Zosano Pharma Corp
Form 10-K
March 25, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-36570
ZOSANO PHARMA CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	45-4488360
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

34790 Ardentech Court
Fremont, CA 94555
(Address of principal executive offices) (Zip Code)
(510) 745-1200
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, par value $0.0001 per share	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated

filer" and "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	x		

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2018 (the last business day of the registrant's most recently completed second quarter) was approximately $42,236,103.

As of March 7, 2019, the registrant had a total of 11,973,039 shares of its common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

No documents are incorporated by reference into this Annual Report Form on 10-K.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "intend," "seek," "plan," "a "believe," "estimate," "project," "predict," "potential," or the negative of those terms, and similar expressions and comparable terminology intended to reference future periods. Forward-looking statements include, but are not limited to, statements about:

- the anticipated timing, costs and conduct of our planned clinical trials and preclinical studies, as applicable, for our candidate, Qtrypta™ M207;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- our expectations regarding the clinical effectiveness and safety of our product candidate;
- the ability to obtain and maintain regulatory approval of our product candidate, and the labeling for any approved product;
- our manufacturing capabilities and strategy, and our ability to establish and maintain relationships with contract manufacturing organization(s) to expand our manufacturing capacity;
- our intellectual property position and our ability to obtain and maintain intellectual property protection for our product candidate;
- our expectations regarding competition;
- the anticipated trends and challenges in our business and the markets in which we operate;
- the scope, progress, expansion, and costs of developing and commercializing our product candidate;
- the size and growth of the potential markets for our product candidate and the ability to serve those markets;
- the rate and degree of market acceptance of our product candidate;
- our ability to establish and maintain development partnerships;
- our ability to attract or retain key personnel;
- our expectations regarding federal, state and foreign regulatory requirements; and
- regulatory developments in the United States and foreign countries.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth below in Item 1A, "Risk Factors," and in our other reports filed with the U.S. Securities Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report.

Unless the context otherwise indicates, references in this Annual Report to the terms "Zosano", the "Company", "we", "our" and "us" refer to Zosano Pharma Corporation.

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PART I

Item 1. BUSINESS

Overview

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM, technology. In February 2017, we announced positive results from our ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated Qtrypta™ (M207), which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. In February 2019, we announced the completion of the final milestone in our long-term safety study for Qtrypta™ (M207). We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, in markets where patients remain underserved by existing therapies.

ADAM is our proprietary, investigational intracutaneous delivery system designed to offer rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. ADAM consists of an array of drug-coated titanium microneedles mounted on an adhesive backing that is pressed on to the skin using a reusable handheld applicator. The microneedles penetrate the stratum corneum and allow the drug to be absorbed into the microcapillary system of the skin. We focus on developing products based on our ADAM technology for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, in markets where there is a need for more effective therapies.

Our development efforts are currently focused on our product candidate, Qtrypta™ (M207). Qtrypta™ (M207) is our proprietary formulation of zolmitriptan delivered utilizing our ADAM technology. Zolmitriptan is one of a class of serotonin receptor agonists known as triptans and is used as an acute treatment for migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. The objective of Qtrypta™ (M207) is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding exposure to the gastrointestinal ("GI") tract. Feedback from the United States Food and Drug Administration ("FDA") on Qtrypta™ (M207)’s regulatory path has confirmed that one positive pivotal efficacy study, in addition to the required safety study, is sufficient for submission of a New Drug Application, ("NDA"), seeking approval of Qtrypta™ (M207) for the treatment of migraine, if the results are favorable.

ZOTRIP Phase 2/3 Trial Results

The ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of Qtrypta™ (M207) (1.0mg, 1.9mg, and 3.8mg) to placebo for the treatment of a single migraine attack. As illustrated in the table below, the ZOTRIP trial results showed that the 3.8mg Qtrypta™ (M207) dose demonstrated statistically significant greater pain freedom and most bothersome symptom freedom at two hours, the co-primary endpoints of the study.

ZOTRIP Trial Primary Endpoints Results

Primary endpoint	Placebo	3.8mg M207	p-value*
Pain freedom at 2 hours	14.3%	41.5%	0.0001
Most bothersome symptom freedom at 2 hours	42.9%	68.3%	0.0009

* The "p" value is the probability of an event occurring by chance alone.

The 3.8mg dose also achieved statistical significance in the secondary endpoints of pain freedom at 45 minutes and 60 minutes and showed durability of effect on pain freedom at 24 and 48 hours. While the 1.0mg and 1.9mg doses of Qtrypta™ (M207) demonstrated statistical significance in pain freedom at two hours, they did not demonstrate statistical significance in freedom from most bothersome symptom at two hours.

ZOTRIP Trial Secondary Endpoints Results

Pain Freedom	Placebo	3.8mg M207	p-value*

Pain freedom at 45 minutes	5.2%	17.1%	0.0175
Pain freedom at 60 minutes	10.4%	26.8%	0.0084
Pain freedom at 24 hours	39.0%	69.5%	0.0001
Pain freedom at 48 hours	39.0%	64.6%	0.0013

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* The “p” value is the probability of an event occurring by chance alone. When the p value is less than 5% (0.05) the results are considered to be statistically significant.

Qtrypta™ (M207) was generally well-tolerated with no serious adverse events ("SAE") reported in the ZOTRIP study. The most frequently reported adverse event are shown in the following table:

Most Frequent Adverse Events (≥4% for any treatment group)

	Placebo	ZP-Zolmitriptan 1 mg	ZP-Zolmitriptan 1.9 mg	ZP-Zolmitriptan 3.8 mg
General disorders and administration site conditions				
Application site erythema	10.8 %	16.3 %	19.5 %	26.5 %
Application site bruise	3.6 %	6.3 %	13.8 %	14.5 %
Application site pain	1.2 %	2.5 %	2.3 %	9.6 %
Application site bleeding	— %	3.8 %	5.7 %	4.8 %
Dizziness	— %	1.3 %	— %	4.8 %

M207 Long Term Safety Study

In November 2017, we announced the initiation of enrollment in our long-term safety study for Qtrypta™ (M207) as an acute treatment of migraine (“M207-ADAM”). M207-ADAM was an open label study evaluating the safety of the 3.8mg dose of Qtrypta™ (M207) in migraine patients who had historically experienced at least two migraines per month. Patients were expected to treat a minimum of two migraines per month on average, with no maximum treatment limits. The study was conducted at 31 sites in the United States with a defined data set per protocol in which 150 subjects received repeated doses for six months and 50 subjects received repeated doses for one year. The study was open-label, with investigator visits at months one, two, three, six, nine and twelve to record adverse events, if any. The primary objective of M207-ADAM was to assess safety of Qtrypta™ (M207) during repeated use over six and twelve months. Other endpoints were electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response.

In October 2018, we announced the completion of the first phase of our long-term safety study with more than 150 evaluable subjects completing six months of treatment with Qtrypta™. In February 2019, we announced the completion of the second phase of our long-term safety study with more than 50 evaluable subjects completing one year of treatment with Qtrypta™. Throughout the clinical program, as of February 2019, over 5,800 migraine attacks have been treated with Qtrypta™. Investigators reported 831 adverse events, of which 297 were reported as application site reactions and 161 were reported as treatment related adverse events. As of February 2019, following treatment with Qtrypta™, 44% of patients reported pain freedom at two hours, 68% of patients reported relief from most bothersome symptom, while pain relief at two hours was reported for 81% of migraine attacks treated.

Our Strategy

Our goal is to make intracutaneous drug delivery a preferred delivery modality for indications where fast onset provides a therapeutic benefit to patients. Our near-term focus is the continued development of our lead product candidate, Qtrypta™ (M207). The key elements of our strategy are to:

- Develop and commercialize Qtrypta™ (M207). We believe that Qtrypta™ (M207), if approved by the FDA, will offer significant therapeutic and practical advantages as compared to existing migraine therapeutics, including its rapid onset, ease of use and stability. We have retained worldwide commercial rights to Qtrypta™ (M207). While we currently intend to develop Qtrypta™ (M207) through FDA approval and commercialization in the United States

ourselves, we are also considering collaborations with potential strategic partners to maximize the strategic value of our product and our company.

- Focus on regulatory support and market opportunities for Qtrypta™ (M207). We intend to focus our resources on the clinical and other studies, including our long-term safety study, required for NDA filing and, if approved, would support market acceptance and expansion for Qtrypta™ (M207).
- Pursue indications outside migraine. We have performed initial feasibility studies on a number of compounds and have observed that our ADAM intracutaneous delivery system may have potential applications for use with large molecules, small molecules, and vaccines. These programs are in CNS and other therapeutic indications, where rapid drug delivery could

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provide a therapeutic benefit to patients. We are pursuing these indications ourselves but would also consider collaborations with strategic partners to further the clinical and commercial development of such product candidates.

Qtrypta™ (M207) for Migraine

The focus of our development efforts is on our product candidate Qtrypta™ (M207), our proprietary formulation of zolmitriptan, a class of serotonin receptor agonists known as triptans, used for the treatment of migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. Our Qtrypta™ (M207) intracutaneous delivery system is applied to an individual's upper arm to deliver zolmitriptan to the circulation, with the objective of providing rapid absorption of drug and sustained freedom of migraine symptoms while avoiding exposure to the GI tract.

According to the Migraine Research Foundation, migraine is the third most prevalent illness in the world. Migraine affects approximately 39 million people in the United States, representing approximately 18% of women, 6% of men and 10% of children in the country. Nearly one in four United States households includes someone who suffers from migraine. Migraines often last between four and 24 hours, but they may last as long as three days. According to published studies, 63% of migraine patients experience one or more migraines per month and 48% of migraine attacks occur in early morning and are already at peak intensity on awakening. Physicians recommend treating migraine at earliest detection. However, because treatment for morning migraines is often delayed, these migraines can be more difficult to treat.

The Migraine Research Foundation provides that, among women, who are disproportionately affected by migraine, 25% of migraine sufferers experience four or more severe attacks per month. Migraine attacks are estimated to lead to lost productivity costs as high as $36 billion annually in the United States and, in 2015, the medical cost of treating chronic migraine was more than $5.4 billion. In addition, more than 90% of migraine sufferers are unable to work or function normally during an attack.

We believe that each of the currently available methods of non-oral administration, including nasal spray and subcutaneous injection, have significant disadvantages. Nasal sprays have been associated with taste disturbances. Patients are hesitant to self-administer injections and thus primarily seek an injectable triptan at an urgent care setting or at the physicians' office. There are other delivery technologies in development, such as pulmonary delivery. However, none has been approved to date.

ZOTRIP Phase 2/3 Trial achieved statistical significance on co-primary endpoints with the 3.8mg dose

On February 13, 2017 the Company announced the results of our ZOTRIP pivotal efficacy trial for Qtrypta™ (M207). Our ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of Qtrypta™ (M207) (1.0mg, 1.9mg, and 3.8mg) to placebo for the treatment of a single migraine attack. Subjects were enrolled in the ZOTRIP trial at 36 centers across the United States. Those subjects recruited into the trial had a history of at least one year of migraine episodes with or without aura. Upon recruitment, the subjects entered a one-month run-in period that ensured they met the key eligibility criteria of two to eight migraine attacks per month, which was documented using an electronic diary or an app on their cell phone. Subjects also identified the most bothersome symptoms and indicated the presence or absence of nausea, phonophobia or photophobia, during the episodes in the run-in period. Successfully screened subjects were then randomized into the treatment/dosing period in which they had 8 weeks to confirm and receive blinded treatment for a single migraine attack, termed "qualifying migraine," in which the subject's most bothersome symptom had to be present. During a qualifying migraine, subjects scored the severity of pain on a 4-point scale, the presence or absence of migraine-associated symptoms (phonophobia, photophobia, or nausea), starting pre-dose and then at several intervals over 48 hours post-dose.

The co-primary endpoints for the trial were those defined in the October 2014 FDA Draft Guidance—"Migraine: Developing Drugs for Acute Treatment" as pain freedom and most bothersome symptom freedom at two hours. Safety was assessed by adverse events reported and other standard safety measures.

589 subjects were enrolled in the ZOTRIP trial, of which 365 were randomized. Of those randomized, 333 subjects were treated and are included in the safety analysis, and 321 qualified for the modified intent-to-treat ("mITT") population. With the multiple doses and multiple endpoints in the trial, a sequential testing procedure was used

beginning with the highest dose and the co-primary endpoints. Since statistical significance was not achieved for most bothersome symptom in the 1.9 mg group, statistical significance cannot be claimed for testing thereafter. Therefore, p-values for secondary endpoints should be considered nominal p-values.

As illustrated in the tables and figure below, the ZOTRIP trial results demonstrated that the 3.8mg Qtrypta™ (M207) dose achieved statistically significant pain freedom and most bothersome symptom freedom at two hours. The 3.8mg dose also achieved statistical significance in the secondary endpoints of pain freedom at 45 minutes and 60 minutes and showed durability of effect on pain freedom at 24 and 48 hours. Additionally, Qtrypta™ (M207) was not associated with any SAEs. While the 1.0mg and 1.9mg doses of Qtrypta™ (M207) demonstrated statistical significance in pain freedom at two hours, they did not achieve statistical

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significance in freedom from most bothersome symptom at two hours. Statistical significance is an indicator of the likelihood of an observed effect being due to the study drug rather than due to chance. The “p” value is the probability of an event occurring by chance alone. When the p value is less than 5% (0.05) the results are considered to be statistically significant.

ZOTRIP Trial Co-Primary Endpoint Results for 3.8mg

Primary endpoint	Placebo	3.8mg M207	p-value
Pain freedom at 2 hours	14.3%	41.5%	0.0001
Most bothersome symptom free at 2 hours	42.9%	68.3%	0.0009

ZOTRIP Trial Secondary Endpoint Results for 3.8mg

Pain Freedom	Placebo	3.8mg M207	p-value
Pain freedom at 45 minutes	5.2%	17.1%	0.0175
Pain freedom at 60 minutes	10.4%	26.8%	0.0084
Pain freedom at 24 hours	39.0%	69.5%	0.0001
Pain freedom at 48 hours	39.0%	64.6%	0.0013

Qtrypta™ (M207) was generally well-tolerated with no SAEs reported in the ZOTRIP trial. The most frequently reported adverse event was redness at the application site (18.3% of subjects) and all cases of redness resolved. Thirteen subjects (3.9%) reported pain at the application site; with application site pain reported as mild in all but three subjects. Additionally, five (1.5%) subjects across Qtrypta™ (M207)-treated groups reported dizziness versus zero subjects in the placebo group, and four (1.2%), subjects across Qtrypta™ (M207)-treated groups reported nausea whereas zero subjects in the placebo group reported this event.

The ZOTRIP trial results demonstrating pain freedom after treatment with Qtrypta™ (M207) are illustrated below:

Preplanned sub group analysis:

Pain Freedom at 2 Hours	Placebo	3.8mg M207	p-value
All Subjects	14.3%	41.5%	0.0001
Morning Migraine	15.9%	44.4%	0.0056

Sustained Pain Freedom	Placebo	3.8mg M207	p-value*
2 – 24 Hours	10.4%	31.7%	0.001
2 – 48 Hours	9.1%	26.8%	0.0035

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Pain Relief	Placebo	3.8mg M207	p-value*
1 Hour	53.2%	68.3%	< 0.05
2 Hours	57.1%	80.5%	< 0.05

Sustained Pain Relief	Placebo	3.8mg M207	p-value*
2 – 24 Hours	37.7%	68.3%	< 0.0001
2 – 48 Hours	32.5%	63.4%	< 0.0001

Nausea Freedom	Placebo	3.8mg M207	p-value*
2 Hours	63.6%	81.7%	< 0.05

* The "p" value is the probability of an event occurring by chance alone. p-values are nominal because of order of statistical testing.

Qtrypta™ (M207) Long Term Safety Study

In November 2017, we announced the initiation of enrollment in our long-term safety study for Qtrypta™ (M207) as an acute treatment of migraine. M207-ADAM was an open label study evaluating the safety of the 3.8mg dose of Qtrypta™ (M207) in migraine patients who had historically experienced at least two migraines per month. Patients were expected to treat a minimum of two migraines per month on average, with no maximum treatment limits. The study was conducted at 31 sites in the United States with a defined data set per protocol in which 150 subjects received repeated doses for six months and 50 subjects received repeated doses for one year. The study was open-label, with investigator visits at months one, two, three, six, nine and twelve to record adverse events, if any. The primary objective of M207-ADAM was to assess safety of Qtrypta™ (M207) during repeated use over six and twelve months. Other endpoints included electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response.

In October 2018, we announced the completion of the first phase of our long-term safety study with more than 150 evaluable subjects completing six months of treatment with Qtrypta™. In February 2019, we announced the completion of the second phase of our long-term safety study with more than 50 evaluable subjects completing one year of treatment with Qtrypta™. Throughout the clinical program, as of February 2019, over 5,800 migraine attacks have been treated with Qtrypta™. Investigators reported 831 adverse events, of which 297 were reported as application site reactions and 161 were reported as treatment related adverse events. As of February 2019, following treatment with Qtrypta™, 44% of patients reported pain freedom at two hours, 68% of patients reported relief from most bothersome symptom, while pain relief at two hours was reported for 81% of migraine attacks treated.

Our Research Programs

Our internal research and development programs use molecules with demonstrated safety and efficacy that are formulated to enable delivery through our proprietary ADAM technology. In selecting our development candidates, we consider the therapeutic advantage of rapid onset, the size of the market, the level of competition and the potential selling price.

