)
Income tax expense	4	15
Net loss	(23,432)	(46,378)
Net loss attributable to noncontrolling interests	(2,365)	(715)
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$(21,067)	\$(45,663)
Net loss per Class A common units outstanding, basic and diluted	\$ (3.77)	\$ (8.16)
Weighted average Class A common units outstanding, basic and diluted	5,594	5,597

# Zentalis Pharmaceuticals, LLC

# Consolidated Statements of Changes in Convertible Preferred Units and Members' Equity (Deficit) (In thousands, except per unit amounts)

		vertible red Units		ertible ed Units		ass A non Units		ass B non Units	Accumulated	Total Zentalis Pharmaceuticals, LLC Members'	Noncontrolling	Total Equity
	Units	Amount	Units	Amount	Units	Amount	Units	Amount	Deficit	Equity (Deficit)	Interests	(Deficit)
Balance at December 31, 2017			4,314	\$ 50,374	5,594	\$ 643	703	\$ 1,319	\$ (17,125)	\$ 35,211	\$ 9,885	\$ 45,096
Cumulative-effect adjustment from									, , ,			
adoption of ASU 2014-09	_	_	_	_	_	_	_	_	862	862	_	862
Issuance of Series B convertible preferred												
units at \$12.43 per unit net of issuance												
costs	_	_	789	9,456	_	_	_	_	_	9,456	_	9,456
Issuance of profit interest awards, net	_	_	_	_	_		909	_	_	_	_	
Share-based compensation expenses	_	_	_	_	_	29	_	279	_	308	_	308
Proceeds from exercise of equity awards												
from consolidated VIE			_						_	_	16	16
Net loss attributable to noncontrolling												
interest	_	_	_	_	_	_	_	_	_	_	(2,365)	(2,365)
Net loss attributable to Zentalis									(04.065)	(04.007)		(04.005)
Pharmaceuticals, LLC									(21,067)	(21,067)		(21,067)
Balance at December 31, 2018	_	_	5,103	59,830	5,594	672	1,612	1,598	(37,330)	24,770	7,536	32,306
Issuance of Series C convertible preferred												
units at \$17.50 per unit net of issuance												
costs	4,847	81,876	_		_	_	_			_		
Reclassification of convertible preferred												
units for contingent liquidation												
features not within the Company's	F 100	E0 020	(F 100)	(50,030)						(50,000)		(50,020)
control	5,103	59,830	(5,103)	(59,830)	_	_	1.050	_	_	(59,830)	_	(59,830)
Issuance of profit interest awards, net			_		7	37	1,059	580		617	_	617
Share-based compensation expense	_	_	_	_	/	3/	_	580	_	017	_	017
Net loss attributable to non-controlling interest											(715)	(715)
Net loss attributable to Zentalis			_	_					_	_	(715)	(715)
Pharmaceuticals, LLC									(45,663)	(45,663)		(45,663)
·	0.050	£141.70C		<u></u>	F CO1	<u></u>	2.671	¢ 2.170			¢ 0001	
Balance at December 31, 2019	9,950	\$141,706		<u> </u>	5,601	\$ 709	2,671	\$ 2,178	<u>\$ (82,993)</u>	<u>\$ (80,106)</u>	\$ 6,821	<u>\$(73,285</u> )

# Zentalis Pharmaceuticals, LLC

# Consolidated Statements of Cash Flows (in thousands)

	Year F Deceml	
	2018	2019
Operating Activities:		
Consolidated net loss	\$(23,432)	\$(46,378)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	51	111
Share-based compensation	308	617
Changes in operating assets and liabilities:		
Accounts receivable	(254)	777
Prepaid expenses and other assets	(1,861)	(1,508)
Accounts payable and accrued liabilities	977	7,123
Lease payments recognized (deferred)	(40)	115
Net cash used in operating activities	(24,251)	(39,143)
Investing activities:		
Purchases of property and equipment	(227)	(352)
Net cash used in investing activities	(227)	(352)
Financing Activities:		
Proceeds from the issuance of Series B convertible preferred units, net	9,456	_
Proceeds from the issuance of Series C convertible preferred units, net	_	81,876
Issuance of common stock under VIE equity incentive plan	16	
Deferred financing costs		(46)
Net cash provided by financing activities	9,472	81,830
Increase/(decrease) in cash, cash equivalents and restricted cash	(15,006)	42,335
Cash, cash equivalents and restricted cash at beginning of year	40,160	25,154
Cash, cash equivalents and restricted cash at end of year	\$ 25,154	\$ 67,489
Supplemental disclosure of cash flow information:		
Income taxes paid	\$ 4	\$ 15
Supplemental disclosure of non-cash investing and financing activities:	<del></del>	
Amounts accrued for purchases of property and equipment	\$ 10	\$ —
Right-of-use assets obtained in exchange for operating lease liabilities	\$ —	\$ 1,412
Costs incurred in connection with initial public offering included in accounts payable and accrued expenses	\$ —	\$ 795

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:

	Decem	ber 31,
	2018	2019
Cash and cash equivalents	\$25,154	\$67,246
Restricted cash, non-current		243
Total cash, cash equivalents and restricted cash reported in the Consolidated Statement of Cash Flows	\$25,154	\$67,489

#### Zentalis Pharmaceuticals, LLC

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Business

#### Organization

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 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. exchange for Class B common incentive units in Zeno, 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. See Members' Equity note 9 for additional information.

Zentalis Pharmaceuticals, LLC is a is a Delaware limited liability company. 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.

#### Liquidity

The accompanying financial statements have been prepared assuming that we will continue as a going concern. Management evaluates whether there are relevant conditions and events that in aggregate raise substantial doubt about our ability to continue as a going concern and to meet our obligations as they become due within one year from the date the financial statements are issued.

We are subject to risk and uncertainties common to early-stage biotechnology companies including, but not limited to significant competition from therapies in development by other companies or already approved for sale by the U.S. Food and Drug Administration, protection of intellectual property, dependence on key personnel and compliance with government regulations.

Management has prepared cash flow forecasts which indicate that there is not substantial doubt about our ability to continue as a going concern for the twelve months after the date the financial statements for the year ended December 31, 2019 are issued. We expect to incur substantial operating losses to continue development of drug candidates, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if our drug development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

# 2. Summary of Significant Accounting Policies

# **Basis of Presentation**

The consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP") and include our wholly owned subsidiaries, 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.

#### **Zentalis Pharmaceuticals, LLC**

We evaluate our ownership, contractual and other interests in entities that are not wholly-owned to determine if these entities are VIEs, and, if so, whether we are the primary beneficiary of a VIE and therefore required to consolidate the VIE, we apply a qualitative approach that determines whether we have both (1) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and (2) the obligation to absorb losses of, or the rights to receive benefits from, the VIE that could potentially be significant to that VIE. On December 21, 2017, the Company acquired a 25% equity interest in Kalyra. Based on our assessment, we concluded that Kalyra is a variable interest entity and we are the primary beneficiary. Prior to the acquisition, Zeno 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 the Company's consolidated financial statements from December 21, 2017, the date we became the primary beneficiary. The liabilities recognized as a result of consolidating Kalyra do not represent additional claims on the Company's general assets.

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

# **Noncontrolling Interests**

Noncontrolling interests represent the portion of equity (net assets) in Kalyra, our consolidated but not wholly-owned entity, that is neither directly nor indirectly attributable to us.

#### Use of Estimates

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

## Cash and Cash Equivalents

Cash equivalents are comprised of short-term, highly-liquid investments with maturities of 90 days or less at the date of purchase. As of December 31, 2018 and 2019, our cash equivalents consisted of money market funds.

## **Restricted Cash**

Under the terms of our office lease, we are required to maintain a letter of credit as a security deposit during the term of such lease. At December 31, 2019, restricted cash of \$0.2 million was pledged as collateral for the letter of credit. We were not required to maintain a letter of credit as a security deposit as of December 31, 2018.

#### Fair Value of Financial Instruments

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

#### Zentalis Pharmaceuticals, LLC

Our financial instruments include cash equivalents, accounts receivable, prepaid expenses and other assets, accounts payable and accrued expenses. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgement and therefore cannot be determined with precision. The carrying amount of cash equivalents, account receivable, prepaid expenses and other assets, accounts payable and accrued expenses are generally considered to be representative of their respective values because of the short-term nature of those instruments.

# Concentrations of Credit Risk, Sources of Supply and Significant Customers

We are subject to credit risk from our portfolio of cash equivalents. We maintain our cash and cash equivalent balances with two major commercial banks. Deposits held with the financial institutions exceed the amount of insurance provided on such deposits. We are exposed to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents to the extent recorded on the consolidated balance sheets.