Our ADAM technology patch consists of a $3cm^2$ to $6cm^2$ array of titanium microneedles approximately 200-350 microns in length, coated with a hydrophilic formulation of drug, and attached to an adhesive patch. The maximum amount of drug that can be coated on a patch's microneedle array depends on the active molecule of the drug formulation, the weight of the excipients in the drug formulation, and the coatable surface area of the microneedle array. For example, we use patches with $2cm^2$, $3cm^2$ and $6cm^2$ microneedle arrays. In the pivotal trial for Qtrypta™ (M207), we used two $3cm^2$ patches to deliver the appropriate dose. Based on our testing, we believe 3.8mg of zolmitriptan could also be coated on a single patch with a $6cm^2$ microneedle array while maintaining acceptable tolerability. The patch is applied with a hand-held applicator that presses the microneedles into the skin to a uniform depth in each application, close to the capillary bed, allowing for dissolution and absorption of the drug, but not deep

enough to contact the nerve endings in the skin. The typical patch wear time is generally thirty to sixty minutes. We have tested our ADAM technology in preclinical and clinical proof of concept studies that demonstrated its technical feasibility with multiple compounds, ranging from small molecules to proteins. Based on this research, we believe that our ADAM technology can be used to deliver treatments for a wide variety of indications in which rapid absorption can enhance onset of efficacy and sustainability of effect. That coupled with ease of use might offer particularly important therapeutic, practical, and commercial advantages over existing options.

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Competition

Competition for our product candidate

The development and commercialization of new products to treat migraine is highly competitive. We expect to have considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have substantially greater financial, technical and other resources than we do. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization.

Companies marketing products that treat migraine that may compete with our Qtrypta™ (M207) product candidate include Teva Pharmaceutical Industries, Inc., GlaxoSmithKline plc, Eli Lilly & Company, AstraZeneca plc, Allergan, Inc., Biohaven Pharmaceuticals, Alder Biopharmaceuticals, Amgen Inc. and Promius Pharma, LLC.

Competition in drug delivery platforms

In addition to competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies that develop and market products that compete against those that we develop, we face additional competition from companies that may develop and license drug delivery platforms similar to ours, and from alternative formulations and methods of delivery of the drugs on which we have focused, including oral formulations, nasal sprays, intracutaneous patches, intramuscular and subcutaneous injections and infusions. Such companies include, but are not limited to, 3M Company, Endo Pharmaceuticals, Corium International, Inc. and Pantec Biosolutions AG.

Research and Development and Manufacturing

As of December 31, 2018, our research and development group consisted of 38 employees, located in our headquarters in Fremont, California. Our research and development staff have broad knowledge and skills in a range of disciplines applicable to formulation of drugs and the design and manufacture of our ADAM technology. Our research and development group has particular expertise in two areas critical to our success: developing drug formulations that can be delivered using our ADAM technology and optimizing the technology to deliver those drugs. The goals of our research and development efforts are to identify and develop drugs that can be delivered using our intracutaneous delivery system. In the years ended December 31, 2018 and 2017, we incurred $25.5 million and $20.1 million, respectively, of research and development expense. See Part II–Item 7–“Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report for additional detail regarding our research and development activities.

We operate a manufacturing facility in Fremont, California, designed to comply with current good manufacturing practices ("cGMP") and believe we have adequate manufacturing capabilities and capacity to produce our ADAM technology for preclinical and Phase 1 and Phase 2 clinical trials, and for some Phase 3 trials. We continue to expand our manufacturing capabilities and have implemented automation of certain processes to further expand our capacity. We produced 3 cGMP registration batches of Qtrypta™ (M207) in the third quarter of 2018, which will be used to support our NDA filing with the FDA. We purchase various components or intermediates of our ADAM technology from third party vendors, including titanium foil, active pharmaceutical ingredients and excipients, inner ring, adhesive backing, ring and backing assembly, outer ring and primary and secondary packing components. The majority of these components and intermediaries are available from multiple sources. We also outsource the manufacturing of our applicators.

The manufacturing process for our ADAM technology patch consists of two primary operations: (1) the formation of the microneedle array, involving etching of titanium foil and subsequent pad-forming; and (2) application of the drug formulation to the microneedle array.

Intellectual Property

Our strategy is to rely on a combination of patent, trade secret and trademark laws in the United States and other jurisdictions, and to rely on license and confidentiality agreements to protect our proprietary technology and brand. The laws of some countries in which our products are licensed may not protect our intellectual property rights to the same extent as the laws of the United States.

As of January 8, 2019, we held exclusive licenses to or owned 25 United States patents and 6 pending United States patent applications, as well as one pending Patent Cooperation Treaty patent application, covering key features of our intracutaneous delivery system, such as formulation, methods of treatment, coating, array design, patch anchoring, patch application, delivery, manufacturing and packaging.

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We license all of these patents and patent applications, other than an issued US patent and 3 pending US, a European and international-applications covering the formulation of Qtrypta™ (M207); and 2 US and 1 EP patents, a pending US and a pending EP application covering stable glucagon peptide formulation and a new applicator design described below, from ALZA Corporation, a subsidiary of Johnson & Johnson ("ALZA"), on an exclusive basis for all countries. These patents and patent applications are foundational and apply generally to our product candidate and its related applicator. Under the terms of the license agreement with ALZA, we are responsible for all development and development costs related to our intracutaneous delivery system. We are also responsible for commercializing our intracutaneous delivery system, including preparing and paying for all related regulatory filings. We are obligated to pay ALZA royalties in the low to mid-single digits on sales by us of products that would otherwise infringe one of the licensed patents or that is developed by us based on certain ALZA know-how or inventions, and to pay ALZA amounts equal to the greater of royalties in the low to mid- single digits on sales by our sublicensees of such products or a percentage in the mid-tens to low twenties of royalties received by us on sales by our sublicensees of such products. We are also obligated to pay ALZA a percentage of non-royalty revenue that we receive from our sublicensees based on sales of such products. The license agreement will terminate upon the expiration of our obligations to make the royalty and other payments described above to ALZA. Additionally, we may terminate the agreement at any time for convenience upon prior written notice to ALZA, and either party may terminate the agreement upon a material breach of the agreement by the other party.

We have filed six pending United States patent applications, two pending European applications, a pending Patent Cooperation Treaty application covering our single-use applicator and formulations of zolmitriptan and stable glucagon peptide. The last of our issued technology platform patents are projected to expire in 2027.

We rely on trade secrets to protect substantial portions of our technology. We generally seek to protect these trade secrets by entering into non-disclosure agreements and other contractual provisions with our employees, consultants and partners, and have restricted access to our manufacturing facilities and other technology.

We have one registered trademark to Zosano, “ZOSANO PHARMA,” Reg. No. 3705884 and six pending trademark applications: Trademark App. No. 87525805 for "ADAM," Trademark App. No. 87851807 for "QNOVIS," Trademark App. No. 87851814 for "QTRYPTA," Trademark App. No. 87855458 for "TIZOVIAL," Trademark App. No. 87855469 for "QIXONTI," and Trademark App. No. 87855481 "AXILARIM."

Government Regulation and Product Approval

United States—FDA Process

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are subject to extensive regulation by governmental authorities in the United States and other countries. Our product candidate is subject to regulation by the FDA as a drug/device combination product. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. To facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. The determination whether a product is a combination product, or two separate products is made by the FDA on a case-by-case basis. We have discussed our development strategy with the FDA on our Qtrypta™ (M207) program and we believe the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our product candidate. Accordingly, we have investigated Qtrypta™ (M207) through the Investigational New Drug ("IND") framework and plan to seek approval through the NDA pathway. Based on our discussion with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the device component of Qtrypta™ (M207), but this could change during its review of any marketing application that we may submit.

In the United States, the FDA regulates drugs and devices pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending marketing applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Drug Approval Process

None of our product candidates may be marketed in the United States until the product has received FDA approval. The steps to be completed before a drug may be marketed in the United States include:

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- preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials in the U.S. may begin and must be updated annually;
- approval by an independent institutional review board ("IRB"), at each clinical trial site before each trial may be initiated;
- adequate and well-controlled human clinical trials, in accordance with good clinical practice ("GCP") requirements, to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of an NDA;
- FDA acceptance and review of the NDA, which may require an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and
- FDA approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The results of the preclinical tests, together with manufacturing information, analytical data, product chemistry, controls and a proposed clinical trial protocol, are submitted to the FDA as part of an IND, which must become effective before human clinical trials in the U.S. may begin. An IND will automatically become effective thirty days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. We submitted an IND for Qtrypta™ (M207) in the second quarter of 2016.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials necessary for product approval are typically conducted in the following three sequential phases, but the phases may overlap.

- Phase 1: In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

- Phase 2: Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

- Phase 3: Phase 3 trials help obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances.

Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication or otherwise when requested by the FDA in the form of post-market commitments. Failure to promptly conduct any required Phase 4 post-market studies could result in withdrawal of approval.

The trial protocol and informed consent information for trial subjects in clinical trials must also be approved by an IRB for each institution where the trials will be conducted, and each IRB must monitor the trial until completion. Trial subjects must sign an informed consent form before participating in a clinical trial. Clinical testing also must comply with extensive laws, rules and GCP regulations, including requirements for informed consent, and laws and regulations governing privacy of individually identifiable information.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions

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governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA reviews any NDA submitted to ensure that it is sufficiently complete for substantive review before the FDA accepts the NDA for filing.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that such NDA is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept the NDA for filing. FDA reviews NDAs through a two-tiered classification system, Standard Review and Priority Review. The FDA endeavors to review Standard Review applications within ten to twelve months, whereas FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity. Even if the NDA is filed, companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of an NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized. Further, the FDA may place conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the benefits of the drug outweigh the potential risks. If the FDA requires a REMS, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS 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. If a REMS is required as part of any commercialization effort, it could materially affect the potential market and profitability of a drug. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless the manufacturing is in compliance with cGMP regulations. If the FDA does not approve of the NDA or the manufacturing facilities, it will issue a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information required for the FDA to reconsider the application. If the NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug’s safety or efficacy or impose other conditions. Approval may also be contingent on an approved REMS that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. Drugs may be marketed only for the approved indication(s) and in accordance with the provisions of the approved label.

In addition, under the Pediatric Research Equity Act (“PREA”), an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is

safe and effective. The FDA has indicated that our product candidate Qtrypta™ (M207) is covered by the PREA, but the FDA may, on its own initiative or at the request of an applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical trials be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements

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Oftentimes, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical trials. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. This latter effort includes assessment of ongoing compliance with cGMP regulations. We have used and intend to continue to use third party manufacturers to produce active pharmaceutical ingredients, ("API"), for our product candidate in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, discovery of problems with a product after approval may result in restrictions on a product, including withdrawal of the product from the market. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of the drug.

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

Hatch-Waxman Act

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman Amendments, which provide alternative pathways to regulatory approval through section 505(i) and 505(b)(2) of the FDCA, were enacted. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(i) permits applicants with generic drug products to submit an abbreviated new drug application ("ANDA") in reliance upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. Under these pathways, the FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by Section 505(b)(2) applicant. We anticipate seeking approval of our product candidate through a 505(b)(2) NDA.

To the extent that an ANDA or Section 505(b)(2) applicant is relying on studies conducted for an already approved product, which is referred to as the Reference Listed Drug, the applicant is required to certify to the FDA concerning any listed patents in the FDA's Orange Book publication that relate to the Reference Listed Drug. Specifically, the applicant must certify for all listed patents one of the following certifications: (i) the required patent information has not been filed by the original applicant; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. A

certification that the new product will not infringe the Reference Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the new application. The application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Referenced Listed Drug has expired.

If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the Reference Listed Drug once the applicant’s NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or Section 505(b)(2) NDA by imposing a 30-month automatic stay on approval, which may be shortened by the court in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30-month stay terminates if a court issues a final order determining that the patent is invalid, unenforceable or not infringed. Alternatively, if the listed patent

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holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

The Hatch-Waxman Act provides five years of data exclusivity for new chemical entities which prevents the FDA from accepting ANDAs and 505(b)(2) applications, including Section 505(b)(2) NDAs, containing the protected active ingredient. The Hatch-Waxman Act also provides three years of market exclusivity for applications containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new uses of approved products such as new indications, delivery mechanisms, dosage forms, strengths, or conditions of use. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, the FDA can accept an application and begin the review process during the three-year exclusivity period.

Coverage, Pricing and Reimbursement

Sales of products that we may market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of coverage and the level of reimbursement from third party payers such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and also the out-of-pocket obligations of member patients for such products. In addition, particularly in the United States and increasingly in other countries, we will be required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of any of our products, if approved, that are reimbursed by such entities. We have consciously selected compounds for development that offer therapeutic benefit based on fast onset of action. If our product candidate is approved by the FDA, we intend to work with payers to demonstrate the clinical benefits of our products over other delivery modalities and we intend to secure adequate and commercially favorable pricing and reimbursement levels, but we cannot guarantee that coverage or adequate reimbursement will be available.

In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidate that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek coverage and reimbursement from third party payors. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One third party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third party payors may not consider our product or product candidate to be medically

necessary or cost-effective compared to other available therapies

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products or product candidates if approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third party reimbursement for our products once approved or a decision by a third party payor to not cover our products could

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reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates once approved or additional pricing pressures.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 ("ACA"), which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidate are:

- An annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- Beginning in 2013, entities that manufacture, produce or import medical devices were required to pay an excise tax in an amount equal to 2.3% of the price for which such devices are sold in the United States. Through a series of legislative amendments, the tax was suspended for 2016 through 2019, but is scheduled to return beginning in 2020, absent further Congressional action.
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of two percent (2%) per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the ACA was invalid due to the legislative repeal of the individual mandate. While the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business. There may be additional challenges and amendments to the ACA in the future. In addition, Congress could consider subsequent legislation to replace repealed elements of the ACA. At this time, the full effect of the ACA and any subsequent legislation or related regulatory action on our business remains unclear.

If we establish international operations, we will be subject to compliance with the Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA for activities by our partners, collaborators, contract research organizations, vendors or other agents.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject

to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

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Other Healthcare Laws and Compliance Requirements

Healthcare providers and third party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business, many of which may become more applicable to us if our product candidate is approved and we begin commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations, including those described below. The federal Anti-Kickback Statute, prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

The federal transparency requirements known as the federal Physician Payments Sunshine Act, under ACA, requires certain manufacturers of 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 report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf.

We are also and may become subject to analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. 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.

Employees

As of December 31, 2018, we had 53 employees, all of whom are full time, 5 of whom hold doctorate degrees in their respective scientific and pharmaceutical fields and 1 of whom holds a Doctor of Medicine degree. We make extensive

use of third party contractors, consultants and advisors to perform many of our present activities.

Special Stockholder Meeting, Reverse Split and Authorized Share Increase

On January 23, 2018, we held a special meeting of stockholders. At the special meeting, the stockholders approved, among other things, an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 100,000,000 to 250,000,000 shares. A Certificate of Amendment to the Amended and Restated Certificate of Incorporation authorizing the authorized share increase was filed with the Secretary of State of the State of Delaware on January 24, 2018, and the authorized share increase became effective in accordance with the terms of the Certificate of Amendment upon filing with the Secretary of State of the State of Delaware.

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The stockholders also approved a proposal authorizing the board of directors, in its discretion, to effect a reverse stock split of our outstanding shares of common stock at a ratio ranging from 1-for-5 to 1-for-20 to be determined by the Board of Directors and effected, if at all, no later than November 23, 2018. On January 23, 2018, following the special stockholder meeting, the board of directors approved a 1-for-20 reverse stock split of the common stock and the filing of a Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company to effectuate the reverse stock split. A Certificate of Amendment to the Amended and Restated Certificate of Incorporation authorizing the reverse stock split was filed with the Secretary of State of the State of Delaware on January 24, 2018, and the reverse stock split became effective in accordance with the terms of the Certificate of Amendment at 5:00 p.m. Eastern Time on January 25, 2018, which we refer to as the Effective Time.

At the Effective Time, every twenty shares of common stock issued and outstanding was automatically combined into one share of issued and outstanding common stock, without any change in the par value per share. The reverse stock split did not affect the number of authorized shares of common stock, which, after giving effect to the authorized share increase, is 250,000,000 shares. In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of the Company's outstanding equity awards, options and warrants to purchase shares of common stock and the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans.

Corporate Information

We were incorporated under the laws of the State of Delaware as ZP Holdings, Inc. in January 2012, and changed our name to Zosano Pharma Corporation in June 2014. Our business was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006. We were originally incorporated under the name The Macroflux Corporation, and changed our name to Zosano Pharma, Inc. in 2007 following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of ZP Holdings was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of ZP Holdings. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc. ZP Group LLC, a former subsidiary that was originally formed as a joint venture with Asahi Kasei Pharmaceuticals USA (Asahi), ceased operations in December 2013 and was dissolved on December 30, 2016. On November 1, 2017, ZP Opco, Inc. merged with and into Zosano Pharma Corporation, with Zosano Pharma Corporation as the surviving corporation of the merger.

Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. Our telephone number is (510) 745-1200. Our website address is www.zosanopharma.com. The information contained on our website is neither incorporated by reference into nor a part of this Annual Report on Form 10-K.

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Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, as well as general economic and business risks, and all of the other information contained in this Annual Report on Form 10-K and other documents that we file with the U.S. Securities and Exchange Commission, or the SEC. Any of the following risks could have a material adverse effect on our business, operating results, financial condition and prospects and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. You should also refer to the other information contained in this Annual Report on Form 10-K, including our audited financial statements and the related notes thereto.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We will need substantial additional funding to fund our operations, and we may not be able to continue as a going concern if we are unable to do so. We could also be forced to delay, reduce or terminate our product development, other operations or commercialization effort.

Developing and commercializing biopharmaceutical products, including launching new products into the marketplace and conducting preclinical studies and clinical trials, is an expensive and highly uncertain process that takes years to complete. As of December 31, 2018, we had an accumulated deficit of $261.2 million as well as negative cash flows from operating activities. As of December 31, 2018, we had approximately $23.0 million in cash, cash equivalents and marketable securities, and we do not have sufficient cash, cash equivalents and marketable securities to fund our anticipated level of operations and meet our obligations as they become due during the twelve months following the date of issuance of this Annual Report on Form 10-K. Further, to continue operations for the remainder of 2019, we will need to, and are actively seeking to, obtain additional capital resources by the end of the third quarter of 2019 through an equity offering, a debt financing, a license or collaboration agreement, or through a combination of such sources of capital. The aforementioned factors raise substantial doubt about our ability to continue as a going concern. There is no assurance that such additional funds will be obtained for our ongoing operations or that we will succeed in our future operations. Our audited financial statements included in our Annual Report for the year ended December 31, 2018 include an explanatory paragraph regarding our ability to continue as a going concern which may discourage some third parties from contracting with us and some investors from purchasing our stock or providing alternative capital financing, which could adversely affect our business, financial condition, results of operations and prospects.

We have a history of operating losses. We expect to continue to incur losses over the next several years and may never become profitable.

Since inception, we have incurred significant operating losses. For the year ended December 31, 2018 we incurred a net loss of $35.4 million. As of December 31, 2018, we had an accumulated deficit of $261.2 million. We expect to continue to incur additional significant operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue the development of our product candidate, Qtrypta™ (M207), or any other products we develop. These expenditures will be incurred for development, clinical trials, regulatory compliance, infrastructure, and manufacturing. Even if we succeed in developing, obtaining regulatory approval for and commercializing Qtrypta™ (M207) or any other products we develop, because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict that we will ever be able to manufacture, distribute and sell any of our products profitably, and we may never generate revenue that is significant enough to achieve or maintain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We have generated only limited revenues and will need additional capital to develop and commercialize our product candidate, which may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or lead product candidate.

Since inception, we have generated no revenues from product sales. We are not approved to make and have not made any commercial sales of products. We expect that our product development activities will require additional significant operating and capital expenditures resulting in negative cash flow for the foreseeable future.

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We expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. 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.

However, adequate and additional funding may not be available to us on acceptable terms or at all. 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 on our common stock.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or product candidate 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 or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our development or future commercialization efforts or partner with third parties to develop and market product candidate that we would otherwise prefer to develop and market ourselves. The amount and timing of our future financing requirements will depend on many factors, including:

- the scope, progress, expansion, and costs of manufacturing our product candidate;
- the scope, progress, expansion, costs, and results of our clinical trials;
- the timing of, and costs involved in, obtaining regulatory approvals;
- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- our ability to establish and maintain development partnering arrangements;
- the timing, receipt and amount of contingent, royalty, and other payments from any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and if approved, commercializing our product candidate;
- our ability to draw funds from our build-to-suit arrangement; and
- the costs associated with being a public company.

Our build-to-suit arrangement with Trinity Capital Fund III, L.P. (“Trinity”) imposes restrictions on our business, and if we default on our obligations, Trinity would have a right to request payment in full of the build-to-suit obligation.

We also agreed to covenants in connection with the Trinity build-to-suit arrangement that may limit our ability to take some actions without the consent of Trinity, as applicable. In particular, without Trinity’s consent under the terms of the loan facility or the secured note, as applicable, we are restricted in our ability to:

- create liens on our property;
- sell, transfer, or otherwise dispose of all or substantially all of our assets;
- transfer, dispose or relocate financed equipment;
- acquire or merge with another entity; and
- engage in a transaction that would constitute 50% or more in change in control.

Our indebtedness to Trinity may prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding obligation, which may not be desirable or possible.

We have pledged substantially all of our assets, including our intellectual property, to secure our obligations to Trinity. If we default on our obligations prior to repaying this indebtedness and are unable to obtain a waiver for such default, Trinity would have a right to accelerate our payments under the build-to-suit arrangement, as applicable, and

possibly foreclose on the collateral,

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which would potentially include our intellectual property. Any such action on the part of Trinity would significantly harm our business and our ability to operate.

We have limited operating history and capabilities.

Although our business was formed in 2006, we have had limited operations since that time. We do not currently have the ability to perform the sales, marketing and manufacturing functions necessary for the production and sale of Qtrypta™ (M207) on a commercial scale. The successful commercialization of Qtrypta™ (M207) will require us to perform a variety of functions, including:

- continuing to conduct clinical development of our product candidate;
- obtaining required regulatory approvals;
- formulating and manufacturing product; and
- conducting sales and marketing activities.

Our operations continue to be focused on acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our product candidate.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to transition at some point from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATE

The development and commercialization of our product candidate is subject to many risks. If we do not successfully develop, receive approval for, and commercialize our product candidate, our business will be adversely affected.

We have focused our clinical development efforts on our product candidate, Qtrypta™ (M207). The development and commercialization of Qtrypta™ (M207) and any product candidate we may develop and commercialize in the future is subject to many risks including:

- we may be unable to obtain additional funding to develop our product candidate;
- we may experience delays in regulatory review and approval of our product candidate in clinical development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies or trials;
- the FDA may not accept data generated at our clinical trial sites;
- we may be unable to obtain and maintain regulatory approval of our product candidate in the United States and foreign jurisdictions;
- potential side effects of our product candidate could delay or prevent commercialization, limit the indications for any approved product candidate, require the establishment of a risk evaluation and mitigation strategy, or REMS, or cause an approved product candidate to be taken off the market;
- the FDA may identify deficiencies in our manufacturing processes or facilities or those of our contract manufacturing organizations CMOs;
- the FDA may change its approval policies or adopt new regulations;
- we may need to depend on third party manufacturers to supply or manufacture our products;
- we depend on contract research organizations to conduct our clinical trials;

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- we may experience delays in the commencement of, enrollment of patients in and timing of our clinical trials;
- we may not be able to demonstrate that our product candidate is safe and effective as a treatment for its intended indications to the satisfaction of the FDA or other similar regulatory bodies;
- we may be unable to establish or maintain collaborations, licensing or other arrangements;
- the market may not accept our product candidate;
- we may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- we may experience competition from existing products or new products that may emerge; and
- we and our licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our product candidate.

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 regulatory authorities, which may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of a study. This could result in a delay in approval, or rejection, of our marketing applications. If any of these risks materializes, we could experience significant delays or an inability to successfully commercialize our product candidate, which would have a material adverse effect on our business, financial condition and results of operations.

The long-term safety study for Qtrypta™ (M207) is an important step in the development of Qtrypta™ (M207). If we cannot produce results that satisfy FDA requirements, the regulatory approval process could be delayed, and our business could be adversely affected.

In February 2019, we announced the completion of the final phase of our long-term safety study where more than 50 evaluable subjects were treated for a year. This long-term safety study will need to produce results that satisfy FDA requirements. If the results do not satisfy the FDA's requirements it could require us to delay, limit, reduce or terminate our development of Qtrypta™ (M207). Also, even though we have discussed our development strategy with the FDA on our Qtrypta™ (M207) program and received feedback from the FDA about the size and the length of the safety study, the FDA may decide to expand on the requirements that have already been provided to us, which would further delay the regulatory approval process and require additional clinical work.

If the FDA does not conclude that our product candidate satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of our product candidate under Section 505(b)(2) are not as we expect, the approval pathway for our product candidate will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful. We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our product candidate described in this Annual Report on Form 10-K. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidate, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market our product candidate. The time and financial resources required to obtain FDA approval for our product candidate would likely substantially increase. The conduct of later-stage clinical trials and the submission of a successful NDA is a complicated process. To date, we have conducted only one Phase 2/3 clinical trial and have initiated a long-term safety study of Qtrypta™ (M207), we have limited experience in preparing and submitting regulatory filings, and we have not previously submitted an NDA for any product candidate. Consequently, we may be unable to successfully and efficiently execute and complete

necessary clinical trials in a way that leads to an NDA submission for Qtrypta™ (M207) or for any other product candidate we may develop in the future.

Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidate, which could materially adversely impact our competitive position and prospects. Even

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if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite approvals for commercialization of such product candidate.

In addition, our competitors may file petitions with the FDA in an attempt to persuade the FDA that our product candidate, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Clinical trials are very expensive, time-consuming and difficult to design and implement.

Human clinical trials are very expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements, and their outcome is inherently uncertain. Furthermore, failure of a product candidate can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials.

Further, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials may be delayed by several factors, including:

- changes in government regulation, administrative action or changes in FDA policy with respect to clinical trials that change the requirements for approval;
- delays in obtaining authorization from regulators and required IRB approval at each site to commence a trial;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authority;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, or failure by such CROs or trial sites to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to end their participation in one of our clinical trials, which would likely have detrimental effect on subject enrollment;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we, the FDA, or other regulatory authorities and ethics committees with jurisdiction over our studies may terminate or suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or other authorities find deficiencies in our regulatory submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for existing or future clinical trials. Any such unexpected expenses or delays in our clinical trials could increase our need for additional capital, which may not be available on favorable terms or at all.

If we are required to conduct additional clinical trials or other testing of our product candidate beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidate or other testing, if the results of these clinical trials or tests are not positive or are only modestly positive and/or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidate;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

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- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have our product candidate(s) removed from the market after obtaining marketing approval.

Our development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring a product candidate to market before we do, and thereby impair our ability to successfully commercialize our product candidate.

The results of our clinical trials may not support the intended use of Qtrypta™ (M207) or any other product candidates we may develop.

Even if our clinical trials are completed as planned, we cannot be certain that the results will support the intended use of our products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidate is safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDA with the FDA and, ultimately, our ability to commercialize our product candidate and generate revenues. In addition, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing, early clinical trials and even later stage clinical trials, like our phase 2/3 ZOTRIP trial, does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While members of our management team have experience in designing clinical trials, we have limited experience in designing clinical trials and we may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If our product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

We may in the future conduct clinical trials for product candidates in sites around the world, and government regulators, including the FDA in the United States, may choose to not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States.

There is no guarantee that data from these clinical trials will be accepted by regulators approving our product candidate for commercial sale. In the case of the United States, although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be conducted in accordance with GCP and conducted such that the FDA is able to

validate the data from the study through an onsite inspection if deemed necessary. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials, it would likely result in the need for additional clinical trials, which would be both costly and time-consuming and likely to delay or permanently halt our development of a product candidate. Similar regulations and risks apply to other jurisdictions as well.

In addition, the conduct of clinical trials outside the United States could have a significant negative impact on us. Risks inherent in conducting international clinical trials include:

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- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

We will not be able to sell our products if we do not obtain required United States regulatory approvals.

We cannot assure you that we will receive the approvals necessary to commercialize Qtrypta™ (M207) or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidate in the United States. In order to obtain FDA approval of any product candidate, we expect that we will have to submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended indication and indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our product candidate will ultimately be considered safe for humans and effective for indicated uses by the FDA. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our products;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

We may never obtain regulatory approval for any of our product candidates. Failure to obtain approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, unless other products can be developed. There is no guarantee that we will ever be able to develop or acquire another product.

Even if Qtrypta™ (M207) or any other product candidates we develop in the future receive regulatory approval, our business is subject to extensive regulatory requirements which include ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize our products.

The manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for our product candidates will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. The regulatory approvals for our product candidate may be subject to limitations on the indicated uses for which the products may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product candidate. The FDA closely regulates the post-approval marketing and promotion of drugs and drug delivery devices to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and, if we do not market our product candidate for their approved indications, we may be subject to enforcement action for off-label marketing. The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing authorization to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which

impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also

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potentially subject to U.S. federal and state consumer protection and unfair competition laws and similar requirements in other countries.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our products, physicians may nevertheless legally prescribe our products 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 and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, later discovery of previously unknown problems with our product candidate, manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidate, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies 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, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical

activities. If a prolonged government shutdown

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occurs, 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.

We or any of our future partners may choose not to continue developing a product or product candidate at any time during development or commercialize it after approval, which would reduce or eliminate our potential return on investment for that product or product candidate.

We currently do not have any products approved for sale and currently are focusing our clinical development efforts solely on Qtrypta™ (M207). Currently, we do not have any collaborations with any partners for any of our products. At any time, we or any partners with whom we collaborate in the future may decide to discontinue the development of a marketed product or product candidate or not to continue commercializing a marketed product or a product candidate for a variety of reasons, including the appearance of new technologies that make our product obsolete, the position of our partner in the market, competition from another product, or changes in or failure to comply with applicable regulatory requirements. If we or our partners terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have lost the opportunity to allocate those resources to potentially more productive uses. If one of our future partners terminates a development program or ceases to market an approved or commercial product, we will not receive any future milestone payments or royalties relating to that program or product under a partnership agreement with that party.

We may not be able to complete the clinical trials required for our product candidate.

We may not be able to complete the clinical trials required for our product candidate in a timely manner, or at all, and ultimately obtain regulatory approval for any of our product candidates. If we are unable to complete clinical trials of and obtain regulatory approval for our product candidate, our business will be significantly affected.

Our long-term growth will be limited unless we successfully develop a pipeline of additional product candidates.

Our long-term growth will be limited unless we successfully develop a pipeline of additional product candidates. We do not have internal new drug discovery capabilities, and our primary focus is on developing improved intracutaneous drug delivery systems by reformulating drugs previously approved by the FDA using our proprietary technologies. If we are unable to expand our product candidate pipeline and obtain regulatory approval for our product candidate on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would harm our long-term business, results of operations, financial condition and prospects.

Our product candidate may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following market approval, if any.

Qtrypta™ (M207) and any other product candidates we develop in the future may have undesirable side effects or have characteristics that are unexpected. These could be attributed to the active ingredient or class of drug or to our unique formulation of our product candidate, or other potentially harmful characteristics. Such characteristics could cause use, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials, including the imposition of clinical holds, and could result in a more restrictive label or delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

In addition, if our product candidate receives marketing approval, and we or others later identify serious adverse events or undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product candidate is administered, conduct additional clinical trials or change the labeling of the product;
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we may be required to implement REMS, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product candidate;

- we may be required to limit the patients who can receive the product candidate;

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- we may be subject to limitations on how we promote the product candidate;
- sales of the product candidate may decrease significantly;
- regulatory authorities may require us to take our approved product candidate off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our product candidate.

We may encounter manufacturing risks or failures that could impede or delay supply for our clinical trials of our product candidate.

While we currently manufacture Qtrypta™ (M207) internally, we have entered into agreements with third party CMOs related to the development, manufacture, and supply of Qtrypta™ (M207). Any failure or delay in our internal manufacturing operations or those of our CMOs, or the technology transfer process in connection with our plan to transition to rely on such CMOs for manufacture and supply, could hinder our ability to meet Qtrypta™ (M207) production demand for our clinical trials and delay the development or regulatory approval of Qtrypta™ (M207). We and our CMOs may encounter difficulties involving, among other things, material supplies, production yields, regulatory compliance, quality control and quality assurance, and shortages of qualified personnel. The manufacturing facilities in which Qtrypta™ (M207), or our future product candidates, are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. We may incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Regulatory approval of Qtrypta™ (M207) or our future product candidates could be impeded, delayed, limited or denied if the FDA does not maintain the approval of the manufacturing processes and facilities in which such product candidates are made.

Difficulties in relevant manufacturing processes and facilities implicated could result in supply shortfalls of Qtrypta™ (M207) or our future product candidates, and could delay our preclinical studies, clinical trials and regulatory submissions with respect thereto. In addition, Qtrypta™ (M207) (or our future product candidates) that has been produced and is stored for later use, may degrade, become contaminated or suffer other quality defects (including in connection with any shipment thereof), which may cause the affected product candidate to no longer be suitable for its intended use in clinical trials or other development activities. If the defective product candidate cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidate.

We have only manufactured our proposed product candidate for our clinical trials and we have no experience manufacturing on a commercial scale.

We have limited experience manufacturing our product candidate, Qtrypta™ (M207), and to date have only manufactured our product candidate for our clinical trials. If our product candidate is approved, we will need to scale up our own capabilities or those of our CMOs to support the production of commercial level quantities of our product candidate, which may require expensive process improvements.

While we intend to rely on CMOs, including Patheon to support commercial scale manufacture of Qtrypta™ (M207) and have entered into agreements regarding the same, we may nevertheless not be able to successfully produce, develop and market Qtrypta™ (M207) or our future product candidates, or we may be delayed in doing so. Significant scale up of manufacturing may also require process improvements as well as additional technologies and validation studies, which are costly, may not be successful and which the FDA must review and approve. If we or our CMOs are unable to establish a new manufacturing facility or expand existing manufacturing facilities, purchase equipment, hire adequate personnel to support our manufacturing efforts, or comply with cGMPs, or implement necessary process improvements, we may be unable to produce commercial materials or meet demand, if any should develop, for

Qtrypta™ (M207) or our future product candidates. Any such failure would have a material adverse effect on our business, financial condition and results of operations.

Reliance on CMOs also entails risks to which we would not be subject if we manufactured the product candidate ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidate in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory

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authorities require that our product candidate be manufactured according to cGMP and similar foreign standards. Any failure by our CMOs to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of our product candidate in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidate, or a recall or withdrawal of approval in the future. CMOs may not be able to manufacture our product candidate at a cost or in quantities or in a timely manner necessary to develop and commercialize it. If our CMOs are unable to successfully scale up the manufacture of our product candidate in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects. Our reliance on CMOs will further expose us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

Even if we receive regulatory approval for any product candidate, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of Qtrypta™ (M207) or any product candidates we develop in the future will depend upon their acceptance by the medical community, including physicians, patients and health care payers. The degree of market acceptance of any product candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of our products generally;
- relative convenience and ease of administration;
- prevalence and severity of any adverse effects;
- willingness of physicians to prescribe our product and of the target patient population to try new therapies and routes of administration;
- efficacy and safety of our products compared to competing products;
- introduction of any new products, including generics, that may in the future become available to treat indications for which our products may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our products may show utility;
- pricing and cost-effectiveness;
- effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling; and
- our ability to obtain and maintain sufficient third party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third party payers.