We are also subject to credit risk from our accounts receivable related to our revenues under our license and collaboration agreement and reimbursements under our government grants. We have a license and collaboration agreement under which we receive payments for license fees, milestone payments and reimbursements of research and development services. Management monitors our exposure to accounts receivable by periodically evaluating the collectability of the accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, we recorded no allowance for doubtful accounts at December 31, 2018 and 2019. As of December 31, 2018 and 2019, all of the outstanding accounts receivables are due from government entities.

We rely on third-party manufacturers for the supply of active pharmaceutical ingredients.

#### Accounts Receivable, Net

Accounts receivable is recorded at the invoiced amount and is non-interest bearing. Accounts receivable is recorded net of allowances for doubtful accounts. We recorded no allowance for doubtful accounts at December 31, 2019 and 2018 as the collectability of accounts receivable was reasonably assured.

## Property and Equipment, Net

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

#### Leases

We have entered into operating leases for real estate. We determine if an arrangement is a lease at inception and evaluate each lease agreement to determine whether the lease is an operating or finance lease. For leases where we are the lessee, right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Liabilities from operating leases are included in accrued expenses and other long-term liabilities on our consolidated balance sheet. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As our leases do not provide an implicit interest rate, we use our incremental borrowing rate based on the information available at the commencement date in

#### Zentalis Pharmaceuticals, LLC

determining the present value of lease payments. The operating lease ROU asset also includes any prepaid lease payments, lease incentives received, and costs which will be incurred in exiting a lease. Our leases often include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that we will exercise that option. As of December 31, 2019 it is not reasonably certain that these options will be exercised and they are not included within the lease term. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. We have lease agreements with lease and non-lease components which are accounted for separately.

# Impairment of Long-Lived Assets

We account for long-lived assets in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. To date, we have not experienced any significant impairment losses.

# Goodwill and In-Process Research and Development

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

Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Upon conclusion of the relevant research and development project, we will amortize the acquired IPR&D over its estimated useful life or expense the acquired IPR&D should the research and development project be unsuccessful with no future alternative use. We base the useful lives and related amortization expense on our estimate of the period that the assets will generate revenues or otherwise be used. We assess the carrying value of our IPR&D assets at least annually, or more frequently if an event occurs indicating the potential for impairment, which requires us to make assumptions and judgements regarding the future cash flows of these assets. If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by a combination of third-party sources and forecasted discounted cash flows.

Goodwill is reviewed for impairment at least annually, or more frequently if an event occurs indicating the potential for impairment. During the impairment review process, we consider qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than the carrying amount, including goodwill. If we determine that it is not more likely than not that the fair value of our reporting unit is less than the carrying amount, then no additional assessment is deemed necessary. Otherwise, we perform the two-step test for goodwill impairment. The first step involves comparing the estimated fair values of the reporting units with the carrying values, including goodwill. If the carrying amounts of the reporting units exceed the fair values, the second step of the goodwill impairment test is performed to determine the amount of loss, which involves comparing the implied fair values of the goodwill to the carrying values of the goodwill. We completed our most recent annual evaluation for impairment for goodwill and IPR&D as of December 31, 2019 using the qualitative assessment and determined that no impairment existed, and no charges were recorded.

#### Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB") issued accounting guidance on the recognition of revenue from customers. This guidance supersedes the revenue recognition requirements we

#### **Zentalis Pharmaceuticals, LLC**

previously followed in Accounting Standards Codification, or ASC, Topic 605, *Revenue Recognition*, or ASC 605, and created a new Topic 606, *Revenue from Contracts with Customers*, or ASC 606. Under ASC 606, an entity will recognize revenue when it transfers control of promised goods or services to customers in an amount that reflects what the entity expects to receive in exchange for the goods or services, and the performance obligation(s) under the related contracts are satisfied. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the promised goods or services in the contract; (ii) identify the performance obligations in the contract, including whether they are distinct in the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations.

We generate revenues from payments received under a collaboration arrangement which included payments for nonrefundable fees at the inception of the agreement, license fees, milestone-based payments and reimbursements for research and development efforts. As of January 1, 2018, we adopted ASC 606, *Revenue from Contracts with Customers*. We applied the provisions of ASC 606 using the modified retrospective approach, with the cumulative effect of the adoption recognized as of January 1, 2018, to the contract that had not been completed as of that date. Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as contract liabilities in long-term liabilities.

Prior to the ASC 606 adoption, revenue was recognized when all the following criteria were met; (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured. Under the previous guidance, we recognized the upfront payment received from our collaborative partner on a straight-line basis over the performance period arrangement or from receipt until May 2036. There were no other adoption differences in revenue recognized due to the transition from the previously applied authoritative accounting literature to ASC 606.

Upon the adoption of ASC 606, we concluded that all services had been rendered over the research period and recognized an adjustment to decrease deferred revenues and accumulated deficit by approximately \$0.9 million. The impact of applying the provisions of ASC 606 in the year ended December 31, 2018 was to decrease revenues by forty-six thousand dollars. Under the previously existing authoritative accounting literature, at December 31, 2018 our deferred revenue would have been approximately \$0.8 million higher than the amounts reported in our consolidated balance sheet. ASC 606 did not have an aggregate impact on our net cash used in operating activities but resulted in offsetting changes in net loss and liabilities within net cash used in operating activities in the consolidated statements of cash flows.

#### Revenue under Collaborative Agreements

We entered into a collaboration and license agreement ("the agreement") with a specialty pharmaceutical company for the development and commercialization of products and product candidates for the treatment of various diseases and conditions relating to the field of oncology. Pursuant to the terms of the original agreement and related amendment, the collaborator made an upfront non-refundable license payment, milestone payments and payments for the reimbursement of research and development expenses to us during the research period. The collaborator may be required to make royalty payments on sales of products in the collaborator's territories resulting from the collaborative arrangement. Although this agreement is, in form, structured as a collaboration agreement, we concluded for accounting purposes that it represented a contract with a customer, and is not subject to accounting literature on collaborative arrangements. This is because we granted licenses to our

#### **Zentalis Pharmaceuticals, LLC**

intellectual property and provided research and development services which are all outputs of our ongoing activities in exchange for consideration. We do not share in significant risks of their development or commercialization activities.

Our collaboration partner can select additional compounds to add to the licenses granted. We consider these rights to be options without material rights, as these rights require additional fees and future royalties which do not represent discounts to similar licenses to a new collaboration partner. We consider grants of additional licenses upon exercises to be separate contracts.

Under the collaboration agreement, we have identified a pre-clinical development license, a development and commercial license, a license to manufacture product (collectively referred to as "licenses"), associated research and development services and joint steering committee participation (collectively referred to as "services") for the co-development of a single named compound as the performance obligations of the contract. As our ongoing participation in the research and development was required for the collaborator to benefit from the licenses, the promised licenses and services were not separable or distinct and were accounted for as a single performance obligation satisfied over the term of the research period.

The transaction price is the amount of consideration to which we expect to be entitled for transferring promised goods or services. The transaction price does not include amounts subject to uncertainties unless it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated to the amount is resolved. Upfront fees are contractually obligated and included in the transaction price. Consideration we may have received in exchange for milestones achieved were subject to significant uncertainties inherent in product development and were not included in the transaction price until deemed probable that the amount would not result in a significant reversal of revenue in the future. At the conclusion of each reporting period, we reassessed the probability of milestone achievement and expected payments for research and development services, and if necessary, adjusted our total estimated transaction price.

As our collaboration agreement had one distinct bundle of performance obligations comprised of services and licenses delivered concurrently and were not subject to the right of return, allocation of the transaction price was not required.

Upfront amounts allocated to licenses and ongoing services were recognized as revenue commencing upon transfer of the licenses over the research period of the target on a percentage of total costs to be incurred basis. We completed our ongoing services under the collaboration agreement during the fourth quarter of 2017 and therefore considered our performance obligations to have been fully satisfied at that time. Development milestones are recognized as revenue when the consideration is included in the transaction price over the remaining term of the research period. Royalties will be recognized when the underlying sales occur based on estimates. We will record a true-up of the estimated royalty revenues to the actual royalties earned when royalty reports are received.

We provide standard indemnification and protection of licensed intellectual property for our customers. These provisions are part of assurance that the licenses meet the agreement's representations and are not an obligation to provide goods or services.

# Research and Development Expenses

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

#### Zentalis Pharmaceuticals, LLC

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

# **Clinical Trial Expenses**

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

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

#### **Share-Based Compensation**

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

## **Income Taxes**

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

Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the period and the change during the

# Zentalis Pharmaceuticals, LLC

period in deferred tax assets and liabilities. We follow the accounting guidance on accounting for uncertainty in income taxes. The guidance prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities based on the technical merits of the position.

# Comprehensive Loss

Comprehensive loss is equal to net loss for the years ended December 31, 2018 and 2019.