If our product candidate is approved but does not achieve an adequate level of acceptance by physicians, health care payers and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third party payers on the benefits of our product candidate may require significant resources and may never be successful.

Even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidate successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidate not commercially viable. For example, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place

conditions on approvals including potential requirements or risk management plans and the requirement for a REMS to assure the safe use of the drug or a black-box warning (which is a warning required by the FDA that appears on the package insert for or in literature describing certain prescription drugs, signifying that medical studies indicate that the drug carries a significant risk of serious adverse effects). If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed

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REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS 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. A black-box warning will limit how we are able to market and advertise our product. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidate. Moreover, approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of product candidate. Any of the foregoing scenarios could materially harm the commercial success of our product candidate.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on a product candidate that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we have decided to focus on developing our product candidate Qtrypta™ (M207) for treatment of migraine. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and product candidate 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 to such product candidate.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We use customized equipment to coat and package our microneedle patch system; any production or equipment performance failures could negatively impact our clinical trials of Qtrypta™ (M207) or any other product candidates we may develop or sales of our product candidate(s), if approved.

We presently use customized equipment to coat and package our microneedle patch system. We also rely on third parties to manufacture our equipment. If we experience equipment malfunctions and we do not have adequate inventory of spare parts or qualified personnel to repair the equipment, we may encounter delays in the manufacture of our microneedle patch system and may not have sufficient inventory to meet the demands of our clinical development programs of any future product candidates and if approved, our customers' demands for Qtrypta™ (M207) or our future approved product candidate(s), if any each of which could adversely affect our business, financial condition and results of operations.

We rely on CMOs for various components of our microneedle patch system, and our business could be harmed if those third parties fail to provide us with sufficient quantities of those components at acceptable quality levels and prices or fail to maintain or achieve satisfactory regulatory compliance.

We rely on CMOs for various components of our microneedle patch system, including API raw materials used in manufacturing, and capital equipment. Reliance on third party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance. In addition, CMOs may not be able to comply with cGMP, or similar regulatory requirements outside the United States. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. 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 products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate or any other product candidates that we may develop.

There can be no assurance that our supply of these various components will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers and cannot ensure that they will deliver to us the components we order on time, or at all. Any failure or refusal to supply the components for

Qtrypta™ (M207) or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our CMOs were to fail to fill our purchase orders, the development or commercialization of the affected product candidate could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable, the lead time needed to establish a new relationship can be lengthy, and because the expenses relating to the transfer of necessary technology and processes could be significant. It may take several years to establish

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an alternative source of supply for our product candidate and to have any such new source approved by the FDA, the European Medicines Agency, or EMA, or any other relevant regulatory authorities.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to comply with applicable regulatory requirements or to meet deadlines for the completion of such trials.

We rely on a third party contract research organization, or CRO, to manage our clinical trials. In addition, we rely on other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. While we have agreements governing their activities, we will have limited influence over their actual performance and we will control only certain aspects of their activities. In addition, the use of third party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If there is any dispute or disruption in our relationship with our CROs or if we need to enter into alternative arrangements, that would delay our product development activities. There are limited number of third party service providers that specialize or have the expertise required to achieve our business objectives. In particular, there would be a significant increase in clinical trial expenses, including adopting a new electronic data capture platform or other technology platforms, the need to enter into new contracts and costs associated with the transfer of data, as well as an increased risk of the loss of data. Identifying, qualifying and managing performance of third party service providers can be difficult, time-consuming and may cause delays in our development programs. These investigators and CROs will not be 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 candidate and clinical trials. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely affected. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CRO or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed, or we may be required to repeat such clinical trials, which would delay the regulatory approval process. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or if the quality of the clinical data they obtain is compromised due to the failure to conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidate and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidate.

We currently depend primarily on one supplier for manufacture of our product. If this manufacturer fails to provide us or our collaborators with adequate supplies of materials for clinical trials or commercial product or fails to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize Qtrypta™ (M207) or any other product candidates we may develop.

We have contracted with CMOs (including Patheon) to produce, in collaboration with us, Qtrypta™ (M207), for commercial use in the United States. We have not entered into any agreements with any alternate suppliers for Qtrypta™ (M207) product or API. Even if we were able to enter into other long-term agreements for manufacture of

commercial supply on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of Qtrypta™ (M207). Additionally, if Qtrypta™ (M207) or any other future product candidates is approved by the FDA or other regulatory agencies for commercial sale or if Qtrypta™ (M207) is approved for commercial sale in jurisdictions outside the United States, we will need to contract with a third party to manufacture such products for commercial sale in the United States and/or in such other jurisdictions.

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Our dependence on single source suppliers with respect to our supply chain for Qtrypta™ (M207) exposes us to certain risks, including the following:

- our supplier may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all;
- delays caused by supply issues may harm our reputation; and
- our ability to progress our business could be materially and adversely impacted if our single-source supplier upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating regulatory or quality compliance issues, or other legal or reputational issues.

Even though we have an agreement with a CMO, Patheon, to supply Qtrypta™ (M207), and even if we enter into other long-term agreements with other CMOs, the FDA may not approve the facilities of such CMOs, the CMOs may not perform as agreed or the CMOs may terminate their agreements with us. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, maintain or obtain, as applicable, regulatory approval for or market Qtrypta™ (M207) or any other future product candidate. In the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

The manufacturer(s) of Qtrypta™ (M207) are obliged to operate in accordance with FDA-mandated or cGMPs, and we have limited control over the ability of CMOs to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance to cGMPs. In addition, the facilities used by our CMOs to manufacture Qtrypta™ (M207) must be approved by the FDA pursuant to inspections that will be conducted prior to any grant or regulatory approval by the FDA. If any of our CMOs are unable to successfully manufacture material that conform to our specifications and the FDA's strict regulatory requirements, and pass regulatory inspections, they will not be able to secure or maintain approval for the manufacturing facilities. Additionally, a failure by any of our CMOs to establish and follow cGMPs or to document their adherence to such practices may negatively impact our commercialization or lead to significant delays in the launch and commercialization of any other products that we may have in the future. Failure by our CMOs or us to comply with application regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspensions or withdrawal of approvals, seizures or recalls of product, operating restrictions, and criminal prosecutions.

The manufacturer of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly-enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of Qtrypta™ (M207) will not occur in the future. Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes. If our CMOs were to encounter difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize Qtrypta™ (M207) in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand for Qtrypta™ (M207) will result in the loss of potential revenue and could adversely affect our ability to gain market acceptance for these products.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede commercialize of Qtrypta™ (M207) and could have a material adverse effect on our business, results of operations, financial conditions and prospects.

If we are not able to establish collaborations, we may have to alter our development plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund our expenses. We may seek to collaborate with third parties for certain of our development programs, and potentially for the commercialization of our lead product candidate, Qtrypta™ (M207).

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive collaborative agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential existence of competing drugs, the existence of uncertainty with respect to our ownership of

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technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available on which to collaborate and whether such a collaboration could be more attractive than the one with us for our product candidate. In addition, there have been a significant number of recent business transactions among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under collaboration agreements from entering into agreements with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail, reduce or delay the development of a particular product candidate, or one or more of our other development programs, delay its or their potential commercialization or reduce the scope of our 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 will not be able to bring our product candidate to market and generate revenue.

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties may be terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We may form strategic partnerships and collaborations in the future, and we may not realize the benefits of such alliances.

We may seek strategic partnerships, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. 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. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex.

The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may shift its priorities and resources away from our product candidate due to a change in business strategy, or a merger, acquisition, sale or downsizing;
- a collaboration partner may not devote sufficient resources towards, or cease development in, therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;
- a collaboration partner could develop a product candidate that competes, either directly or indirectly, with our product candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
-

a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;

- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;

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- a dispute may arise between us and a collaboration partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- a collaboration partner may use our products or technology in such a way as to invite litigation from a third party; and
- a collaboration partner may exercise a contractual right to terminate a strategic alliance, making us ineligible to receive milestone or royalty payments under such agreement.

RISKS RELATED TO MARKETING AND SALE OF OUR PRODUCTS

We have no experience selling, marketing or distributing approved product candidates and have no internal capabilities to do so.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate developing adequate sales and marketing support for any of our product candidates, if approved by the FDA. Although we may develop a targeted commercial infrastructure to market and distribute our proprietary product candidates, our future success may depend, in part, on our ability to enter into and maintain collaborative relationships to provide such capabilities, on the collaborators' strategic interest in the product candidates under development and on such collaborators' ability to successfully market and sell any such product candidates. There can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our product candidates, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with the needed technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

If Qtrypta™ (M207) does not obtain sufficient market share against competitive products, we may not achieve substantial product revenues and our business will suffer.

The market for our product candidate is characterized by intense competition and rapid technological advances. Our product candidates will, if approved, compete with a number of existing and future drug delivery systems and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our product candidate or may offer comparable performance at a lower cost. If our product candidate fails to capture and maintain market share, we may not achieve sufficient revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial and other resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

The development and commercialization of new products to treat migraine is highly competitive. We expect to have considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Companies marketing products that treat migraine that may compete with Qtrypta™ (M207) include Alder

Biopharmaceuticals, Allergan, Inc., AstraZeneca plc, Biohaven Pharmaceuticals, Eli Lilly & Company, GlaxoSmithKline plc, Promius Pharma, LLC, Teva Pharmaceutical Industries, Inc., and Zogenix, Inc.

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Products developed or under development by competitors may render our product candidate or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our product candidate will have to compete with existing therapies, new formulations of existing drugs and new therapies that may be developed in the future. We face competition from pharmaceutical, biotechnology and medical device companies, including intracutaneous delivery companies, in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and may have to limit development of a product candidate or commercialization of an approved product.

The use of our product candidate in clinical trials and the sale of any product candidate for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product candidate. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for an approved product and loss of revenue;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize an approved product candidate.

Insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate, but we may be unable to obtain commercially reasonable product liability insurance for any product candidate approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or a series of claims brought against us, particularly if judgments exceed our insurance coverage, could cause our stock price to decline and could adversely affect our results of operations and business.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Business disruptions could seriously harm our future revenues, results of operations and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we fail to comply with our obligations to our licensor in our intellectual property license, we could lose license rights that are important to our business.

We are a party to an Intellectual Property License Agreement dated October 5, 2006, as amended, with ALZA and we may enter into additional license agreements in the future. Our existing license agreement imposes, and we expect that any future license agreements will impose, various diligence, product payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. These risks could delay or prevent us from offering our product candidate. We might not have the necessary rights or the financial resources to develop, manufacture or market our current or future product candidates without the rights granted under these licenses, and the loss of sales or potential sales in such product candidate(s) could have a material adverse effect on our business, financial condition, results of operations and prospects. The occurrence of such events could have a material adverse effect on our business, financial condition and results of operations. Determining the scope of licenses and related obligations may be difficult and could lead to disputes between us and the licensor. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under a license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

Additionally, the agreement under which we currently license intellectual property is complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the third party's financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our failure to obtain and maintain patent protection for our technology and our product candidates could permit our competitors to develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidate may be adversely affected.

Our commercial success is significantly dependent on intellectual property related to our product candidate portfolio. We are either the licensee or assignee of numerous issued and pending patent applications that cover various aspects of our assets, including, most importantly, our microneedle patch system and our product candidate.

Our success depends in large part on our and our licensor's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidate. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or product that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent prosecution process is expensive, time-consuming and complex, and we 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, or we may not be financially able to protect our proprietary rights at all. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent

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our pending patent applications from issuing as patents. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives or provide any competitive advantage. 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, 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. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensor's patent rights are highly uncertain. Our and our licensor's pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The standards which the United States Patent and Trademark Office ("USPTO") and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these non-U.S. countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our product candidates will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue are valid, enforceable and have claims of adequate scope to provide competitive advantage. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidate without infringing third party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may have patents that could prevent us from marketing our own patented product candidate. Third parties may also seek to market generic versions of any of our approved product. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidate. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Bearing the costs and other requirements associated with prosecution of pending patent applications and maintenance of issued patents are essential to procurement and maintenance of patents integral to our product candidate, and our patent protection could be reduced or eliminated for non-compliance for these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ legal help and related professionals as needed to comply with those requirements. Failure to meet a required fee payment, document production or procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances, the defect can be cured through late compliance, but there are situations where the failure to meet the required deadline cannot be cured. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical product candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product candidate.

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Our business will be harmed if we do not successfully protect the confidentiality of our trade secrets.

In addition to our patented technology and product candidates, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach the agreements and disclose our proprietary information, 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, or third party with authorized access. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

We could be prevented from selling our product candidate, if approved, and could be forced to pay damages and defend against litigation, if we infringe the rights of third parties.

We conduct freedom-to-operate studies to guide our early-stage research and development away from areas where we are likely to encounter obstacles in the form of third party intellectual property conflicts, and to assess the advisability of licensing third party intellectual property or taking other appropriate steps to address any freedom-to-operate or development issues. However, with respect to third party intellectual property, it is impossible to establish with certainty that our product candidate will be free of claims by third party intellectual property holders or whether we will require licenses from such third parties. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications.

In the pharmaceutical industry, significant litigation and other proceedings, including interferences, oppositions, reexamination, inter partes review, derivation and post-grant review proceedings before the USPTO and corresponding foreign patent offices, regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and,
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if a license to necessary intellectual property is terminated, the licensor may initiate litigation claiming that our processes or products infringe, misappropriate or otherwise violate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

Third parties may assert that we are employing their proprietary technology without authorization or have infringed upon, misappropriated or otherwise violated their intellectual property or other rights. Even if we believe third party claims of infringement against us or our collaborators are without merit, there is a risk that a court would decide that we or our collaborators are infringing the third party's valid and enforceable patents. If our product candidates, methods, processes or other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;

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- abandon an infringing product;
- redesign our product candidate or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose and which could result in a substantial diversion of our financial and management resources.

We intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for Qtrypta™ (M207) and potentially for our future product candidates where applicable. Such filings involve significant costs, and we may also encounter difficulties or delays in obtaining regulatory approval for Qtrypta™ (M207) or any future product candidates under Section 505(b)(2).

We intend to pursue regulatory approval for Qtrypta™ (M207) and potentially for any future product candidates, pursuant to Section 505(b)(2) of the FDCA. A Section 505(b)(2) application is a type of NDA that enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of a previously approved product for which the applicant has no right of reference, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Such applications involve significant costs, including filing fees.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved product or the FDA's prior findings of safety and effectiveness for a previously approved product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies and that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed by the original applicant; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product candidate have expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed.

If we rely in our Section 505(b)(2) regulatory filings on clinical trials conducted, or the FDA's prior findings of safety and effectiveness, for a previously approved product that involves patents referenced in the Orange Book, then we will need to make the patent certifications or the Paragraph IV certification described above. If we make a Paragraph IV certification and the holder of the previously approved product that we referenced in our application initiates patent litigation within the time periods described above, then any FDA approval of our Section 505(b)(2) application would be delayed until the earlier of 30 months, resolution of the lawsuit, or the other events described above. Accordingly, our anticipated dates of commercial introduction of our product candidate would be delayed. In addition, we would incur the expenses, which could be material, involved with any such patent litigation. As a result, we may invest a significant amount of time and expense in the development of our product candidate only to be subject to significant delay and patent litigation before our product candidate may be commercialized, if at all.

In addition, even if we submit a Section 505(b)(2) application that relies on clinical trials conducted for a previously approved product where there are no patents referenced in the Orange Book for such other product with respect to which we have to provide certifications, we are subject to the risk that the FDA could disagree with our reliance on the particular previously approved product, conclude that such previously approved product is not an acceptable reference product, and require us instead to rely as a reference product on another previously approved product that involves patents referenced in the Orange Book, requiring us to make the certifications described above and subjecting us to additional delay, expense and the other risks described above.

We may become involved in costly and time-consuming lawsuits with uncertain outcomes to protect or enforce our patents.

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Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. If we initiate legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including a lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte reexamination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

There is a risk that a court or administrative body would decide to revoke, cancel or amend our patents in such a way that they no longer cover and protect a product candidate. In addition, a court or administrative body may decide that our patents are invalid, unenforceable or not infringed by a third party's activities. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. An adverse result in any litigation or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we may be reliant on them to do so.

An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that patents and applications we have filed to protect inventions of these employees, even those related to our product candidate, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all employees complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be self-executing and despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent

that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

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Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

There is a great deal of litigation concerning intellectual property in our industry, and we could become involved in litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and ability to compete in the marketplace.

Recent 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.

On September 16, 2011, the Leahy-Smith America Invents Act ("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 to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

The USPTO is implementing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. In addition, courts continue to decide how to interpret and enforce patent law. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

We may not be successful in obtaining necessary rights to future product candidates through acquisitions and in-licenses.

Any future programs we choose to pursue may require the use of proprietary rights held by third parties, and the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary

rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third party intellectual property from third parties that we later identify as necessary for our future product candidates or such intellectual property may not be available on commercially reasonable terms. The licensing and acquisition of third party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources, and greater clinical development and commercialization capabilities.

For example, we may in the future collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so,

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the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable product candidate or program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third party intellectual property rights necessary for the development of a product candidate or program on reasonable terms or at all, we may have to abandon development of that product candidate or program and our business and financial condition could materially adversely suffer.

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

Filing, prosecuting, and defending patents on our product candidate in all countries throughout the world may be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe can be less extensive than those in the United States and Europe. In addition, the laws of some countries outside the United States and Europe do not protect intellectual property rights to the same extent as federal and state laws in the United States and laws in Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and Europe, or from selling or importing products made using our inventions in and into the United States, Europe or other jurisdictions. Third parties may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our product and our patents or other intellectual property 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 jurisdictions outside the United States and Europe. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, the reproduction of our manufacturing or other know-how or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our intellectual property rights in jurisdictions outside the United States and Europe, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 any of our licensors is 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.

If we do not obtain patent term extensions and data exclusivity for Qtrypta™ (M207) or any of our future product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidate, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act and similar legislation in the EU. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or

a method for manufacturing it may be extended. However, we may not receive an extension, for example, if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our business, financial condition, results of operations, and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

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Our pending or future registered or unregistered trademarks or trade names may not issue and may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to any competitive advantage we may have. 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. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our product candidate, which are aimed initially at the generic market and are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- 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 pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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.

RISKS RELATED TO LEGISLATION AND ADMINISTRATIVE ACTIONS

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payers 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 any 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 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; The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for

purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

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- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties and exclude the entity from participation in Medicare, Medicaid and other government healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its 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 false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and analogous state laws and regulations, such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.
- analogous state laws and regulations, such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

State and non-U.S. 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve 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 civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare

programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Our ability to generate revenue from the sale of our product candidate will be diminished if we are unable to obtain third party coverage and adequate levels of reimbursement for any approved product candidate.

Our ability to commercialize any product candidate for which we receive regulatory approval, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the product candidate will be available from:

- government and health administration authorities;

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- private health maintenance organizations and health insurers; and
- other healthcare payers.

A substantial portion of our potential future revenue depends or will depend, in part, on the extent to which the costs of our products, purchased by our customers are reimbursed by third party payers, including Medicare, Medicaid, other U.S. government sponsored programs, non-U.S. governmental payers and private payers. Our customers' ability to obtain adequate reimbursement for products and services from these third party payers affects the selection of products they purchase and the prices they are willing to pay. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. If we are forced to lower the price we will charge for our US product candidate, if approved, our profit margins will decrease, which will adversely affect our ability to invest in and grow our business. With the global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of, and the level of reimbursement for, new therapies. Any limitations on, decreases in or elimination of payments by third party payers may have an adverse effect on our financial condition, business, prospects and/or results of operations.

Additionally, healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidate is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover the product candidate. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our product candidate, once approved, market acceptance of the product could be reduced.

Healthcare reform may have a material adverse effect on our industry and our results of operations.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the ACA is significantly changing the way healthcare is financed by both governmental and private insurers. From time to time, legislation is implemented to rein in rising healthcare expenditures. The ACA included a number of provisions affecting the pharmaceutical industry, including annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. The ACA included new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, entities that manufacture, produce or import medical devices were required to pay an excise tax in an amount equal to 2.3% of the price for which such devices are sold in the United States. Through a series of legislative amendments, the tax was suspended for 2016 through 2019, but is scheduled to return beginning in 2020, absent further Congressional action. In addition, among other things, the ACA also established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. The increased funding and focus on comparative clinical effectiveness research, which compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products, may result in lower reimbursements by payers for our product and decreased profits to us. Other federal legislative changes have been proposed and adopted since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2027 unless additional Congressional action is taken. 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 out-licensed products and product candidates (if and when approved) and accordingly, our financial results.

As noted above, the ACA is significantly changing the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on any product that we may commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of

most of the ACA, several states have not implemented certain sections of the ACA, including 19 that have rejected the expansion of Medicaid eligibility for low income citizens, and some members of the U.S. Congress are still working to repeal the ACA. More recently, President Trump is seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 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”. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, 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. While the Trump Administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business. Congress may consider other legislation

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to repeal or replace elements of the ACA in the future. We cannot predict what legislation, if any, to repeal or replace the ACA will become law, or what impact any such legislation may have on our product candidate.

If our product candidate becomes subject to recall it could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our product in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our product candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our product candidate in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those actions as recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Governments outside the United States may impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement for our product candidate is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

RISKS RELATED TO EMPLOYEE MATTERS, OUR OPERATIONS AND MANAGING GROWTH

We may enter into or seek to enter into business partnerships, combinations and/or acquisitions which may be difficult to integrate, disrupt our business, divert management attention or dilute stockholder value.

We may enter into business partnerships, combinations and/or acquisitions. We have limited experience in making acquisitions, which are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- potential unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

If we are not successful in completing acquisitions that we may pursue in the future, we would be required to reevaluate our business strategy and we may have incurred substantial expenses and devoted significant management time and resources in seeking to complete the acquisitions. In addition, we could use substantial portions of our available cash as all or a portion of the purchase price, or we could issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

We rely on key executive officers and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our chief executive officer and our chief financial officer. We do not have “key person” life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise

of any of our key personnel could result in delays in product development and diversion of management resources, which could have a material adverse effect on our business, financial condition and results of operations.

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If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.
We will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.
We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent improper activities 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 be in compliance with such 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 fines or other sanctions, including civil, criminal or administrative.
We may not successfully manage our growth.
Our success will depend upon the effective management of our growth, which will place a significant strain on our management and on administrative, operational and financial resources. To manage this growth, we may be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. Our inability to manage this growth could have a material adverse effect on our business, financial condition and results of operations.
Our business and operations would suffer in the event of computer system failures or security breaches.
Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development and manufacturing programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidate could be delayed.
Risks associated with use of our company-wide enterprise resource planning (“ERP”) system may adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.
We began implementing a company-wide ERP system in the third fiscal quarter of 2018 to handle the business and financial processes within our operations and corporate functions. To reap the benefits of our ERP system, we were required to change certain business and financial processes. Our business and results of operations may be adversely affected if we experience operating problems or cost overruns during the implementation process, or if the systems

and the associated process changes do not give rise to the benefits that we expect. If we do not effectively implement, maintain or integrate the ERP system as planned or if the systems do not operate as intended, it may adversely affect our ability to manage and run our business operations, file reports with the SEC in a timely manner, and/or otherwise affect our internal control environment. Any of these consequences could have an adverse effect on our results of operations and financial condition.

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Failure in our information technology systems, including by cybersecurity attacks or other data security incidents, could significantly disrupt our operations.

Our operations depend, in part, on the continued performance of our information technology systems. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Failure of our information technology systems could adversely affect our business, profitability and financial condition. Although we have information technology security systems, a successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is possible that a cybersecurity attack might not be noticed for some period of time. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our shareholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

RISKS RELATING TO AN INVESTMENT IN OUR COMMON STOCK

The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.

Our stock price has been and, in the future, may be subject to substantial volatility. During the period from January 2, 2018 through December 31, 2018, for example, our stock has traded in a range with a low of $1.85 and a high of $25.70. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. We do not, for example, have any explanation for the volatility in our stock price or the heavy volume of trading (on some days exceeding six times the number of shares currently outstanding) that has occurred in our common stock in February and March of 2018. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;
- results of clinical trials of our product candidates or those of our competitors;
- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- disputes concerning our intellectual property or other proprietary rights;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

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If we are unable to maintain listing of our securities on the Nasdaq Capital Market or another reputable stock exchange, it may be more difficult for our stockholders to sell their securities.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. On November 28, 2017, we received a letter from the Nasdaq Stock Market, LLC (the "Letter") stating that we had failed to maintain at least a $1.00 minimum bid price for our common stock (the "Minimum Bid Requirement") as required for continued listing of our common stock on the Nasdaq Capital Market. We subsequently effected a 1-for-20 reverse stock split of our outstanding common stock and, on February 9, 2018, we received a letter from the Director of Nasdaq Listing Qualifications indicating that we had regained compliance with the Minimum Bid Requirement under Nasdaq Rule 5550(a)(2).

If, for any reason, Nasdaq should delist our securities from trading on its exchange (including if we fail to comply with the Minimum Bid Requirement in the future) and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Substantial future sales of shares by existing stockholders, or the perception that such sales may occur, could cause our stock price to decline.

If our existing stockholders, particularly our directors and executive officers, are perceived by the public market as intending to sell substantial amounts of our common stock, the trading price of our common stock could decline significantly. As of March 7, 2019, we had 11,973,039 shares of common stock outstanding. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, certain holders of our common stock and warrants to purchase our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended ("Securities Act"). As long as the registration statements covering the resale of such shares remain in effect, such shares shall be freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by existing stockholders could have a material adverse effect on the market price of our common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities and industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes unfavorable research about our business, or if our clinical trials or operating results fail to meet the analysts' expectations, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Requirements associated with being a public reporting company will continue to increase our costs significantly, as well as divert significant company resources and management attention.

We have only been subject to the reporting requirements of the Securities Exchange Act of 1934, as amended ("Exchange Act") and the other rules and regulations of the SEC since January 2015. We are working with our legal, independent accounting, and financial advisors to identify those areas in which changes should be made to our

financial and management control systems to manage our growth and our obligations as a public reporting company. These areas include corporate governance, corporate control, disclosure controls and procedures, and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. Compliance with the various reporting and other requirements applicable to public reporting companies will require considerable time, attention of management, and financial resources.

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Further, the listing requirements of the Nasdaq Capital Market require that we satisfy certain corporate governance requirements relating to director independence, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time and financial resources to ensure that we comply with all of these requirements. These reporting and corporate governance requirements, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

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

We have never declared or paid any cash dividends on our common stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. Additionally, our existing debt agreements contain covenants that restrict our ability to pay dividends. Therefore, we do not expect to declare or pay any dividends on our common stock for the foreseeable future. As a result, your ability to receive a return on an investment in our common stock will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which you purchased it.

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

Our directors, executive officers, and the holders of more than 10% of our common stock together with their affiliates beneficially own a significant number of shares of our common stock. These stockholders, acting together, 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.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, certain provisions of the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Capital Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our disclosure controls and procedures may not be effective to ensure that we make all required disclosures.

As a public reporting company, we are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or

fraud may occur and not be detected.

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Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions in Delaware law, might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that could have the effect of rendering more difficult or discouraging an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

- providing for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors;
- limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board and stockholder meetings;
- limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our board of directors then in office; and
- providing that directors may be removed by stockholders only for cause.

These provisions, alone or together, could delay hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which 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.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that our stockholders could receive a premium for their common stock in an acquisition.

We are an “emerging growth company,” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

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We cannot predict whether investors will find our common stock less attractive because we will 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 may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenue of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2020, the end of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement filed under the Securities Act.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. We have an operating lease for our headquarters in Fremont, California. Under the Seventh Amendment, we extended the term of the lease for our headquarters for an additional 65 months from March 31, 2019 through August 31, 2024, with an option to further extend the lease for an additional 60 months, subject to certain terms and conditions. We do not own any real property. We believe our present facilities are sufficient for our current and planned near-term operations.

Item 3. LEGAL PROCEEDINGS

We are not party to any material pending legal proceedings. However, we may from time to time become involved in litigation relating to claims arising in the ordinary course of our business.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is publicly traded and listed on the Nasdaq Capital Market under the symbol "ZSAN."

Holders of Common Stock

As of March 1, 2019, there were 9 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information with respect to our compensation plans under which equity securities are authorized for issuance.

Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide a performance graph.

Recent Sale of Unregistered Securities

We did not sell any unregistered equity securities during the period covered by this Annual Report on Form 10-K that have not already been reported in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

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Item 6. SELECTED FINANCIAL DATA

The selected financial data in the tables below should be read together with our financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report on Form 10-K. The selected financial data in this section is not intended to replace our financial statements and the accompanying notes. Our historical results are not necessarily indicative of our expected future results. The statements of operations data for 2018 and 2017 and the balance sheet data as of December 31, 2018 and 2017 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,	
	2018	2017
	(in thousands, except per share and share data)	
Statements of Operations Data:		
Revenue	$ —	$ —
Operating expenses:		
Research and development [1]	25,508	20,118
General and administrative [1]	9,357	8,182
Impairment loss [1]	511	70
Total operating expenses	35,376	28,370
Loss from operations	(35,376)	(28,370)
Other income (expense):		
Interest income [1]	381	75
Interest expense [1]	(379)	(817)
Other income, net [1]	16	7
Net loss	$ (35,358)	$ (29,105)
Net loss per common share — basic and diluted	$ (3.74)	$ (16.82)
Weighted-average common shares outstanding — basic and diluted	9,452,491	1,730,388

	December 31,	
	2018	2017
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 9,140	$ 11,651
Marketable securities at fair value [2]	$ 13,862	$ —
Working capital [2]	$ 12,073	$ 2,936
Total assets	$ 35,780	$ 18,000
Build-to-suit obligation, net of debt issuance costs and discount [3]	$ 6,804	$ —
Secured promissory note (including accrued interest), net of issuance costs [4]	$ —	$ 6,687
Accumulated deficit	$ (261,232)	$ (225,874)
Total stockholders' equity	$ 18,710	$ 7,048

[1] See Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of the Annual Report on Form 10-K for a discussion of our year-to-year results of operations.

[2] In April 2018, we issued common stock in a public offering. We invested a portion of the cash proceeds from the public offering in marketable securities.

(3) In September 2018, we entered into a build-to-suit arrangement with Trinity with an aggregate value of $14.0 million. As of December 31, 2018, we had drawn $7.8 million on the build-to-suit arrangement.
(4) In September 2018, we paid all of our outstanding obligations under a term loan with Hercules Capital, Inc.

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Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, this discussion and analysis contains forward-looking statements that reflect our plans, estimates and beliefs. You should not place undue reliance on these forward-looking statements, which involve risks and uncertainties. As a result of many factors, including but not limited to those set forth under ''Risk Factors,'' our actual results may differ materially from those anticipated in these forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements."

On January 23, 2018, our stockholders approved an increase to the number of authorized shares of our common stock from 100,000,000 to 250,000,000 shares. Our stockholders also approved a proposal authorizing the board of directors, in its discretion, to effect a reverse stock split of our outstanding shares of common stock at a ratio ranging from 1-for-5 to 1-for-20 to be determined by the board of directors and effected, if at all, no later than November 23, 2018. On January 23, 2018, our board of directors approved a 1-for-20 reverse stock split of our outstanding common stock, which was effected on January 25, 2018. At the effective time, every 20 shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock. The par value of our stock remained unchanged at $0.0001 per share. No fractional shares of our common stock were issued in the reverse stock split, but in lieu thereof, each holder of our common stock who would otherwise have been entitled to a fraction of a share in the reverse stock split received a cash payment. In addition, by reducing the number of our outstanding shares, our loss per share in all prior periods increased by a factor of 20. A proportionate adjustment was also made to the per share exercise price and the number of shares issuable upon the exercise of our outstanding equity awards, options and warrants to purchase shares of our common stock and to the number of shares reserved for issuance pursuant to our equity incentive compensation plans. The reverse stock split affected all stockholders of our common stock uniformly and did not affect any stockholder's percentage of ownership interest. Unless otherwise noted, all share and per share information included in this report has been retroactively adjusted to give effect to the reverse stock split.

The reverse stock split did not affect the number of authorized shares of common stock, which, after giving effect to the authorized share increase, is 250,000,000 shares.

Overview

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM, technology. In February 2017, we announced positive results from our ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated Qtrypta™ (M207), which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. In February 2019, we announced the completion of the final milestone in our long-term safety study for Qtrypta™ (M207). We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, in markets where patients remain underserved by existing therapies. We anticipate that many of our current and future development programs may enable us to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards commercialization.

ADAM is our proprietary, investigational technology platform designed to offer rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. ADAM consists of an array of drug-coated titanium microprojections mounted on an adhesive backing that is pressed on to the skin using a reusable handheld applicator. The microprojections penetrate the stratum corneum and allow the drug to be absorbed into the microcapillary system of the skin. We focus on developing products based on our ADAM technology for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, in markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, Qtrypta™ (M207). Qtrypta™ (M207) is our proprietary formulation of zolmitriptan delivered utilizing our ADAM technology. Zolmitriptan is one of a class of serotonin receptor agonists known as triptans and is used as an acute treatment for migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. The objective of Qtrypta™ (M207) is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding the GI tract. Feedback from the FDA on Qtrypta™ (M207)'s regulatory path has also been encouraging. The agency has indicated that one positive pivotal efficacy study, in addition to the required safety study, would be sufficient for approval of Qtrypta™ (M207) for the treatment of migraine.

We will use contract manufacturers for the production of Qtrypta™. These contract manufacturers include companies that will produce our applicator, the various components that comprise our patch, as well as the final packaging of the finished product. Where required, these contract manufacturers will operate within the specifications and in accordance with good manufacturing

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practices as defined by the FDA. These companies are located in the United States and have expertise and experience in contract manufacturing.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the FDA, or equivalent foreign regulatory bodies, to market and sell our product candidate. Accordingly, our success depends not only on the development, but also on our ability to finance the development of the product. We will require substantial additional funding to complete development and seek regulatory approval for these products. Additionally, we currently have no sales, marketing or distribution capabilities and thus our ability to market our products in the future will depend in part on our ability to develop such capabilities either alone or with collaboration partners.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported results of operations during the reporting periods. Our estimates are based on our historical experience and on 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. Actual results could 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 included elsewhere in this Annual Report on Form 10-K, we believe that the accounting policies discussed below are those that are most critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

We are an "emerging growth company" as defined in the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Research and Development Expenses

Research and development costs are charged to expense as incurred and consist of costs related to (i) furthering our research and development efforts, (ii) seeking regulatory approval of our primary drug candidate, Qtrypta™ (M207), and (iii) pre-commercialization efforts for Qtrypta™ (M207). Research and development costs include salaries and related employee benefits, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, costs of active pharmaceutical ingredients and raw materials, research and development related overhead expenses and fees paid to contract manufacturing organizations that conduct manufacturing activities on our behalf.

Stock-Based Compensation

We account for stock-based compensation, recorded as an expense, based on the fair value of the stock-based awards on the date that the grants are ultimately expected to vest. The fair value of employee stock option grants is estimated on the date of grant using the Black-Scholes option pricing model and is recognized as expense on a straight-line basis over the employee's requisite service period (generally the vesting period), net of estimated forfeitures.