# Net Loss per Class A Common Unit

Basic net loss per Class A common unit is computed by dividing net loss, after adjusting for preferred unit dividends, if declared by the weighted-average number of Class A common units outstanding during the period. Diluted net loss per common unit is computed using the weighted-average number of Class A common units outstanding during the period and, if dilutive the weighted average number of potential shares of Class A common units. The effect of the conversion of preferred units into Class A common unit is excluded from the computation of diluted net loss per common unit for the period as their effect is antidilutive. Additionally, Class A common unit equivalents are excluded from the computation of diluted net loss per common unit for all periods as their effect is antidilutive.

# Zentalis Pharmaceuticals, LLC

Effect on the Financial

# 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:

<u>Standard</u>	Description	Effective Date	Statements or Other Significant Matters
In January 2016, the FASB issued ASU 2016-01, Financial Instruments—Overall; Recognition and Measurement of Financial Assets and Financial Liabilities.	The new guidance supersedes the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and requires equity securities to be measured at fair value with changes in the fair value recognized through net income. The new guidance requires public business entities that are required to disclose fair value of financial instruments measured at amortized cost on the balance sheet to measure that fair value using the exit price notion consistent with Topic 820, Fair Value Measurement.	January 1, 2018	We currently do not hold equity securities and therefore the adoption did not have a material impact on our consolidated financial position or results of operations.
In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). In March, April, May and December 2016, the FASB issued additional guidance related to Topic 606.	The new standard will supersede nearly all existing revenue recognition guidance.  Under Topic 606, an entity is required to recognize revenue upon transfer of promised goods or services to customers in an amount that reflects the expected consideration to be received in exchange for those goods or services. Topic 606 defines a five-step process in order to achieve this core principle, which may require the use of judgment and estimates, and also requires expanded qualitative and quantitative disclosures relating to the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers, including significant judgments and estimates used. The new standard also defines accounting for certain costs related to origination and fulfillment of contracts with customers, including whether such costs should be capitalized. The new standard permits adoption either by using (i) a full retrospective approach for all periods presented in the period of adoption or (ii) a modified retrospective approach where the new standard is applied in the financial statements starting with the year	January 1, 2019	We have adopted the new guidance on January 1, 2018 using the modified retrospective approach. Refer to Note 2 "Revenue Recognition" for additional detail regarding the impact of the adoption.
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# Zentalis Pharmaceuticals, LLC

Effect on the Financial

Standard	Description	Effective Date	Statements or Other Significant Matters
	of adoption. Under both approaches, cumulative impact of the adoption is reflected as an adjustment to retained earnings (accumulated equity (deficit)) as of the earliest date presented in accordance with the new standard.		
In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share- Based Payment Accounting	The FASB issued the new guidance as part of its ongoing Simplification Initiative. The ASU supersedes Subtopic 505-50 by expanding the scope of Topic 718 to include nonemployee awards and generally aligning the accounting for nonemployee awards with the accounting for employee awards with limited exceptions.	January 1, 2019	We have adopted the new guidance on January 1, 2018. The impact of the adoption was not material to the consolidated financial statements.
In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842).	This guidance revises the accounting related to leases by requiring lessees to recognize a lease liability and a right-of-use asset for all leases. The new lease guidance also simplifies the accounting for sale-leaseback transactions.	January 1, 2019	We have adopted Topic 842 on January 1, 2019 using a modified retrospective transition basis for leases existing as of the period of adoption. We implemented new processes and used the available practical expedients to implement the guidance. The practical expedients allowed us to carry forward our historical assessment of whether existing agreements are or contain a lease and the classification of our existing lease arrangements. All of our real-estate operating lease commitments are recognized as lease liabilities with corresponding right-of-use assets, which resulted in an increase in the assets
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# Zentalis Pharmaceuticals, LLC

<u>Standard</u>	Description	Effective Date	Effect on the Financial Statements or Other Significant Matters  and liabilities of the consolidated balance sheet of \$1.5 million, using an assumed weighted average discount rate of 11.0%. The adoption did not have an impact on our consolidated statements of operations and did not require recognition of a cumulative-effect adjustment to the opening balance of accumulated deficit in the period of adoption. We elected to continue applying the guidance under ASU 840, Leases for comparative periods, as allowed through ASU 2018-11, Leases
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	certain other instruments that aren't measured at fair value	January 1, 2020	(Topic 842): Targeted Improvements.  We do not believe the adoption will have a material impact on our consolidated financial position or results of operations.
May of 2019, the FASB issued additional guidance related to Topic 326.  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, 2021	We do not believe the adoption will have a material impact on our consolidated financial position or results of operations.
			1

#### Zentalis Pharmaceuticals, LLC

#### 3. Business Combinations

# Kalyra Pharmaceuticals, Inc.

On December 21, 2017, we acquired \$4.5 million of Kalyra Pharmaceuticals, Inc.'s Series B Preferred Stock representing a 25% equity interest in Kalyra Pharmaceuticals, Inc. 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, Zeno 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 December 31, 2018 and 2019 are as follows (in thousands):

	Decem	ıber 31,
	2018	2019
Cash and cash equivalents	\$1,482	\$ 712
Other current assets	933	21
In-process research and development	8,800	8,800
Goodwill	3,736	3,736
Other long-term assets	48	14
Accounts payable and accrued expenses	1,224	391
Deferred tax liability	2,463	2,463
Noncontrolling interests	\$7,536	\$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 Zeno 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):

	Decemb	oer 31,
	2018	2019
Noncontrolling interest at beginning of period	\$ 9,885	\$7,536
Net loss attributable to noncontrolling interest	(2,365)	(715)
Issuance of VIE shares under equity incentive plan	16	_
Noncontrolling interest at end of period	\$ 7,536	\$6,821

## 4. Fair Value Measurement

As of December 31, 2018 and 2019, we held approximately \$23.2 million and \$63.0 million of money market funds measured at fair value on a recurring basis and categorized as Level 1 securities using the fair value hierarchy.

# Zentalis Pharmaceuticals, LLC

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the years ended December 31, 2018 and 2019. We had no instruments that were classified within Level 3 as of December 31, 2018 and 2019.

# 5. Prepaid Expenses and Other Assets

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

	Decem	ber 31,
	2018	2019
Prepaid insurance	\$ 98	\$ 150
Prepaid software licenses and maintenance	126	238
Prepaid research and development expenses	1,715	2,985
Prepaid rent and related security deposits	104	168
Other prepaid expenses	88	98
Total prepaid expenses and other current assets	2,131	3,639
Less long-term portion	1,525	2,134
Total prepaid expenses and other assets, current	\$ 606	\$1,505

# 6. Property and Equipment, net

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

	December 31,	
	2018	2019
Computer and Office Equipment	\$ 39	\$ 243
Lab Equipment	277	401
Leasehold Improvements	—	24
Subtotal	316	668
Accumulated depreciation and amortization	(56)	(167)
Property and equipment, net	\$260	\$ 501

Depreciation and amortization expense was approximately \$0.1 million and \$0.1 million for the years ended December 31, 2018 and 2019, respectively.

# 7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2018	2019
Accrued research and development expenses	\$1,137	\$ 5,465
Accrued employee expenses	1,023	2,977
Accrued general and administrative expenses	356	1,356
Lease liability, current portion	_	781
Other	38	29
Total accrued expenses	\$2,554	\$10,608

#### Zentalis Pharmaceuticals, LLC

#### 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 (see note 9).

# 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.

The authorized, issued, and outstanding shares of convertible preferred units at December 31, 2018 and 2019 were as follows:

	December 31, 2018			
		Shares Issued		
	Units	and	Liquidation	Carrying
<u>Series</u>	Authorized	Outstanding	Value	Value
Series A convertible preferred units	1,638,000	1,579,309	\$ 18,319,984	\$ 18,225,809
Series B convertible preferred units	3,621,000	3,523,739	43,800,076	41,603,945
Total	5,259,000	5,103,048	\$ 62,120,060	\$ 59,829,754

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

#### Zentalis Pharmaceuticals, LLC

At December 31, 2018, the convertible preferred units were classified in members' equity. During 2019, we reclassified the convertible preferred units 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, 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. Subsequent adjustments to increase the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur.

#### Dividends

Dividends are payable if and when declared by the Board of Directors. No dividends were declared during the years ended December 31, 2018 and 2019.

#### Conversion

Each Series A preferred unit, Series B preferred unit and Series C preferred unit shall be 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 is \$11.60, \$12.43 and \$17.50 per unit, respectively. The convertible preferred units will automatically convert 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 unit will be 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).

#### Anti-dilution protection

The holders of the convertible preferred unit have 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, shall be on a broad-based weighted average basis.

## Protective rights

The holders of the convertible preferred unit have 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 must 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 must 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 are not redeemable except in the event of certain effected deemed liquidation events. As of December 31, 2019, we have classified convertible preferred

#### Zentalis Pharmaceuticals, LLC

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 are 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 are 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 are 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 are 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 are unvested shall vote together as a single class. Each holder of Series A, Series B and Series C convertible preferred units shall be entitled to the number of votes calculated on an as converted to Class A common unit basis.

## 9. Members' Equity

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.