Financial Operations Overview

General

As of December 31, 2018, we had an accumulated deficit of approximately $261.2 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our Qtrypta™ (M207) product candidate into later stages of development and, if approved, commercialization. We cannot assure you that we will receive additional capital or collaboration revenue in the future, as a result of any partnership that we might pursue.

We expect our research and development expenses and manufacturing expenses related to the development of our Qtrypta™ (M207) product candidate to increase as we continue to advance this program towards regulatory filing and approval. Because of the numerous risks and uncertainties associated with our technology and drug development, we cannot forecast with any degree of certainty the timing or amount of expenses incurred or when, or if, we will be able to achieve profitability.

We will require additional capital to undertake our planned research and development activities and to meet our operating requirements beyond 2018. We intend to raise such capital through the issuance of additional equity through public or private

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offerings, debt financing, strategic alliances with pharmaceutical partners, or any combination of the above. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to further reduce our operating expenses and suspend, delay or reduce the scope of our Qtrypta™ (M207) development program, out-license intellectual property rights to our intracutaneous delivery technology, or a combination of the above, which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all.

Financing

In September 2018, we entered into a build-to-suit arrangement with Trinity with a maximum funding amount of $14.0 million for the third party construction of our commercial coating and primary packaging system, expected to be completed in the second quarter of 2020. In September 2018, we drew $5.0 million with a stated interest rate of 9.43% and an effective interest rate of 26.28%. In December 2018, we drew $2.8 million with a stated interest rate of 9.68% and an effective interest rate of 19.58%. Each drawdown has a 36-month-term beginning the first day of the month following the drawdown. The remaining $6.2 million is available to us in increments of not less than $500,000 until March 30, 2020. Any unused portion of the $14.0 million at March 30, 2020, is subject to a non-utilization fee equal to 3% of the unused amount. In consideration of the financing arrangement, as collateral, Trinity has a first-priority lien and security interest in substantially all of our assets.

Under the financing arrangement, each individual drawdown represents a separate financing arrangement with its own 36-month-term and stated interest rate. Each drawdown is non-cancelable, with no prepayment options. Each drawdown has embedded optional purchase options to (i) extend the term for an additional three months, with the option to purchase the equipment at 4% of the total cost, which is equal to the drawdown amount, following the end of such extended term, or (ii) purchase the equipment at 12% of total cost, which is equal to the drawdown amount, at the end of the 36-month-term. We intend to exercise the optional purchase option of 12% at the end of each 36-month-term ("Purchase Option Fee"). The transfer of title from Trinity to us will occur at the end of the final 36-month-term, provided that the purchase option was executed and the Purchase Option Fee was paid in full at the end of each 36-month-term. Failure to pay any of the Purchase Option Fees will result in Trinity retaining title to the commercial coating and primary packaging system and a 6% restocking fee.

In June 2014, we entered into a loan and security agreement with Hercules Capital, Inc. ("Hercules"). Hercules provided us a $15.0 million loan ("Hercules Term Loan") of which equal installment payments of principal and interest were due monthly, with a scheduled maturity date of December 1, 2018. On September 25, 2018, we paid all of our outstanding obligations under the Hercules Term Loan, including an end of term charge of approximately $0.4 million.

On April 3, 2018, we closed a public offering of 10,000,000 shares of common stock at a public offering price of $5.00 per share. We received approximately $45.6 million of net proceeds from this offering. We primarily used the net proceeds to fund continued advancement of our Qtrypta™ (M207) product candidate, to service our debt obligation with Hercules, to fund clinical development, and for working capital and other general corporate purposes.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our proprietary product candidates. We recognize all research and development expenses as they are incurred.

Research and development expenses consist of:

- production costs which include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation expense, drug formulation, and clinical trials;
- expenses related to the purchase of active pharmaceutical ingredients and raw materials for the production of our intracutaneous delivery system, including fees paid to contract manufacturing organizations;
- fees paid to CROs, clinical consultants, clinical trial sites and vendors, including IRBs, in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related

fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- fees paid to conduct clinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;
- other consulting fees paid to third parties; and
- allocation of certain shared costs, such as facilities-related costs.

We expect our research and development expenses to increase in the future. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time consuming. We consider the active management and development of our

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clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors, including, but not limited to: the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. In situations in which third parties have control over the clinical development of a product candidate, the estimated completion dates are largely under the control of such third parties and not under our control. Additionally, a future collaborative partner may only be interested in applying our technology in the development and advancement of their own product candidates.

In 2018, our research and development efforts and resources focused primarily on advancing the development of Qtrypta™ (M207). While we currently intend to continue clinical development of Qtrypta™ (M207) through commercialization in the United States ourselves, we remain open to opportunities with potential strategic partners to ensure Qtrypta™ (M207) will receive the best chance of commercial success. We are actively seeking opportunities to evaluate collaborations with strategic partners to further the clinical and commercial development of our other product candidates. We cannot forecast with any degree of certainty if Qtrypta™ (M207) or any of our future product candidates, if any, will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development. As a public company, we expect to invest significant resources to comply with evolving laws, regulations and standards, including the implementation of effective internal controls over financial reporting and compliance with the Sarbanes-Oxley Act.

Impairment Loss

We evaluate our long-lived assets for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets is measured by a comparison of the carrying amount of the asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Other Income and Expense

Interest income. Interest income consists primarily of interest, dividends and amortization of purchase premiums and discounts related to our marketable securities.

Interest expense. Interest expense consists primarily of interest costs related to our Hercules Term Loan and the related amortization of debt discount and issuance costs.

Other income, net. Other income, net consists of miscellaneous income or expenses that are not included in other categories of the statement of operations and comprehensive loss.

Results of Operations

Comparison of the year ended December 31, 2018 and 2017

Research and development expenses

	Year Ended December 31,		Change	
	2018	2017	Amount	%
	(In thousands)			
Research and development	$25,508	$20,118	$5,390	27%

For the year ended December 31, 2018, the increase in research and development expense of $5.4 million was primarily due to an increase of $4.4 million in clinical trial costs related to the long-term safety study of Qtrypta™ (M207), $1.6 million in increased compensation expenses and an increase of $1.1 million for facility set-up

and technology transfer fees to our commercial

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manufacturing organization. The increase in research and development expense was partially offset by $1.8 million related to lower depreciation expense due to manufacturing related leasehold improvement assets becoming fully amortized in 2017.

General and administrative expenses

	Year Ended December 31,		Change	
	2018	2017	Amount	%
	(In thousands)			
General and administrative	$ 9,357	$ 8,182	$ 1,175	14%

For the year ended December 31, 2018, the increase in general and administrative expense was due to an increase in compensation expense of $0.8 million and an increase in corporate taxes of $0.4 million.

Impairment Loss

	Year Ended December 31,		Change	
	2018	2017	Amount	%
	(In thousands)			
Impairment loss	$ 511	$ 70	$ 441	630%

For the year ended December 31, 2018, the impairment loss was due to our focus on our Qtrypta™ (M207) commercial manufacturing strategy. Certain assets related to a former D107 program and custom manufacturing equipment that will be replaced by new commercial production manufacturing equipment were determined to be impaired. For the year ended December 31, 2017, $70,000 was recorded for the impairment of laboratory equipment.

Other income and expense

	Year Ended December 31,		Change	
	2018	2017	Amount	%
	(In thousands)			
Interest income	$ 381	$ 75	$ 306	408 %
Interest expense	$ (379)	$ (817)	$ 438	(54)%
Other income, net	$ 16	$ 7	$ 9	129 %

For the years ended December 31, 2018 and 2017, interest income resulted primarily from interest recognized related to our marketable securities. The increase for the year ended December 31, 2018 as compared to the same period in 2017 resulted from investing the proceeds of the April 2018 public offering in marketable securities in the second quarter of 2018.

For the years ended December 31, 2018 and 2017, interest expense consisted primarily of interest, amortization of debt discount and amortization of deferred financing costs. The decrease in interest expense resulted from the decrease in the Hercules Term Loan principal balance in 2018 as compared to 2017. Interest of $0.3 million related to our build-to-suit arrangement with Trinity was capitalized as construction-in-progress in 2018.

For the year ended December 31, 2018 and 2017, other income, net consisted primarily of gains from the sale of equipment.

Income Taxes

As of December 31, 2018, we had net deferred tax assets of $16.5 million. The deferred tax assets primarily consisted of federal and state tax net operating losses and research and development tax credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these tax assets, a full valuation allowance has been established to offset our deferred tax assets. As of December 31, 2018, we had federal net operating loss carryforwards of approximately $41.1 million and state net operating loss carryforwards of approximately $33.2 million. As of December 31, 2017, we had federal net operating loss carryforwards of approximately $43.8 million and state net operating loss carryforwards of approximately $43.5 million. If not utilized, certain of the federal net operating loss carryforwards will expire beginning in 2026, and state net operating loss carryforwards will expire beginning in 2028.

As of December 31, 2018, we had federal and state research and development credit carryforwards of approximately $0.6 million and $5.1 million, respectively. As of December 31, 2017, we had federal and state research and development credit

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carryforwards of approximately $0.4 million and $4.6 million, respectively. If not utilized, the federal tax credits will begin to expire in 2026; state tax credits currently do not expire.

Utilization of net operating loss carryforwards and research and development credit carryforwards may also be subject to an annual limitation due to the ownership change limitations. These annual limitations may result in the expiration of the net operating loss carryforwards and research and development credit carryforwards before utilization. We have performed an analysis under Internal Revenue Code Sections 382 and 383 to determine the amount of our net operating loss carryforwards and research and development credit carryforwards that will be subject to annual limitation. As a result of the analysis, a portion of the net operating loss carryforwards and research and development credit carryforwards have been derecognized due to the annual limitation.

See Note 12. Income Taxes, for discussion of the impact of the Tax Cuts and Jobs Act, which was enacted in December 2017.

Liquidity and Capital Resources

As of December 31, 2018, we had an accumulated deficit of $261.2 million and $29.1 million of negative cash flows from operating activities for the year ended December 31, 2018. As of December 31, 2018, we had approximately $23.0 million in cash, cash equivalents and marketable securities. Presently, we do not have sufficient cash, cash equivalents and marketable securities to enable us to fund our anticipated level of operations and meet our obligations as they become due during the twelve months following the date of issuance of this Annual Report on Form 10-K. Further, to continue operations for the remainder of 2019, we will need to, and we are actively seeking to, obtain additional capital resources by the end of the third quarter of 2019 through an equity offering, a debt financing, a license or collaboration agreement, or through a combination of such sources of capital. The aforementioned factors raise substantial doubt about our ability to continue as a going concern.

Our ability to complete the sale and access the market as a source of liquidity is dependent on investor demand, market conditions and other factors. Therefore, we can provide no assurance that any such offering will be on terms favorable to us or our stockholders, or that such offering will be successful at all. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

Since our inception in October 2006, we have funded our operations primarily through a combination of equity offerings, secured and unsecured borrowings from private investors, bank credit facilities, and licensing and service revenue from license and collaboration agreements. We also have an equity line of credit pursuant to a purchase agreement with Lincoln Park, which provides for the purchase of up to $35.0 million worth of our common stock over the term of the purchase agreement, subject to certain conditions and limitations. Additionally, we have access to $6.2 million from our Trinity arrangement to fund the manufacture of our commercial coating and primary packaging machine.

We expect to incur additional losses in the future and will require additional financing to develop our Qtrypta™ (M207) product candidate, conduct pre-commercialization manufacturing activities and fund our operations. Failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the scope, progress, expansion and costs of manufacturing our product candidates;
- the scope, progress, expansion, costs and results of our clinical trials;
- the timing of and costs involved in obtaining regulatory approvals;
- the scope, progress, expansion, costs and results of our clinical trials;
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- our ability to establish and maintain development partnering arrangements;

- the timing, receipt and amount of contingent, royalty and other payments from any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing and, if approved, commercializing our product candidates;

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- our ability to draw funds from our build-to-suit arrangement; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to suspend, delay, reduce, or terminate our development programs and clinical trials. We may also be required to sell or license our technologies, clinical product candidates, or programs, if any, which we would prefer to develop and commercialize ourselves.

The following table shows a summary of our cash flows for the years ended December 31, 2018 and 2017:

	2018	2017
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$(29,122)	$(26,839)
Investing activities	(19,213)	(1,228)
Financing activities	45,824	24,995
Decrease in cash, cash equivalents, and restricted cash	$(2,511)	$(3,072)

Operating Cash Flow: Net cash used in operating activities was $29.1 million and $26.8 million for the years ended December 31, 2018 and 2017, respectively. Net cash used during 2018 was primarily due to clinical trial costs related to the long-term safety study of Qtrypta™ (M207) and general and administrative costs. Net cash used during 2017 was primarily due to the costs of completion of the ZOTRIP trial and start up and initiation costs related to our long-term safety study, in addition to other professional fees and administrative expenses incurred in the course of continuing operations.

Investing Cash Flow: Net cash used for investing activities was $19.2 million and $1.2 million for the years ended December 31, 2018 and 2017, respectively. Net cash used in 2018 was primarily due to the purchase of marketable securities and the investment in our commercial coating and primary packaging machine, partially offset by maturities of marketable securities. In 2017, our cash used for investments was primarily related to equipment purchases.

Financing Cash Flow: Net cash provided by financing activities was $45.8 million and $25.0 million for the years ended December 31, 2018 and 2017, respectively. Net cash provided by financing activities for 2018 was primarily due to net proceeds of $45.6 million from a registered public offering of common stock. Net cash provided by financing activities for 2017 was primarily due to net proceeds from a registered public offering of $26.6 million and proceeds of $4.0 million from the exercise of warrants to purchase 136,301 shares of common stock. These increases were partially offset by payments on the Hercules Term Loan of approximately $5.8 million.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018:

	Payment Due by Period				
	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Contractual Obligations					
Operating lease obligations [1]	$10,664	$ 1,762	$ 3,678	$ 5,224	$ —
Capital lease obligation	34	10	20	4	—
Build-to-suit obligation [2]	9,113	2,909	6,204	—	—
Equipment purchase commitments [3]	11,763	8,115	3,648	—	—
Contract manufacturing commitments [4]	3,919	3,919	—	—	—
Total contractual obligations	$35,493	$ 16,715	$ 13,550	$ 5,228	$ —

[1] Operating leases

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Our operating lease obligations primarily consist of a lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings, for our office, research and development, and manufacturing facilities in Fremont, California. In addition to the minimum rental commitments, our leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses. See Note 9. Commitments and Contingencies, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(2) Build-to-suit obligation

The build-to-suit obligation consists of principal and interest payments and Purchase Option Fees related to our build-to-suit obligation with Trinity. See Note 7. Debt Financing, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(3) Equipment purchase commitments

Equipment purchase commitments primarily relate to a purchase commitment with a manufacturer to build a commercial coating and primary packaging system for the production of our product candidate, Qtrypta™ (M207), and additional commitments with manufacturers to build pre-commercialization equipment. The terms of the purchase commitments are generally contingent upon performance of certain milestones. We anticipate that the obligations will be paid over an 18-month period. In February 2019, we entered into an amendment to our purchase order with the manufacturer of our commercial coating and primary packaging machine to increase the aggregate purchase price by $1.3 million. See Note 9. Commitments and Contingencies and Note 14. Subsequent Event, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(4) Contract manufacturing commitments

Our contract manufacturing commitments consist of non-cancelable commitments with our contract manufacturing organizations for the construction of dedicated manufacturing space and technology transfer fees.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Recently Issued Accounting Pronouncements

See Note 2. Summary of Significant Accounting Policies, to the accompanying financial statements for Recently Issued Accounting Pronouncements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Some of the securities that we invest in have market risk where a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, as well as investments in marketable securities. We had cash and cash equivalents of $9.1 million as of December 31, 2018, which consisted of bank deposits, money market funds and investments in marketable securities with an original maturity of 90 days or less. We had investments in marketable securities at fair value of $13.9 million as of December 31, 2018, which consisted primarily of commercial paper, corporate notes and bonds, and U.S. treasuries. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Our cash and cash equivalents are held for working capital purposes. Cash balances are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to regulatory limits, and we are exposed to credit risk when our cash balances exceed FDIC insurance limits. Our total cash and cash equivalent balances exceed the maximum amounts insured by the FDIC.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. We hold interest-earning instruments, which carry a degree of interest rate risk. In addition, the monthly rent factor on additional drawdowns from our build-to-suit arrangement is determined and indexed to the Prime Lending Rate as reported in the Wall Street Journal. To date, fluctuations in interest income and expense have not been significant. However, fluctuations in market interest rates in the future could have a material impact on our financial condition and results of operations.

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate controls over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the guidelines established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting includes policies and procedures that provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. GAAP.

Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2018. We reviewed the results of management's assessment with our audit committee.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to the deferral allowed under the JOBS Act for emerging growth companies.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) during the year ended December 31, 2018, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected.

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Item 9B. OTHER INFORMATION
None.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

Our executive officers and directors, their positions and their ages as of March 1, 2019 are set forth below:

Name	Age	Position
Class I Directors whose term expires at the 2021 Annual Meeting of Stockholders		
John P. Walker	70	President, Chief Executive Officer, and Chairman of the Board of Directors
Linda Grais M.D., J.D. (1)	62	Director
Class II Directors whose term expire at the 2019 Annual Meeting of Stockholders		
Steven A. Elms (3)	55	Director
Kenneth R. Greathouse (3)	66	Director
Class II Directors whose term expire at the 2020 Annual Meeting of Stockholders		
Joseph “Jay” P. Hagan (1) (2)	50	Director
Troy Wilson, Ph.D., J.D. (1) (2)	50	Director
Kleanthis G. Xanthopoulos, Ph.D. (2) (3)	60	Director
Executive Officers (other than Mr. Walker):		
Gregory Kitchener	48	Chief Financial Officer
Donald Kellerman, PharmD	64	VP Clinical Development and Medical Affairs
Hayley Lewis	43	Senior Vice President, Operations

(1)Member of the Audit Committee.

(2)Member of the Nominating and Corporate Governance Committee.

(3)Member of the Compensation Committee.

Business Experience

The following is a brief description of the education and business experience of our current directors and executive officers:

John P. Walker has served as our President and Chief Executive Officer since August 2017 and as member of our board of directors since May 2016. Mr. Walker served as our Interim Chief Executive Officer from May 2017 until August 2017. Mr. Walker is currently the Executive Chairman of Vizuri Health Sciences, LLC and served as a Managing Director of Four Oaks Partners, a life sciences transaction advisory firm, which he co-founded in March 2012 until January 2015. As part of his activities with Four Oaks Partners, Mr. Walker served as the Chairman and Interim Chief Executive Officer of Neuraltus Pharmaceuticals, Inc., a privately held biopharmaceutical company, until October 2013. From February 2009 until July 2010, Mr. Walker was the Chief Executive Officer at iPierian Inc., a company focused on the use of inducible stem cells for drug discovery. From 2006 until 2009, Mr. Walker served as the Chairman and Chief Executive Officer of Novacea, Inc., a pharmaceutical company that merged with Trancept Pharmaceuticals, Inc., in 2009. Since 2001, Mr. Walker, acting as a consultant, was Chairman and Interim Chief Executive Officer at Kai Pharmaceuticals, Guava Technologies, Centaur Pharmaceuticals, Inc., and Chairman and Chief Executive Officer of Bayhill Therapeutics. From 1993 until 2001, Mr. Walker was the Chairman and Chief

Executive Officer of Arris Pharmaceuticals Corporation and its successor, Axys Pharmaceuticals Inc. Mr. Walker previously served on the board of directors of Geron Corporation and Evotec AG. Mr. Walker currently serves on the board of directors of Lucile Packard Children's Hospital at Stanford University, is the Chairman of Packard Children's Health Alliance, and is a member of the Board of Trustees at the University of Puget Sound. Mr. Walker is a graduate of the Advance Executive Program at the Kellogg School of Management at Northwestern University and holds a B.A. from the State University of New York at Buffalo. We believe Mr. Walker’s 40 years in the life sciences

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industry and his experience as Chairman and Chief Executive Officer of a number of development and commercial stage companies, including his service as our President and Chief Executive Officer qualify him to serve as a member of our board of directors.

Linda Grais has served as a member of our Board or Directors since January 2019. She currently serves on the Board of Directors of Arca Biopharma, Corvus Pharmaceuticals, both biopharmaceutical companies, and PRA Health Sciences, a public contract research organization. From 2012 to 2017, Dr. Grais was President, Chief Executive Officer, and a member of the Board of Directors of Ocera Therapeutics, Inc., a biopharmaceutical company, which was acquired by Mallinckrodt, a pharmaceutical company, in 2017. Prior to her employment by Ocera, Dr. Grais served as a Managing Member at InterWest Partners, a venture capital firm, from 2005 until 2011, investing in biotechnology and medical device companies. From July 1998 to July 2003, Dr. Grais was a founder and executive vice president of SGX Pharmaceuticals Inc., a drug discovery company which was acquired by Eli Lilly & Co., a pharmaceutical company, in 2008. Prior to that, she worked as an attorney at Wilson Sonsini Goodrich & Rosati, where she represented Life Science companies. Before practicing law, Dr. Grais worked as an assistant clinical professor of Internal Medicine and Critical Care at the University of California, San Francisco. Dr. Grais received a B.A. from Yale University, an M.D. from Yale Medical School and a J.D. from Stanford Law School. We believe that Ms. Grais' extensive experience in the biopharmaceutical industry and as an executive officer of pharmaceutical and biotechnology companies qualifies her to serve as a member of our board of directors.

Steven A. Elms has served as a member of our board of directors since May 2018. He currently serves as a Managing Partner of Aisling Capital LLC, a private equity firm. He joined Aisling Capital LLC in 2000 from the life sciences investment banking group of Chase H&Q (formerly Hambrecht and Quist Group Inc.) where he was a principal. Mr. Elms serves on the board of directors of ADMA Biologics, Inc. Previously, Mr. Elms served on the board of directors of Ambit Biosciences Corp. from 2001 to 2014, MAP Pharmaceuticals, Inc. from 2004 to 2011 and has served on the boards of directors of a number of private companies. Mr. Elms received his B.A. in Human Biology from Stanford University and his M.B.A. from the Kellogg Graduate School of Management at Northwestern University. We believe that Mr. Elms' extensive financial services background and experience in the pharmaceutical and healthcare industries equip him to serve on our board of directors.

Kenneth R. Greathouse has served as a member of our board of directors since October 2017. Mr. Greathouse co-founded and has served as President of Argent Development Group since 2004, co-founded and has served as Chief Executive Officer of Melbourne Laboratories since 2012, co-founded and has served as Chief Executive Officer of Valcrest Pharmaceuticals since 2015 and co-founded and has served as Chief Executive Officer of Hesperian BioPharma since 2015. Mr. Greathouse has served as a member of the board of directors of Grove Sleep Holdings since 2009 and as a member of the board of directors of The Zitter Group since 2000. Mr. Greathouse received a B.S. from the University of California, Berkeley. We believe that Mr. Greathouse's extensive experience in the pharmaceutical industry and as an executive officer of pharmaceutical and biotechnology companies qualifies him to serve as a member of our board of directors.

Joseph "Jay" P. Hagan has served as a member of our board of directors since May 2015. Mr. Hagan has served as Regulus' Chief Executive Officer since May 2017. Previously, he served as Regulus' Chief Operating Officer, Principal Financial Officer and Principal Accounting Officer since January 2016. From 2011 to December 2015, Mr. Hagan served as Orexigen's Chief Business & Financial Officer. From May 2009 to June 2011, Mr. Hagan served as Orexigen's Senior Vice President, Corporate Development, Strategy and Communications. Prior to Orexigen, Mr. Hagan worked at Amgen, from September 1998 to April 2008, where he served in various senior business development roles, including founder and Managing Director of Amgen Ventures. Prior to starting the Amgen Ventures fund, Mr. Hagan was Head of Corporate Development at Amgen, leading such notable transactions as the acquisition of Immunex and Tularik and the spinouts of Novatrone and Relypsa, as well as numerous other business development efforts totaling over $15 billion in value. Before joining Amgen, Mr. Hagan spent five years in the bioengineering labs at Genzyme and Advance Tissue Sciences. He has served as a member of the board of directors of

Aurinia Pharmaceuticals, Inc. a clinical stage biopharmaceutical company, since February 2018. He received an M.B.A. from Northwestern University and a B.S. in Physiology and Neuroscience from the University of California, San Diego. We believe that Mr. Hagan's education and professional background in science and business management, and his work as a senior executive in the biotechnology industry qualify him to serve as a member of our board of directors.

Troy Wilson, Ph.D., J.D. has served as a member of our board of directors since June 2014. Dr. Wilson has been President and Chief Executive Officer and a member of the board of directors of Kura Oncology, Inc., a public company, since August 2014. He has served as Executive Chairman since February 2019 and as a member of the board of managers since November 2012 of Avidity Biosciences LLC, a private biopharmaceutical company and as President and Chief Executive Officer and a member of the board of managers of Wellspring Biosciences, Inc., a private biopharmaceutical company, since July 2012 and May 2012, respectively. He has been a Director of Puma Biotechnology, Inc., a public company, since October 2013. He has also been a member of the board of managers of Araxes Pharma LLC, a private biopharmaceutical company, since May 2012. Previously, Dr. Wilson served as President and Chief Executive Officer and a member of the board of directors of Intellikine, Inc., a private biopharmaceutical company, from April 2007 to January 2012 and from August 2007 to January 2012, respectively, until its

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acquisition by Takeda Pharmaceuticals. Dr. Wilson holds a J.D. from New York University and graduated with a Ph.D. in bioorganic chemistry and a B.A. in biophysics from the University of California, Berkeley. We believe that Dr. Wilson's senior executive experience managing, leading and developing various biopharmaceutical companies and his extensive industry knowledge and board-level experience in the biopharmaceutical industry qualify him to serve as a member of our board of directors.

Kleanthis G. Xanthopoulos, Ph.D. has served as a member of our board of directors since April 2013. Dr. Xanthopoulos is a serial entrepreneur whose passion is building healthcare companies focused on innovation. Dr. Xanthopoulos has over two decades of experience in the biotechnology and pharmaceutical research industries as an executive, company founder, chief executive officer, investor and board member. He has founded three companies, has introduced two life science companies to Nasdaq and has financed and brokered numerous creative strategic alliance and partnership deals with large pharmaceutical partners. Dr. Xanthopoulos has served as the President and CEO of IRRAS AB, a commercial stage medical device and drug delivery company, since June 2015 and has served as Managing General Partner at Cerus DMCC since August 2015, which focuses on investing and building innovative biotechnology companies. Dr. Xanthopoulos served as President and Chief Executive Officer of Regulus Therapeutics Inc. (Nasdaq: RGLS) from the time of its formation in 2007 until June 2015. Prior to that, he was a managing director of Enterprise Partners Venture Capital. Dr. Xanthopoulos co-founded and served as President and Chief Executive Officer of Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS) from its inception in 2000 to 2006 and remained a Director until its acquisition by Roche in 2011. He was Vice President at Aurora Biosciences (acquired by Vertex Pharmaceuticals, Inc.) from 1997 to 2000. Dr. Xanthopoulos participated in The Human Genome Project as a Section Head of the National Human Genome Research Institute from 1995 to 1997. Prior to this, Dr. Xanthopoulos was an Associate Professor at the Karolinska Institute, in Stockholm, Sweden, after completing a Postdoctoral Research Fellowship at The Rockefeller University, New York. An Onassis Foundation scholar, he was named the E&Y Entrepreneur of the year in 2006 in San Diego and the San Diego Business Journal's Most Admired mid-size company CEO in 2013. Dr. Xanthopoulos received his B.Sc. in Biology with honors from Aristotle University of Thessaloniki, Greece, and received both his M.Sc. in Microbiology and Ph.D. in Molecular Biology from the University of Stockholm, Sweden. In addition to his roles at IRRAS AB, Dr. Xanthopoulos is chairman of the board of directors of Apricus Biosciences (Nasdaq: APRI), a director of LDO S.p.a. (Milan, Italy), and is the co-founder and a member of the board of directors of privately held Sente Inc. We believe that Dr. Xanthopoulos's senior executive experience managing and developing a major biotechnology company and his extensive industry knowledge and leadership experience in the biotechnology industry qualify him to serve as a member of our board of directors.

Greg Kitchener has served as our Chief Financial Officer since October 2018. Prior to joining the Company, he served as Chief Financial Officer and Executive Vice President of BioPharmX Corporation from August 2015 to October 2018 and as Vice President of Finance at Cepheid, a publicly-traded healthcare company, from October 2011 to July 2015, after having served as Executive Director of Finance from April 2011 to October 2011 and as Senior Director of Finance from July 2008 to April 2011. He also previously held financial leadership positions at Synopsys from January 2005 to July 2008, culminating in the position of Director of Corporate Planning/FP&A and M&A, and held various finance positions at Cisco Systems from 2000 to January 2005. He started his career as an account representative at Charles Schwab from 1997 to 1998. Mr. Kitchener holds a Master of Business Administration from Cornell University and a Bachelor of Science in mathematics from the University of California, Santa Cruz.

Donald Kellerman, Pharm.D. has served as our Vice President of Clinical Development and Medical Affairs since July 2015. Prior to joining us, Dr. Kellerman served as Senior Vice President of Clinical Development and Regulatory Affairs at Tonix Pharmaceuticals from April 2014 to April 2015. Previously, from 2008 to 2013, Dr. Kellerman served as Senior Vice President of Clinical Development and Medical Affairs at MAP Pharmaceuticals, Inc. (acquired by Allergan, Inc.). Dr. Kellerman also held the position of Senior Vice President of Development at Inspire Pharmaceuticals, Inc. from 1999 to 2008, where he was responsible for all aspects of drug development, including clinical research, regulatory affairs, project management and biostatistics. He also led groups responsible for running

several clinical programs in the respiratory, ophthalmology and cardiovascular areas. In addition, Dr. Kellerman has served in various clinical and project leadership positions at Glaxo Wellcome, Sepracor, Inc., and E.R. Squibb and Sons, Inc. He has more than 25 years of experience in the development of prescription pharmaceuticals and has lead- or co-authored more than 80 publications. Dr. Kellerman holds Doctor of Pharmacy and Bachelor of Science degrees from the College of Pharmacy at the University of Minnesota.

Hayley Lewis has served as our Senior Vice President, Operations since July 2017 and Vice President of Regulatory Affairs and Quality from October 2015 until June 2017. Prior to joining the Company, Ms. Lewis was Vice President of Regulatory Affairs and Quality at Carbylan Therapeutics from May 2014 until May 2015. While at Carbylan, Ms. Lewis was part of the executive team that took the company public in April 2015, as well as being responsible for all regulatory and quality activities, both internally and for Carbylan's external development programs. From 2003 to 2014, Ms. Lewis held positions of increasing responsibility, most recently as the Senior Director of Regulatory Affairs at Depomed, Inc. During her tenure, she led the company in the approvals of three NDAs, Proquin ® , Glumetza ® , and Gralise ® , as well as approvals of several supplemental NDAs for Gralise ® , Cambia ® , Zipsor ® and Lazanda ® , including a line extension for Glumetza ® , CMC, and labeling changes for the neurology and pain

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product lines for Depomed's portfolio. Ms. Lewis received a B.S. in Pharmaceutical Sciences from the University of Greenwich and completed the Executive Program for Women Leaders at the Stanford Graduate School of Business. There are no family relationships among any of our directors or executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file reports of ownership of, and transactions in, our securities with the Securities and Exchange Commission. These directors, executive officers and ten-percent stockholders are also required to furnish us with copies of all Section 16(a) forms they file.

Based solely on a review of the copies of such forms received by us, and on written representations from certain reporting persons, we believe that during fiscal year 2018 our directors, executive officers and ten-percent stockholders complied with all applicable Section 16(a) filing requirements, except for a Form 4 filing for Dr. Xanthopoulos, Mr. Hagan, Mr. Wilson and Mr. Greathouse that were filed late due to an administrative delay.

Code of Ethics

We have adopted a written code of ethics that applies to our directors, executive officers and employees, and we also have adopted corporate governance guidelines. A copy of our code of ethics is posted on our website, which is located at www.zosanopharma.com, under "Investors — Corporate Governance." If we make any substantive amendments to, or grant any waivers from, a provision of our code of ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

Audit Committee

Our board of directors has established an audit committee. The audit committee, which is one of three standing committees of our board of directors, operates under a charter that has been approved by our board of directors.

The current members of our audit committee are Dr. Grais, Mr. Hagan and Dr. Wilson. Our board of directors has determined that Dr. Grais, Mr. Hagan, and Dr. Wilson satisfy the Nasdaq Stock Market independence standards and the independence standards of Rule 10A-3(b)(1) of the Exchange Act. Each of the members of our audit committee meets the requirements for financial literacy under applicable rules and regulations of the SEC and the Nasdaq Stock Market. The board of directors has also determined that Mr. Hagan qualifies as an "audit committee financial expert," as defined by applicable rules of the Nasdaq Stock Market and the SEC.

The audit committee assists our board of directors in its oversight of:

- the integrity of our financial statements;
- our compliance with legal and regulatory requirements;
- the qualifications and independence of our independent registered public accounting firm; and
- the performance of our independent registered public accounting firm.

The audit committee has direct responsibility for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. The audit committee establishes and implements policies and procedures for the pre-approval of all audit services and all permissible non-audit services provided by our independent registered public accounting firm and reviews and approves any related party transactions entered into by us.

Item 11. EXECUTIVE COMPENSATION

The following is a discussion and analysis of compensation arrangements of our named executive officers. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Our compensation committee, which is appointed by our board of directors, is responsible for establishing, implementing and monitoring our compensation philosophy and objectives. We seek to ensure that the total

compensation paid to our executive

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officers is reasonable and competitive. We have structured the compensation programs for our executives around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our named executive officers for fiscal year 2018 and their positions with the Company were as follows:

- John P. Walker, President and Chief Executive Officer;
- Donald Kellerman, Pharm.D., Vice President, Clinical Development and Medical Affairs; and
- Hayley Lewis, Senior Vice President, Operations.

Summary Compensation Table

The following table sets forth information regarding compensation earned by our named executive officers for fiscal years 2018 and 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Fair Value of Option Awards ($)(3)	All Other Compensation ($)	Total ($)
John P. Walker	2018	446,962	—	—	1,274,020	—	1,720,982
President and Chief Executive Officer (4)	2017	141,923	117,000	82,200	220,710	76,290 (5)	638,123
Donald Kellerman	2018	340,050	—	—	317,730	—	657,780
Vice President, Clinical Development and Medical Affairs	2017	331,200	95,491	—	—	—	426,691
Hayley Lewis	2018	330,000	—	—	317,730	—	647,730
Senior Vice President, Operations	2017	304,987	96,302	—	—	—	401,289

(1) The amounts reported in this column for 2017 represent cash bonuses awarded in respect of 2017 and paid in March 2018. The 2017 bonus amounts were determined pursuant to applicable employment agreements and based on achievement of individual and company performance goals and other factors deemed relevant by our compensation committee and board of directors. The compensation committee has determined that the corporate objectives for our 2018 annual bonuses have been achieved at 100%, but has not made a final determination as to the bonus amount to each named executive officer as of the date of this Annual Report. It is expected that the amounts of the 2018 bonuses will be determined in the second quarter of 2019.
(2) Represents the aggregate grant date fair value of restricted stock awards determined in accordance with FASB ASC 718. (See Note 10. Stock-Based Compensation, to the financial statements included in the Annual Report for a description of the assumptions used in calculating the grant date fair value.)
(3) Represents the aggregate grant date fair value of option awards determined in accordance with FASB ASC 718. (See Note 10. Stock-Based Compensation, to the financial statements included in this Annual Report for a description of the assumptions used in calculating the grant date fair value.)
(4) Interim Chief Executive Officer from May 9, 2017 until August 9, 2017. On August 9, 2017, he became an employee of the Company, in the role of President and Chief Executive Officer.
(5) Represents $36,290 in fees paid to Mr. Walker in cash for his services as a non-employee director from January 1, 2017 through May 8, 2017, and $40,000 in consulting fees.