#### Zentalis Pharmaceuticals, LLC

# 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 years ended December 31, 2018 and 2019, zero and 7,093 Class A common units were issued. As of December 2018 and 2019, 24,236 and 9,572 shares of Class A common units were subject to future vesting conditions, respectively. 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.

Equity Awards

The Zentalis Pharmaceuticals, LLC Profit Interest Plan

We currently grant profit interest awards to employees, consultants and non-employee members of our Board of Directors under the Zeno Pharma, LLC 2017 Profit Interest Plan ("the Plan") as approved and adopted by the Board of Directors on December 21, 2017. The Plan and related Amended and Restated Limited Liability Agreement of Zeno Pharma, LLC ("the LLC Agreement") provides for the grant of up to 3,458,522 shares of Class B common units, subject to restrictions as described in the Plan. Each unvested Class B common unit represents a non-voting equity interest in Zentalis Pharmaceuticals, LLC that entitles the holder to a percentage of the profits and appreciation in the equity value of Zentalis Pharmaceuticals, LLC arising after the date of grant and after such time as an applicable threshold amount is met. Class B common units issued under the Plan with time-based vesting schedules generally vest over a four-year period with cliff vesting for the first year. Class B common awards may utilize performance-based vesting schedules related to certain milestones at the Company.

The fair value of the profit interest awards is estimated using an option pricing model with the following assumptions:

		Year ended December 31,		
		2018		2019
Members' equity value (in thousands)	\$	113,100	\$197	,041 - \$271,207
Threshold amounts (in thousands)	\$134,	000 - \$143,800	\$143	,800 - \$309,824
Risk free rate		2.8%		1.5%
Volatility		75.0%		75.0%
Time to liquidity (in years)		1.3		1.1 - 1.8
Lack of marketability discount		25.0%		18.8% - 26.4%
Grant date fair value	\$	1.85 - \$2.01	\$	1.88 - \$3.06

The Black Scholes option pricing model is used to estimate the fair value of each profit 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 apply the risk-free interest rate based on the U.S. Treasury yield in effect at

# Zentalis Pharmaceuticals, LLC

the time of the grant consistent with the life of the award. The expected volatility is 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.

The following table provides a summary of the Class B common unit activity under the Plan. The amounts include incentive units granted to both employees and non-employees:

	Number of Units	ed Average r Value
Outstanding at December 31, 2017	703,000	\$ 1.47
Granted	947,166	\$ 1.62
Forfeited	(37,855)	\$ 1.47
Outstanding at December 31, 2018	1,612,311	\$ 1.56
Granted	1,095,545	\$ 2.73
Forfeited	(37,188)	\$ 1.62
Outstanding at December 31, 2019	2,670,668	\$ 2.04

At December 31, 2019, there are 1,008,479 and 1,662,189 Class B common units vested and unvested, respectively, and 787,854 Class B common units were available for future grants.

During 2018 and 2019, the share-based compensation expense included in the statement of operations was as follows:

	Year	Year ended	
	Decem	ıber 31,	
	2018	2019	
Research and development expense	\$158	\$339	
General and administrative expense	150	278	
Total share-based compensation expense	\$308	\$617	
	<del></del>		

As of December 31, 2019, there was \$3.8 million of total unrecognized compensation expense related to unvested profit interest award compensation arrangements granted under the Plan. The cost is expected to be recognized over a weighted average period of 3.4 years.

# 10. Commitments and Contingencies

#### **Operating Leases**

We entered into a non-cancellable operating lease agreement in January 2016 to lease 11,121 square feet of laboratory and office space in San Diego. In December 2018, we entered into an amendment to the lease to extend the term of the agreement through June 2022. The lease is subject to further extension or earlier termination and subject to approximately 3% annual increases throughout the term of the lease. We also pay a pro rata share of operating costs, including utilities, maintenance, insurance costs and real property taxes. As part of the amendment, we received incentives in the form of a base rate abatement period.

### Zentalis Pharmaceuticals, LLC

In April 2019, we entered into a lease for approximately 4,800 square feet of office space in New York, New York. The lease commenced in May 2019 and continues through June 30, 2023. The lease is subject to approximately 3.0% annual increases throughout the term of the lease. We received lease incentives under the agreement, including tenant allowances and a free rent period. We also pay for various operating costs, including utilities and real property taxes. The agreement does not contain a renewal option but does contain an early termination provision.

In August 2019, we entered into a sublease for approximately 2,333 square feet of office space adjacent to the existing laboratory and office space in San Diego, California. The lease commenced in October 2019 and continues through February 2022. The lease is subject to approximately 3% annual increases throughout the term of the lease. We also pay for various operating costs, including utilities and real property taxes. The agreement does not contain a renewal option or an early termination provision.

Rent expense recorded by the Company under the leases was approximately \$0.8 million and \$0.4 million for the years ended December 31, 2019 and 2018, respectively.

The following table presents the weighted average remaining lease term and weighted average discount rates related to our operating leases as of December 31, 2019:

Cash paid in 2019 related to operating leases (in thousands)	\$ 700
Weighted average remaining lease term (in years)	2.9
Weighted average discount rate	11.0%

Approximate annual future minimum operating lease payments as of December 31, 2019 are as follows (in thousands):

Year-ending December 31,	Paymo	ent Amount
2020	\$	1,015
2021		1,044
2022		661
2023		187
Total minimum lease payments:		2,907
Less: imputed interest		(431)
Total operating lease liabilities		2,476
Less: current portion		781
Lease liability, net of current portion	\$	1,695

As of December 31, 2018, prior to the adoption of ASU 2016-02, future minimum operating lease payments were \$1.8 million and \$1.3 million for the years ending December 31, 2019 and 2020, respectively.

As of December 31, 2019, we have had no additional significant operating or finance leases that had not yet commenced.

### 11. Income Taxes

Zentalis Pharmaceuticals, LLC is treated as a partnership for tax purposes, and thus, not subject to income taxes. It is the responsibility of the LLC members to report their proportion share of any taxable income or loss generated by Zentalis Pharmaceuticals, LLC to the appropriate taxing authorities and pay the associated taxes, if

# Zentalis Pharmaceuticals, LLC

any. With respect to our consolidated subsidiaries and variable interest entity, these entities are treated as corporations for tax purposes and are subject to income taxes which have been included in the consolidated financial statements. All pre-tax losses have been incurred in the United States.

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

	2018	2019
Current tax provision:	<del>-</del>	
Federal	\$—	<b>\$</b> —
State	4	15
Total current tax provision	4	15
Deferred tax provision:		
Federal	_	_
State	_	_
Total deferred tax provision	<del>-</del>	
Total provision for income taxes:	\$ 4	\$15
-		

A reconciliation of the expected tax computed at the U.S. statutory federal income tax rate to the total provision for income taxes at December 31 follows (in thousands):

	2018	3	2019	
Expected tax at 21%	\$(4,921)	21.0%	\$ (9,730)	21.0%
State income tax, net of federal tax	(1,581)	6.8%	(3,167)	6.8%
Limited liability company loss	8	-0.1%	4	-0.0%
Non-deductible expenses	187	-0.8%	164	-0.3%
Research credits	(1,145)	4.9%	(1,424)	3.1%
Other	191	-0.8%	(2)	0.0%
Change in valuation allowance	7,265	-31.0%	14,170	-30.6%
Provision for income taxes	\$ 4	0.0%	\$ 15	0.0%

Deferred income taxes as of the following period reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

### Zentalis Pharmaceuticals, LLC

Significant components of our net deferred tax asset or liability at December 31, 2018 and 2019 are as follows (in thousands):

	2018	2019
Deferred tax assets		
Net operating loss	\$ 12,425	\$ 25,053
Compensation	13	148
Deferred rent	5	_
ASC 842 lease liability	_	693
State tax	1	1
Research credits	2,079	3,503
Total gross deferred tax assets	14,523	29,398
Valuation allowance	(14,477)	(28,647)
Net deferred tax assets	46	751
Deferred tax liabilities		
Depreciable assets	(46)	(97)
ASC 842 right of use asset	_	(654)
In-process research and development	(2,463)	(2,463)
Deferred tax liabilities	(2,509)	(3,214)
Net deferred tax liabilities	\$ (2,463)	\$ (2,463)

Realization of a portion of our deferred tax assets is dependent upon our generating sufficient taxable income in future years to obtain benefit from the reversal of temporary differences. Management considered all available evidence under existing tax law and anticipated expiration of tax statutes and determined that a valuation allowance of \$28.6 million and \$14.5 million was required as of December 31, 2019 and 2018, for those deferred tax assets that are not expected to provide future tax benefits.

The acquisition of Kalyra (see footnotes 2 and 3) resulted in an allocation of the purchase price to In-process Research and Development (IPR&D). Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. As a result of being treated as an indefinite lived asset, the deferred tax liability is not considered to be a future source of taxable income for purposes of determining the Company's realizability of definite lived deferred tax assets and the amount of the valuation allowance to record. We have adopted an accounting policy to not consider indefinite lived deferred tax liabilities as a future source of taxable income with respect to determining the realizability of indefinite lived deferred tax assets and the amount of valuation allowance recorded against the deferred asset related to the federal net operating losses generated beginning January 1, 2018 and the California R&D tax credits, which do not expire.

At December 31, 2018 and 2019, we have available net operating loss carryforwards of approximately \$44.1 million and \$89.2 million, respectively for the federal income tax purposes, of which \$68.2 million were generated after 2017 and can be carried forward indefinitely under the Tax Cuts and Jobs Act. The remaining federal net operating loss of \$21.0 million, which were generated prior to 2018, will start to expire in 2033 if not utilized.

At December 31, 2018 and 2019, the net operating losses for state purposes are \$45.4 million and \$90.4 million, respectively and will begin to expire in 2033 if not utilized.

At December 31, 2018, we have federal and state income tax credit carryforwards, net of reserves, of approximately \$1.3 million and \$0.9 million, respectively. At December 31, 2019, we have federal and state

### **Zentalis Pharmaceuticals, LLC**

income tax credit carryforwards, net of reserves, of approximately \$2.3 million and \$1.4 million, respectively. The federal credit carryforwards begin to expire in 2033. The state credit carryforwards do not expire.

We have not completed a study to determine whether an ownership change per the provisions of Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions, has occurred. Utilization of our net operating loss and income tax credit carryforwards may be subject to a substantial annual limitation due to ownership changes that may have occurred or that could occur in the future. These ownership changes may limit the amount of the net operating loss and income tax credit carryover that can be utilized annually to offset future taxable income. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders.

### **Uncertain Tax Positions**

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The following table reconciles the beginning and ending amount of unrecognized tax benefits for the year ended December 31, 2018 and 2019 (in thousands):

	2018	2019
Gross unrecognized tax benefits at the beginning of the year	\$325	\$ 741
Additions from tax positions taken in the current year	416	383
Gross unrecognized tax benefits at end of the year	\$741	\$1,124

Of the total unrecognized tax benefits at December 31, 2018 and 2019, no amount will impact our effective tax rate due to the Company's full valuation allowance. We do not anticipate that there will be a substantial change in unrecognized tax benefits within the next 12 months.

We recognize interest and penalties related to unrecognized tax positions within the income tax expense line in the accompanying consolidated statements of operations. There were no accrued interest and penalties associated with uncertain tax positions as of December 31, 2018 or December 31, 2019.

We and our subsidiaries are subject to U.S. federal and state income tax, and in the normal course of business, its income tax returns are subject to examination by the relevant taxing authorities. As of December 31, 2019, the 2016—2019 tax years remain subject to examination in the U.S. federal tax and various state tax jurisdictions. However, to the extent allowed by law, the taxing authorities may have the right to examine the period from 2013 through 2019 where net operating losses and income tax credits were generated and carried forward and make adjustments to the amount of the net operating loss and income tax credit carryforward amount. We are not currently under examination by federal or state jurisdictions.

### 12. Net Loss Per Class A Common Unit

### **Net Loss Per Class A Common Unit**

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

	Year ended December 31,	
	2018	2019
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$(21,067)	\$(45,663)
Weighted average number of Class A common units outstanding, basic and diluted	5,594	5,597
Net loss per Class A common unit	\$ (3.77)	\$ (8.16)

Our potential and dilutive securities, which include preferred units, have been excluded from the computation of diluted net loss per Class A common unit as the effect would be to reduce the net loss per Class A common unit. 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 Class A common unit equivalents have been excluded from the calculations of diluted net loss per Class A common unit because their inclusion would be antidilutive (in thousands).

	Year ended December 31,	
	2018	2019
Preferred units, as if converted to Class A common units	5,103	9,950
Incentive units—Class B common units	1,612	2,671
	6,715	12,621

The unaudited pro forma basic and diluted weighted average common unit outstanding used in the calculation of unaudited pro forma basic and diluted net loss per unit attributable to common unit holders for the year ended December 31, 2019 has been prepared to give effect to the conversion of Zentalis Pharmaceuticals, LLC to a C-corporation, the conversion of Class A common units and Class B common units to common stock and the conversion of preferred units to common stock as if the proposed initial public offering had occurred on January 1, 2019. Shares of common stock issued in the IPO and any related net proceeds are excluded from the pro forma information. Pro forma basic and diluted net loss per unit attributable to common unit holders for the year ended December 31, 2019 was calculated as follows (in thousands except per share amounts):

	_	ear ended cember 31, 2019
Net loss attributable to Zentalis Pharmaceuticals, LLC common units—basic and diluted	\$	(45,663)
Weighted average number of common units outstanding  Pro forma adjustments to reflect automatic conversion of convertible preferred units to common stock upon the completion of the		8,815
proposed initial public offering		9,237
Pro forma weighted average number of shares outstanding—basic and diluted		18,058
Pro forma net loss per common share	\$	(2.53)

### Zentalis Pharmaceuticals, LLC

### 13. Employee Savings Plan

We have an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. All employees are eligible to participate provided that they meet the requirements of the plan. The Company does not make matching contributions under the plan.

### 14. Related Party Disclosures

On December 21, 2017, we acquired 17,307,692 shares of Series B preferred stock of Kalyra Pharmaceuticals, Inc. 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 ("MSA") 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 the years ended December 31, 2018 and 2019, we incurred approximately \$1.3 million and five thousand dollars of expense with Kalyra that was eliminated in consolidation for research and development services provided, respectively. As of December 31, 2018 and 2019, \$1.2 million and seventeen thousand dollars was due to Kalyra and eliminated in consolidation.

We entered into an Intercompany Services Agreement ("ISA") 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 the years ended December 31, 2018 and 2019, we provided \$0.5 million and \$0.7 million of research and development services to Kalyra that was eliminated in consolidation, respectively. As of December 31, 2018 and 2019, \$0.5 million and \$0.2 million was due from Kalyra and eliminated in consolidation, respectively.

### 15. Subsequent Events

### San Diego office expansion

In January 2020, we entered a lease for approximately 36,955 square feet of office and laboratory space in San Diego, California. The targeted lease commencement date is January 2021 and will continue for 120 months thereafter. The lease is subject to approximately 3% annual increases throughout the term of the lease. We also pay for various operating costs, including utilities and real property taxes. The agreement contains extension rights allowing us to extend the term of the lease for five years at the then market rate. The agreement does not contain an early termination provision.

# Zentalis Pharmaceuticals, LLC

The expected future minimum lease obligations under the agreement are as follows (in thousands):

Year-ending December 31,	Payment Amount
2021	\$ 2,018
2022	2,078
2023	2,140
2024	2,205
2025	2,271
Thereafter	12,419
Total minimum lease payments:	12,419 \$23,131

# **Series C Closing**

In February 2020, we issued 867,194 additional units of Series C preferred units under the Series C Preferred Unit Purchase Agreement (the "Series C 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.

We have evaluated subsequent events through the report date.

# FINANCIAL STATEMENTS

# Condensed Consolidated Balance Sheets (Unaudited) (In thousands, except unit amounts)

	March 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 63,650	\$ 67,246
Accounts receivable from government grants, net	139	140
Prepaid expenses and other current assets	2,220	1,505
Total current assets	66,009	68,891
Property and equipment, net	519	501
Operating lease right-of-use assets	2,276	2,335
Prepaid expenses and other assets	2,353	2,134
Deferred financing costs	3,525	841
Goodwill	3,736	3,736
In-process research and development	8,800	8,800
Restricted Cash	411	243
Total assets	\$ 87,629	\$ 87,481
LIABILITIES, CONVERTIBLE PREFERRED UNITS AND DEFICIT		
Current Liabilities		
Accounts payable	\$ 7,019	\$ 4,289
Accrued expenses	9,920	10,608
Total current liabilities	16,939	14,897
Deferred tax liability	2,463	2,463
Other long-term liabilities	1,484	1,700
Total liabilities	20,886	19,060
Commitments and contingencies		
Convertible preferred units; Redemption value of \$162,120,000 and \$146,944,000 at March 31, 2020 and		
December 31, 2019, respectively	155,934	141,706
EQUITY (DEFICIT)		
Class A common units; 20,000,000 units authorized at March 31, 2020 and December 31, 2019; 5,601,478 units		
issued and outstanding at March 31, 2020 and December 31, 2019	709	709
Class B common units, 3,458,522 units authorized at March 31, 2020 and December 31, 2019; 2,607,309 and		
2,670,668 units issued and outstanding at March 31, 2020 and December 31, 2019, respectively	2,507	2,178
Accumulated deficit	(99,119)	(82,993)
Total Zentalis Pharmaceuticals, LLC members' deficit	(95,903)	(80,106)
Noncontrolling interests	6,712	6,821
Total deficit	(89,191)	(73,285)
Total liabilities, convertible preferred units and deficit	\$ 87,629	\$ 87,481

# ${\bf Zentalis\ Pharmaceuticals,\ LLC}$

# Condensed Consolidated Statements of Operations (Unaudited) (In thousands, except per unit amounts)

	Three Months Ended March 31,	
	2020	2019
Operating Expenses		
Research and development	\$ 13,258	\$ 7,089
General and administrative	3,141	1,633
Total operating expenses	16,399	8,722
Operating loss	(16,399)	(8,722)
Other Income (Expense)		
Interest income	164	74
Other expense		(12)
Net loss before income taxes	(16,235)	(8,660)
Income tax expense		3
Net loss	(16,235)	(8,663)
Net loss attributable to noncontrolling interests	(109)	(320)
Net loss attributable to Zentalis Pharmaceuticals, LLC	\$(16,126)	\$(8,343)
Net loss per Class A common unit outstanding, basic and diluted	\$ (2.88)	\$ (1.49)
Units used in computing net loss per Class A common unit, basic and diluted	5,601	5,594

# Condensed Consolidated Statements of Cash Flows (Unaudited) (in thousands)

	7	Three Mor Marc		
Our restore And States	_=	2020	2	019
Operating Activities: Consolidated net loss	<b>¢</b> (	16 225)	¢ ((	0 663)
	Φ(.	16,235)	<b>\$</b> (0	3,663)
Adjustments to reconcile net loss to net cash used in operating activities:		38		21
Depreciation and amortization Share-based compensation		329		129
Changes in operating assets and liabilities:		329		129
Accounts receivable		1		225
Prepaid expenses and other assets		(1,050)		(230)
Accounts payable and accrued liabilities		53		(467)
Operating lease right-of-use assets and liabilities, net		(7)		(21)
	(		((	
Net cash used in operating activities		16,871)	(5	9,006)
Investing activities:		(04)		(44)
Purchases of property and equipment		(31)		(41)
Net cash used in investing activities		(31)		(41)
Financing Activities:				
Proceeds from the issuance of Series C convertible preferred units, net		14,228		_
Deferred financing costs		(754)		
Net cash provided by financing activities		13,474		
Decrease in cash, cash equivalents and restricted cash		(3,428)	(5	9,047)
Cash, cash equivalents and restricted cash at beginning of year	(	67,489		5,154
Cash, cash equivalents and restricted cash at end of year	\$ (	64,061	\$16	5,107
Supplemental disclosure of non-cash investing and financing activities:			-	
Amounts accrued for purchases of property and equipment	\$	25	\$	7
Right-of-use assets obtained in exchange for operating lease liabilities	\$	_	\$ 1	1,369
Costs incurred in connection with initial public offering included in accounts payable and accrued expenses	\$	1,930	\$	

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:

	Mare	ch 31,
	2020	2019
Cash and cash equivalents	\$63,650	\$ 16,107
Restricted cash, non-current	411	
Total cash, cash equivalents and restricted cash reported in the Consolidated Statement of Cash Flows	\$64,061	\$ 16,107

# Condensed Consolidated Statements of Changes in Convertible Preferred Units and Members' Deficit (Unaudited)

(In thousands, except per unit amounts)

		vertible red Units		vertible red Units		ass A non Units		ass B ion Units	Accumulated	Total Zentalis Pharmaceuticals, LLC Members'	Zentalis harmaceuticals,		
	Units	Amount	Units	Amount	Units	Amount	Units	Amount	Deficit	Equity (Deficit)	Interests	Equity (Deficit)	
Balance at December 31, 2019	9,950	\$141,706	_	\$ —	5,601	\$ 709	2,671	\$ 2,178	\$ (82,993)	\$ (80,106)	\$ 6,821	\$(73,285)	
Issuance of Series C convertible preferred units at \$17.50 per unit net	0.07	14 220											
of issuance costs	867	14,228	_						_	_	_	_	
Cancellation of profit interest awards, net	_	_		_		_	(64)	_	_	_	_		
Share-based compensation expense	_	_	_	_	_	_	(O4)	329	_	329	_	329	
Net loss attributable													
to non-controlling interest	_	_	_	_	_	_	_	_	_	_	(109)	(109)	
Net loss attributable to Zentalis Pharmaceuticals, LLC									(16,126)	(16,126)		(16,126)	
Balance at March 31, 2020	10,817	\$155,934		\$ _	5,601	\$ 709	2,607	\$ 2,507	\$ (99,119)	\$ (95,903)	\$ 6,712	\$(89,191)	
	Prefe	nvertible erred Units	Prefe	vertible rred Units	Com	lass A non Units	Comn	lass B non Units	Accumulated	Total Zentalis Pharmaceuticals, LLC Members'	Noncontrolling	Total Equity	
D 1 21 2010	Units	Amount	Units					Amount	<u>Deficit</u>	Equity (Deficit)	Interests	(Deficit)	
Balance at December 31, 2018	_	- \$ —	5,103	\$ 59,830	5,594	\$ 672	1,612 48	\$ 1,598	\$ (37,330)	\$ 24,770	\$ 7,536	\$ 32,306	
Issuance of profit interest awards, net Share-based compensation expense				_				127		129		129	
Net loss attributable to non-controlling interest	_			_	_	_	_	_	_	_	(320)	(320)	
Net loss attributable to Zentalis Pharmaceuticals, LLC	_	_		_	. <u> </u>	_	_	_	(8,343)	(8,343)	_	(8,343)	
Balance at March 31, 2019		\$	5,103	\$ 59,830	5,594	\$ 674	1,660	\$ 1,725	\$ (45,673)	\$ (16,376)	\$ 7,216	\$(23,592)	

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### 1. Organization and Business

### Organization

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 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 incentive 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.

Zentalis Pharmaceuticals, LLC is a Delaware limited liability company. 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.

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. 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.

### 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 March 31, 2020 are issued.

### **Zentalis Pharmaceuticals, LLC**

### 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 Prospectus). 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.

### Comprehensive Loss

Comprehensive loss is equal to net loss for the periods ended March 31, 2020 and 2019.

# Zentalis Pharmaceuticals, LLC

# 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.

### Zentalis Pharmaceuticals, LLC

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, Zeno 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 March 31, 2020 and December 31, 2019 are as follows (in thousands):

	March 31, 2020	 ember 31, 2019
Cash and cash equivalents	\$ 286	\$ 712
Other current assets	77	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	113	391
Deferred tax liability	2,463	2,463
Noncontrolling interests	\$ 6,712	\$ 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 Zeno 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):

	<u>March 31,</u>	<u> March 31,</u>
	2020	2019
Noncontrolling interest at beginning of period	\$ 6,821	\$ 7,536
Net loss attributable to noncontrolling interest	(109)	(320)
Noncontrolling interest at end of period	\$ 6,712	\$ 7,216

### 4. Fair Value Measurement

As of March 31, 2020 and December 31, 2019, we held approximately \$60.3 million and \$63.0 million of money market funds measured at fair value on a recurring basis and categorized as Level 1 securities using the fair value hierarchy.

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

# Zentalis Pharmaceuticals, LLC

# 5. Prepaid Expenses and Other Assets

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

	March 31, 2020	December 31, 2019
Prepaid insurance	\$ 303	\$ 150
Prepaid software licenses and maintenance	299	238
Prepaid research and development expenses	3,668	2,985
Other prepaid expenses	303	266
Total prepaid expenses and other current assets	4,573	3,639
Less long-term portion	2,353	2,134
Total prepaid expenses and other assets, current	\$ 2,220	\$ 1,505

# 6. Property and Equipment, net

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

	<u>March 31,</u> 2020	<u>December 31,</u> 2019
Computer and Office Equipment	\$ 271	\$ 243
Lab Equipment	401	401
Leasehold Improvements	24	24
Construction in Progress	28	_
Subtotal	724	668
Accumulated depreciation and amortization	(205)	(167)
Property and equipment, net	\$ 519	\$ 501

Depreciation and amortization expense for the three months ended March 31, 2020 and 2019 was approximately thirty-eight thousand and twenty-one thousand respectively.

# 7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2020	December 31, 2019
Accrued research and development expenses	\$ 5,103	\$ 5,465
Accrued employee expenses	2,008	2,977
Accrued general and administrative expenses	1,916	1,356
Lease liability	810	781
Other	83	29
Total accrued expenses	\$ 9,920	\$ 10,608

### **Zentalis Pharmaceuticals, LLC**

### 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.

The authorized, issued, and outstanding shares of convertible preferred units at March 31, 2020 and December 31, 2019 were as follows:

	March 31, 2020								
		Shares Issued							
	Units	and		Liquidation		Carrying			
<u>Series</u>	Authorized	Outstanding		Value		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	5,714,300		100,000,250		96,104,453			
Total	10,817,348	10,817,348	\$	162,120,310	\$	155,934,207			

### Zentalis Pharmaceuticals, LLC

	December 31, 2019								
	** *.	Shares Issued		*					
Series	Units Authorized	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 three months ended March 31, 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 through March 31, 2020.

### Conversion

Each Series A preferred unit, Series B preferred unit and Series C preferred unit shall be 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 is \$11.60, \$12.43 and \$17.50 per unit, respectively. The convertible preferred units will automatically convert 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 unit will be 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).

### Anti-dilution protection

The holders of the convertible preferred unit have 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, shall be on a broad-based weighted average basis.

# Protective rights

The holders of the convertible preferred unit have 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 must be approved by a majority of the then outstanding Series A,

### Zentalis Pharmaceuticals, LLC

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 must 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 are not redeemable except in the event of certain effected deemed liquidation events. As of March 31, 2020 and December 31, 2019, we have 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 are 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 are 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 are 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 are 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 are unvested shall vote together as a single class. Each holder of Series A, Series B and Series C convertible preferred units shall be entitled to the number of votes calculated on an as converted to Class A common unit basis.

### 9. Members' Equity

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

### Zentalis Pharmaceuticals, LLC

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 March 31, 2020 and 2019, we did not issue any Class A common units and 9,572 shares of Class A common units were subject to future vesting conditions. During the year ended December 31, 2019, 7,093 Class A common units were issued and 9,572 shares of 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.

### **Share-based Compensation**

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

		Three Montl March		led
	2020		2	019
Research and development expense	\$	136	\$	66
General and administrative expense		193		63
Total share-based compensation expense	\$	329	\$	129

As of March 31, 2020, there was \$3.4 million of total unrecognized compensation expense related to unvested profit interest award compensation arrangements granted under the Zeno Pharma, LLC 2017 Profit Interest Plan (the "Plan"). The cost is expected to be recognized over a weighted average period of 3.2 years.

### Zentalis Pharmaceuticals, LLC

The fair value of the profit interest awards is estimated using an option pricing model with the following assumptions:

	 Three Months Ended March 31,		
	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 option pricing model is used to estimate the fair value of each profit 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 apply 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 is 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 three months ended March 31, 2020 and 2019, we issued 70,000 and 47,500 Class B common units, respectively. As of March 31, 2020 and December 31, 2019, approximately 1.5 million units and 1.7 million units of unvested Class B common units were outstanding.

### 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.

### Zentalis Pharmaceuticals, LLC

### Leases

Our commitments include payments related to operating leases. Approximate annual future minimum operating lease payments as of March 31, 2020 are as follows (in thousands):

<u>Year</u> 2020	Operating <u>Leases</u>
	\$ 765
2021	1,044
2022	661
2023	2,657
Total minimum lease payments:	2,657
Less: imputed interest	(363)
Total operating lease liabilities	2,294

The weighted-average remaining lease term of our operating leases is approximately 2.7 years. As of March 31, 2020, we have entered an additional lease for real estate that has not yet commenced with total minimum lease payments of approximately \$23.1 million. This lease is expected to commence in the first quarter of 2021 and has a lease term of 10 years.

### 11. Net Loss Per Class A Common Unit

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

	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net loss attributable to Zentalis Pharmaceuticals, LLC		\$(8,343)
Denominator:		
Weighted average number of Class A common units outstanding, basic and diluted	5,601	5,594
Net loss per Class A common unit	\$ (2.88)	\$ (1.49)

Our potential and dilutive securities, which include preferred units, have been excluded from the computation of diluted net loss per Class A common unit as the effect would be to reduce the net loss per Class A common unit. 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 Class A common unit equivalents have been excluded from the calculations of diluted net loss per Class A common unit because their inclusion would be antidilutive (in thousands).

	Three Months Ended March 31,	
	2020	2019
Preferred units, as if converted to Class A common units	10,817	5,103
Incentive units—Class B common units		1,660
	13,424	6,763

### Zentalis Pharmaceuticals, LLC

### 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 ("MSA") 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 the three months ended March 31, 2020 and 2019, we incurred approximately seventeen thousand and five thousand dollars of expense with Kalyra that was eliminated in consolidation for research and development services provided, respectively. As of March 31, 2020 and 2019, approximately seventeen thousand and five thousand dollars was due to Kalyra and eliminated in consolidation.

We entered into an Intercompany Services Agreement ("ISA") 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 the three months ended March 31, 2020 and 2019, we provided \$0.1 million and \$0.2 million of research and development services to Kalyra that was eliminated in consolidation, respectively. As of March 31, 2020 and 2019, \$0.1 million and \$0.8 million was due from Kalyra and eliminated in consolidation, respectively.

### 13. Subsequent Events

### 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.

# Zentalis Pharmaceuticals, LLC

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.

3,750,000 Shares



**PROSPECTUS** 

Morgan Stanley

Jefferies

# SVB Leerink Guggenheim Securities

, 2020

### Part II

### INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

	Amount
Securities and Exchange Commission registration fee	\$ 22,172
FINRA filing fee	26,122
Accountants' fees and expenses	100,000
Legal fees and expenses	400,000
Transfer Agent's fees and expenses	5,000
Printing and engraving expenses	165,000
Miscellaneous	31,356
Total expenses	\$ 750,000

### Item 14. Indemnification of Directors and Officers.

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

### Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding unregistered securities issued by us within the past three years. Also included is the consideration received by us for such unregistered securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

- 1. In December 2017, we issued and sold 2,735,320 Series B convertible preferred units for an aggregate purchase price of \$34,000,027.
- 2. In January 2018, we issued and sold an additional 764,281 Series B convertible preferred units for an aggregate purchase price of \$9,500,023.
- 3. In August 2018, we issued and sold an additional 24,138 Series B convertible preferred units for an aggregate purchase price of \$300,035.

- 4. In September 2019, we issued and sold 4,847,106 Series C convertible preferred units for an aggregate purchase price of \$84,824,355.
- 5. In February 2020, we issued and sold an additional 867,194 Series C convertible preferred units for an aggregate purchase price of \$15,175,895.

The offer and sale of all securities listed in this item 15 was made to a limited number of accredited investors and qualified institutional buyers in reliance upon exemptions from the registration requirements pursuant to Section 4(a)(2) under the Securities Act and Regulation D promulgated under the Securities Act. Individuals who purchased securities as described above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates issued in such transactions.

### Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit <u>Number</u>	Description of Exhibit
1.1*	Form of Underwriting Agreement
2.1*	<u>Plan of Conversion</u>
2.2*	Certificate of Conversion of Zentalis Pharmaceuticals, LLC
3.1*	<u>Certificate of Incorporation of Zentalis Pharmaceuticals, Inc. (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-237593) on April 7, 2020 and incorporated herein by reference).</u>
3.2*	Bylaws of Zentalis Pharmaceuticals, Inc. (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration No. 333-237593) on April 7, 2020 and incorporated herein by reference).
3.3*	Second Amended and Restated Limited Liability Company Agreement of Zentalis Pharmaceuticals, LLC (filed as Exhibit 3.3 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
4.1*	Amended and Restated Investors' Rights Agreement, dated as of September 6, 2019, by and among Zentalis Pharmaceuticals, LLC and the investors party thereto (filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
4.2*	Specimen Common Stock Certificate evidencing the shares of common stock (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
5.1*	Opinion of Latham & Watkins LLP
10.1*	Zentalis Pharmaceuticals, LLC 2017 Profits Interest Plan, as amended, and form of profit interest award agreement thereunder (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.2*#	2020 Incentive Award Plan and form of option agreement and restricted stock unit agreement thereunder (filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.3*#	Non-Employee Director Compensation Program (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).

Exhibit <u>Number</u>	Description of Exhibit
10.4*#	2020 Employee Stock Purchase Plan (filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.5*#	Form of Conversion Restricted Stock Award Agreement for former Class B Common Unit Holders (filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.6*	Form of Indemnification Agreement for Directors and Officers (filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.7*	<u>Lease Agreement, dated April 12, 2019, between Zeno Management, Inc. and G&amp;S Realty 1, LLC (filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).</u>
10.8*	Sublease Agreement, dated September 16, 2019, between Zeno Management, Inc. and Lundbeck La Jolla Research Center, Inc. (filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.9*	<u>Lease Agreement, dated November 12, 2015, between the Registrant and BMR-Road to the Cure, LP (filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).</u>
10.10*	First Amendment to Lease Agreement, dated December 6, 2018, between the Registrant and BMR-Road to the Cure, LP (filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.11*	<u>Lease Agreement, dated January</u> 14, 2020, between Zeno Management, Inc. and ARE-SD Region NO. 44, LLC (filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.12*#	Amended and Restated Employment Agreement, dated February 1, 2019, by and between Zeno Management, Inc. and Anthony Y. Sun, M.D. (filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.13*#	Amendment to Amended and Restated Employment Agreement, dated February 25, 2020, by and between Zeno Management, Inc. and Anthony Y. Sun, M.D. (filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.14*#	Employment Agreement, dated September 5, 2019, by and between the Zeno Management, Inc. and Melissa Epperly (filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.15*#	Employment Agreement, dated February 1, 2019, by and between Zeno Management, Inc. and Kevin Bunker, Ph.D. (filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.16*#	Amendment to Employment Agreement, dated February 25, 2020, by and between Zeno Management, Inc. and Kevin Bunker, Ph.D. (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.17*#	Employment Agreement, dated February 1, 2019, by and between Zeno Management, Inc. and Robert Winkler, M.D. (filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).

Exhibit <u>Number</u>	Description of Exhibit
10.18*#	Consulting Agreement, dated February 1, 2019, by and between Zeno Management, Inc. and Cam Gallagher (filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.19*#	Amended and Restated Consulting Agreement, dated February 25, 2020, by and between Zeno Management, Inc. and Cam Gallagher (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.20*#	Employment Agreement, dated March 25, 2020, by and between Zeno Management, Inc. and Dimitris Voliotis, M.D. (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.21*†	Second Amended and Restated License Agreement, dated September 6, 2019, between the Registrant and Recurium IP Holdings, LLC (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1 (Registration No. 333-236959) on March 30, 2020 and incorporated herein by reference).
10.22*	Release Agreement by and between Zeno Management, Inc. and Robert Winkler, M.D.
10.23	Agreement for Termination of Lease and Voluntary Surrender of Premises, dated July 27, 2020, by and between Zeno Management, Inc. and ARE-SD-Region NO. 44, LLC
21.1*	Subsidiaries of the Registrant
23.1	Consent of Independent Registered Public Accounting Firm
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

Previously filed.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

# Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

<sup>#</sup> Indicates management contract or compensatory plan.

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

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

# **SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on this 28th day of July, 2020.

# ZENTALIS PHARMACEUTICALS, INC.

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

Anthony Y. Sun, M.D.
Chief Executive Officer, President and Chairman

# SIGNATURES AND POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Anthony Y. Sun, M.D. Anthony Y. Sun, M.D.	Chief Executive Officer and Chairman (principal executive officer)	July 28, 2020
/s/ Melissa B. Epperly Melissa B. Epperly	Chief Financial Officer (principal financial officer and principal accounting officer)	July 28, 2020
* Cam S. Gallagher	_ Director	July 28, 2020
* Kimberly Blackwell, M.D.	_ Director	July 28, 2020
* Karan S. Takhar	_ Director	July 28, 2020
* David M. Johnson	_ Director	July 28, 2020
*By: Anthony Y. Sun, M.D.  Attorney-in-fact		

# AGREEMENT FOR TERMINATION OF LEASE AND VOLUNTARY SURRENDER OF PREMISES

This Agreement for Termination of Lease and Voluntary Surrender of Premises (this "**Agreement**") is made and entered into as of July 14, 2020, by and between **ARE-SD REGION NO. 44, LLC**, a Delaware limited liability company ("**Landlord**"), and **ZENO MANAGEMENT, INC.**, a Delaware corporation ("**Tenant**"), doing business as Zentalis Pharmaceuticals, with reference to the following:

### **RECITALS**

- A. Pursuant to that certain Lease Agreement dated as of January 14, 2020 (as the same may have been amended, the "Lease"), Tenant now leases from Landlord certain premises consisting of approximately 36,955 rentable square feet ("Premises") in that certain building located at 10578 Science Center Drive, San Diego, California. The Premises are more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.
  - B. The Commencement Date of the Lease has not yet occurred and Tenant has not taken possession of any portion of the Premises.
  - C. Tenant desires to terminate the Lease and Landlord has agreed to terminate the Lease, subject to the terms and conditions set forth below.
  - D. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

NOW, THEREFORE, in consideration of the foregoing and of the mutual promises made herein, and for other good and valuable consideration the receipt of which is hereby acknowledged, Landlord and Tenant agree as follows:

- 1. **Termination Date**. If the Condition Precedent is satisfied (as defined in <u>Section 6</u> below), Landlord and Tenant agree, subject to the terms and conditions set forth in this Agreement, the Lease shall terminate on the date the Condition Precedent is satisfied (the "**Termination Date**").
- 2. **Lease Modification Payment**. Within 5 business days following Tenant's delivery of an executed copy of this Agreement to Landlord, Tenant shall deliver to Landlord funds in the amount of \$928,000.00 (the "**Lease Modification Payment**"), as consideration for Landlord's agreement to enter into this Agreement and accelerate the expiration date of the term of the Lease to the Termination Date.
- 3. **Security Deposit**. Landlord and Tenant acknowledge and agree that Landlord is holding a Letter of Credit in the amount of \$168,145.25 from Tenant as the Security Deposit under the Lease. Within 10 business days after the Termination Date, Landlord shall return the Letter of Credit to Tenant without reduction.
- 4. **Termination**. After the Termination Date, Tenant shall have no further rights of any kind with respect to the Premises. Notwithstanding the foregoing, those provisions of the Lease which, by their terms, survive the termination of the Lease shall survive the surrender of the Premises and termination of the Lease provided for herein.
- 5. **No Further Obligations**. Landlord and Tenant each agree that the other is excused as of the Termination Date from any further obligations under the Lease with respect to the Premises, excepting only such obligations under the Lease which are, by their terms, intended to survive termination of the Lease. In addition, nothing herein shall be deemed to limit or terminate any common law or statutory rights Landlord may have with respect to Tenant in connection with violations of any governmental requirements or requirements of applicable law.



Copyright © 2005, Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary – Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc. 6. **Condition Precedent**. Notwithstanding anything to the contrary contained in this Agreement, Tenant and Landlord acknowledge and agree that the effectiveness of this Agreement shall be subject to the following condition precedent ("**Condition Precedent**") having been satisfied: Landlord shall have entered into a lease agreement with a third party ("**New Tenant**") on or before August 7, 2020, pursuant to which New Tenant agrees to lease the Premises, which lease agreement shall be on terms and conditions acceptable to Landlord, in Landlord's sole and absolute discretion. In the event that the Condition Precedent is not satisfied on or before August 7, 2020, either, Landlord or Tenant shall have the right to terminate this Agreement upon delivery of written notice to the other, in which case this Agreement shall be null and void and of no further force or effect, except for the immediately following paragraph of this Section 6 which shall survive such termination, and Landlord shall reimburse to Tenant the full amount of the Lease Modification Payment. Landlord shall have no liability whatsoever to Tenant relating to or arising from Landlord's inability or failure to cause the Condition Precedent to be satisfied.

Landlord and Tenant acknowledge and agree that (a) because of Tenant's desire to terminate the Lease as provided in this Agreement, Landlord suspended its performance of Landlord's Work under the Lease, and (b) if this Agreement is terminated pursuant to the terms of the immediately preceding paragraph, then the "Target Commencement Date" under the Lease is hereby extended to March 31, 2021.

- 7. **Acknowledgment**. Tenant acknowledges that it has read the provisions of this Agreement, understands them, and is bound by them. Time is of the essence in this Agreement.
- 8. **No Assignment**. Tenant represents and warrants that Tenant has not assigned, mortgaged, subleased, pledged, encumbered or otherwise transferred any interest in the Lease and that Tenant holds the interest in the Premises as set forth in the Lease as of the date of this Agreement.
- 9. **No Modification**. This Agreement may not be modified or terminated except in writing signed by all parties. This Agreement may be signed in counterparts which taken together shall constitute one agreement binding upon the parties.
- 10. **Successors and Assigns**. The covenants and agreements herein contained shall inure to the benefit and be binding upon the parties and their respective successors and assigns.
- 11. **Attorneys' Fees**. In the event of a dispute between the parties, the prevailing party shall be entitled to have its reasonable attorneys' fees and costs paid by the other party.
  - 12. Conflict of Laws. This Agreement shall be governed by the laws of the state in which the Premises are located.
- 13. **OFAC**. Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of this Agreement remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.



Copyright © 2005, Alexandria Real Estate Equities, Inc. ALL RIGHTS RESERVED. Confidential and Proprietary – Do Not Copy or Distribute. Alexandria and the Alexandria Logo are registered trademarks of Alexandria Real Estate Equities, Inc. 14. **Counterparts**. This Agreement may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Agreement and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

### TENANT:

### ZENO MANAGEMENT, INC.,

a Delaware corporation

By: /s/ Anthony Sun

Its: CEO

### LANDLORD:

### ARE-SD REGION NO. 44, LLC,

a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,

a Delaware limited partnership,

managing member

By: ARE-QRS CORP.,

a Maryland corporation, general partner

By: /s/ Gary Dean

Its: EVP-RE Legal Affairs



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# **Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 6, 2020 in the Registration Statement on Form S-1 and related Prospectus of Zentalis Pharmaceuticals, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

San Diego, California July 27, 2020