Narrative Disclosure to Summary Compensation Table
We review compensation annually for all of our employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the

market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long- term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

Our compensation committee is responsible for approving the compensation and benefits of our executive officers.

Employment Agreements

We have a formal employment agreement with John P. Walker, our President and Chief Executive Officer. We also have executed employment offer letters with Donald Kellerman, our Vice President, Clinical Development and Medical Affairs and

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with Hayley Lewis, our Senior Vice President, Operations. These agreements set forth the terms and conditions of employment of each named executive officer, including base salary, annual bonuses, initial equity award grants and standard employee benefit plan participation. The agreements also include certain change in control and severance provisions, described in greater detail further below.

2018 Salaries

At the end of 2018, the annual base salary for each named executive officer was as follows: Mr. Walker ($500,000); Dr . Kellerman ($343,000), and Ms. Lewis ($335,000).

Terms and Conditions of 2018 Annual Bonuses

Annual performance-based bonuses are intended primarily to motivate our named executive officers to achieve annual operational and financial objectives set by the board of directors to promote achievement of our business strategies and increase shareholder value. Whether a named executive officer receives an annual bonus, and if so the amount of that bonus, depends on the achievement of both corporate and individual goals and objectives.

Each named executive officer’s target annual cash bonus is expressed as a percentage of base salary, which is set annually by our board of directors. Our board of directors determines each bonus amount in its discretion based on the achievement of both corporate and individual performance goals. The 2018 annual bonuses for Mr. Walker, Dr. Kellerman, and Ms. Lewis were targeted at 50%, 40% and 40% of their respective base salaries. Actual annual cash bonuses earned by each named executive officer for 2018 depend on

- the Company's performance relative to predetermined corporate objectives (weighted 100%, 80% and 80%, for Mr. Walker, Dr. Kellerman, and Ms. Lewis, respectively); and
- in the case of named executive officers other than Mr. Walker, the named executive officer's individual performance (based on achievement of individual objectives) as determined by the compensation committee based on input from Mr. Walker (weighted 20% for both Dr. Kellerman and Ms. Lewis).

For the fiscal year 2018, the compensation committee established corporate objectives that it considered critical to the near- and long-term success of the Company. The compensation committee has determined that the corporate objectives for our 2018 annual bonuses have been achieved at 100% but has not made a final determination as to the bonus amounts to individual named executive officers. The corporate objectives primarily consisted of the following: the completion of a $50 million public offering of our stock; the enrollment in our long-term safety study for Qtrypta™ (M207); the completion of the first milestone in our long-term safety study of Qtrypta™ (M207) in which 150 subjects treated repeatedly for six months; and the manufacture and release of registration batches for Qtrypta™ (M207) used to support our expected NDA filing.

2018 Equity Award Grants

During 2018, our named executive officers were each granted non-qualified stock options to purchase shares of our common stock under our Amended and Restated 2014 Equity and Incentive Plan. The options awarded to our named executive officers were granted with an exercise price equal to the closing market price of our ordinary shares on the date of grant, and generally require continued employment for four years in order to vest fully. Options therefore compensate our executives only if our share price increases after the date of grant and the executive remains employed for the period required for the option to become fully exercisable. The compensation committee thus considers options a particularly effective incentive and retention tool because it motivates our executives to increase shareholder value and remain with the Company.

The compensation committee determined the size of each named executive officer's option award after considering comparative market data provided by the compensation committee's compensation consultant, as well as the named executive officer's position, responsibilities and performance.

On January 25, 2018, we effected a 1-for-20 reverse stock split of our outstanding common stock. At the effective time, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of our outstanding equity awards, options and warrants to purchase shares of our common stock.

Outstanding Equity Awards at 2018 Fiscal Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2018. The number of shares underlying options and exercise prices reported below have been retroactively adjusted to give effect to the 1-for-20 reverse stock split effected on January 25, 2018.

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	Option Awards [6]				
	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Option Exercise Price ($)	Option Expiration Date	Vesting Start Date
John P. Walker	340 [1]	—	42.20	5/4/2026	5/4/2016
	1,500 [1]	—	11.40	11/2/2026	11/1/2016
	5,000 [2]	10,000 [2]	19.80	8/9/2027	8/9/2017
	50,000 [3]	250,000 [3]	4.24	4/16/2028	4/16/2018
	14,583 [3]	85,417 [3]	4.27	5/17/2028	5/17/2018
Donald Kellerman	1,125 [2]	375 [2]	45.20	12/15/2025	12/15/2015
	412 [2]	188 [2]	51.40	3/29/2026	3/29/2016
	749 [5]	— [5]	51.40	3/29/2026	N/A [5]
	4,687 [4]	4,313 [4]	11.40	11/2/2026	11/1/2016
	16,666 [3]	83,334 [3]	4.24	4/16/2028	4/16/2018
Hayley Lewis	1,187 [2]	313 [2]	45.20	12/15/2025	10/15/2015
	412 [2]	188 [2]	51.40	3/29/2026	3/29/2016
	749 [5]	— [5]	51.40	3/29/2026	N/A [5]
	4,687 [4]	4,313 [4]	11.40	11/2/2026	11/1/2016
	16,666 [3]	83,334 [3]	4.24	4/16/2028	4/16/2018

[1] This option vested and became exercisable in substantially equal monthly installments over one year so that the option was fully vested on the first anniversary of the vesting start date.
[2] This option vests and becomes exercisable as to 25% of the underlying shares on the first anniversary of the vesting start date, and as to the remaining underlying shares in equal monthly installments over three years, resulting in the option being fully vested on the fourth anniversary of the vesting start date.
[3] This option vests and becomes exercisable in substantially equal monthly installments over four years so that the option is fully vested on the fourth anniversary of the vesting start date.
[4] This option vests and becomes exercisable as to 25% of the underlying shares on the first anniversary of the vesting start date, and as to the remaining underlying shares in equal monthly installments over three years, resulting in the option being fully vested on the fourth anniversary of the vesting start date; provided that 100% of any then unvested option shares shall vest and become exercisable upon a change of control of the Company.
[5] This option vested and became exercisable upon achievement of certain milestones so that the option was fully vested upon completion of milestone activity.
[6] The vesting of each option is subject to the holder's continued service with us through the applicable vesting date.

Severance and Change in Control Arrangements

Pursuant to the terms of Mr. Walker’s employment agreement, if the Company terminates Mr. Walker other than for cause or if Mr. Walker terminates his employment for good reason, he will be entitled to receive (i) continued salary for twelve months, (ii) a bonus equal to the amount of the annual bonus awarded to him in respect of the year prior to termination, and (iii) the vesting schedule for any stock options outstanding on the date of termination will automatically accelerate so that 25% of any then unvested option shares shall immediately vest and become

exercisable upon such termination. If during the one-year period following a change in control of the Company, either we terminate Mr. Walker's employment without cause or Mr. Walker resigns for good reason, he will be entitled to receive (i) continued salary for 24 months and a lump sum cash amount equal to 229.56% multiplied by the total cost of the projected premiums for group medical, dental and vision insurance for a period of twenty-four months covering the period from and after the date of termination, (ii) a bonus equal to the amount of the annual bonus awarded to him in respect of the year prior to termination, and (iii) his then outstanding equity awards that were granted after the effective date of the Employment Agreement and that are subject to time based vesting will accelerate vesting in full.

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In 2018, the Company entered into amendments to the employment agreements with Dr. Kellerman and Ms. Lewis. The Agreements provide that in the event of a termination of employment without cause or for good reason, subject to execution of an effective release, the officers will be entitled to receive his or her base salary for a period of six months and healthcare coverage for a period of up to six months. In addition, any stock options and other equity awards will accelerate as to 25% of any then unvested shares. In the event of a termination without cause or for good reason within twelve months following a change in control, subject to his or her execution of an effective release, the officers will be entitled to receive a lump sum severance payment equal to 12 months of base salary and healthcare coverage for a period of up to 12 months and an amount equal to their bonus, if any, earned for the immediately preceding fiscal year. In addition, any stock options and other equity awards will accelerate as to 100% of any then unvested shares. In the event of disability, the Company has also agreed to pay base salary and provide benefits, in each case, for up to 12 weeks during any period of 365 consecutive calendar days.

Director Compensation

Pursuant to our non-employee director compensation program, effective January 1, 2018, our non-employee directors receive compensation as follows:

- for serving as a member of our board of directors, an annual cash retainer of $45,000 and a non-statutory stock option to purchase 1,500 shares of our common stock (at a per share exercise price equal to fair market value on the date of grant) vesting in equal monthly installments over a period of one year; and
- for serving as the chairperson of the audit committee of the board of directors, an additional annual cash retainer of $10,000; for serving as the chairperson of the compensation committee of the board of directors, an additional annual cash retainer of $7,000; for serving as the chairperson of the nominating and corporate governance committee of the board of directors, an additional annual cash retainer of $7,000; for serving as the chairman of the board of directors, an additional annual cash retainer of $25,000; and for serving as lead independent director, an annual cash retainer of $55,000.

The cash fees described above are paid in monthly installments. Non-employee directors are also reimbursed upon request for travel and other out-of-pocket expenses incurred in connection with their attendance at meetings of the board and of committees on which they serve.

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our non-employee directors during fiscal year 2018. John Walker, our President and Chief Executive Officer, served as Chairman of the Board during fiscal year 2018. However, he does not receive additional compensation for his services as a director. For information concerning the compensation paid to Mr. Walker, see “Summary Compensation Table” above. As of June 2018, Kenneth Greathouse served as our lead independent director.

	Fees Earned or Paid in Cash ($)	Option Awards ($) [1]	Total ($)
Steven Elms	28,065	92,207	120,272
Kenneth R. Greathouse	49,167	105,014	154,181
Joseph “Jay” P. Hagan	55,000	105,014	160,014
Troy Wilson, Ph.D., J.D.	52,000	105,014	157,014
Kleanthis G. Xanthopoulos, Ph.D.	52,000	105,014	157,014

(1) Represents the aggregate grant date fair value of stock options granted in fiscal year 2018, determined in accordance with FASB ASC 718. See Note 10. Stock-Based Compensation, to the financial statements included in this Annual Report for a description of the assumptions used in calculating the grant date fair value.

At the end of fiscal year 2018, our non-employee directors held outstanding stock options, as follows:

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	Number of Shares Subject to Outstanding Options
Steven Elms	25,000
Kenneth R. Greathouse	29,500
Joseph “Jay” P. Hagan	28,900
Troy Wilson, Ph.D., J.D.	28,915
Kleanthis G. Xanthopoulos, Ph.D.	28,915

Compensation Committee Interlocks and Insider Participation

During fiscal year 2018, our compensation committee consisted of Mr. Elms, Mr. Greathouse and Dr. Xanthopoulos. None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is an officer or employee of our company, nor has any of them ever been an officer or employee of our company.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance under Equity Compensation Plans

We have two compensation plans under which equity securities are currently authorized for issuance: our Amended and Restated 2014 Equity and Incentive Plan and our 2012 Stock Incentive Plan. In connection with the consummation of our initial public offering of common stock in January 2015, our board of directors terminated the 2012 Stock Incentive Plan effective as of January 27, 2015 and no further awards may be issued under the 2012 Stock Incentive Plan, except that the awards outstanding under the 2012 Stock Incentive Plan at the time of its termination continue to be governed by the terms of the 2012 Stock Incentive Plan. Our 2014 Equity and Incentive Plan was approved by our stockholders in July 2014 and our 2012 Stock Incentive Plan was approved by our stockholders in April 2012. The following table provides certain information as of December 31, 2018, with respect to all of our equity compensation plans in effect on that date.

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders [1] [2]	1,296,157	$ 5.75	55,799
Equity compensation plans not approved by security holders [3] [4]	13,837	$ 20.60	—
Total	1,309,994		55,799

[1] Consists of the Amended and Restated 2014 Equity and Incentive Plan and the 2012 Stock Incentive Plan.

[2] The Amended and Restated 2014 Equity and Incentive Plan contains an "evergreen" provision, pursuant to which the number of shares of common stock reserved for issuance pursuant to awards under such plan automatically increased on the first day of each year beginning, effective January 1, 2016 thereafter, the number of shares of stock

reserved and available for issuance under the Amended and Restated 2014 Equity and Incentive Plan increased by 3% of the number of shares of stock issued and outstanding on the immediately preceding January 1 or such lesser number of shares of stock as determined by the Compensation Committee. Beginning January 1, 2019 and continuing thereafter, the number of shares of common stock reserved and issuable under the Plan increases by (a) 3.5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or (b) the number of shares of common stock as determined by the Compensation Committee.

(3) Represents inducement grants granted without the approval of our stockholders in reliance on Nasdaq Listing Rule 5635(c).

(4) See also Note 10. Stock-Based Compensation, to our Financial Statements included in Item 8 of this report for a description of the material features of these inducement grants.

Security Ownership of Certain Beneficial Owners and Management

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The following table sets forth certain information with respect to beneficial ownership of our common stock, as of February 14, 2019 by:

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

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of February 14, 2019 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name. Except as otherwise indicated, the address of each of the persons in this table is c/o Zosano Pharma Corporation, 34790 Ardentech Court, Fremont, California, 94555.

Each stockholder's percentage ownership is determined in accordance with Rule 13d-3 under the Exchange Act and is based on 11,973,039 shares of our common stock outstanding as of February 14, 2019.

Name of Beneficial Owner [1]	Total Shares Beneficially Owned	Percentage	
5%+ Stockholders			
Aisling Capital IV, LP and affiliates [2] 888 Seventh Avenue, 12th Floor New York, NY 10106	1,600,000	13.4	%
Adage Capital Partners GP, L.L.C. and affiliates [3] 200 Clarendon Street, 52nd Floor Boston, MA 02116	1,000,000	8.4	%
Amzak Capital Management, LLC [4] 980 North Federal Highway, Suite 315 Boca Raton, FL 33432	794,000	6.6	%
Nexthera Capital LP and affiliates [5] 900 Third Avenue, Suite 1100 New York, NY 10022	700,000	5.8	%
Directors and Named Executive Officers:			
John P. Walker [6]	109,868		*
Donald Kellerman, Ph.D. [7]	32,393		*
Hayley Lewis [8]	31,340		*
Kenneth Greathouse [9]	18,354		*
Joseph "Jay" P. Hagan [10]	9,570		*
Troy Wilson, Ph.D., J.D. [11]	9,794		*
Kleanthis Xanthopoulos, Ph.D. [12]	11,536		*
Steve A. Elms [13]	1,600,375	13.4	%
Linda S. Grais	—		*
Current Directors and Executive Officers as a Group (10 persons) [14]	1,823,230	15.0	%

* Less than 1%

(1) Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to shares, subject to community property laws

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where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respects to securities.

(2) Based on information disclosed in the Schedule 13G filed with the SEC on April 9, 2018, Aisling Capital IV, LP, Aisling Capital Partners IV, LP and Aisling Capital Partner IV LLC have sole voting and dispositive power over 1,600,000 ordinary shares and Steven Elms and Andrew Schiff have shared voting and dispositive power over 1,600,000 shares. The address of the principal business office of each reporting person is 888 Seventh Avenue, 12th Floor, New York, New York 10106.

(3) Based on information disclosed in the Schedule 13G filed with the SEC on April 6, 2018, Adage Capital Partners GP, L.L.C., Adage Capital Advisors, L.L.C. Robert Atchinson and Phillip Gross have shared voting and dispositive power over 1,000,000 ordinary shares. The address of the principal business office of each reporting person is 200 Clarendon Street, 52nd floor, Boston, Massachusetts, 02116.

(4) Based on information disclosed in the Schedule 13G/A filed with the SEC on July 5, 2018, Amzak Capital Management, LLC has shared voting and dispositive power over 794,000 ordinary shares. The address of the principal business office of each reporting person is 980 N. Federal Highway, Suite 315, Boca Raton, FL 33432.

(5) Based on information disclosed in the Schedule 13G filed with the SEC on April 5, 2018, Naxthera Capital LP, Nexthera Capital GP LLC, Daniel Malek and Ori Hershkovitz have shared voting and dispositive power over 700,000 ordinary shares. The address of the principal business office of each reporting person is 900 Third Avenue, Suite 110, New York, New York 10022.

(6)Consists of: (i) 9,011 shares of common stock; (ii) 3,185 shares of common stock issuable upon exercise of outstanding warrants exercisable within the 60-day period following February 14, 2019; and (iii) 97,672 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

(7) Consists of: (i) 796 shares of common stock; (ii) 796 shares of common stock issuable upon exercise of outstanding warrants exercisable within the 60-day period following February 14, 2019; and (iii) 30,801 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

(8) Consists of:(i) 238 shares of common stock; (ii) 238 shares of common stock issuable upon exercise of outstanding warrants exercisable within the 60-day period following February 14, 2019; and (iii) 30,864 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

(9)Consists of: (i) 10,000 shares of common stock; and (ii) 8,354 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

(10)Consists of 9,570 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

(11)Consists of: (i) 150 shares of common stock; and (ii) 9,644 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

(12)Consists of: (i) 1,096 shares of common stock; and (ii) 796 shares of common stock issuable upon exercise of outstanding warrants exercisable within the 60-day period following February 14, 2019; and (ii) 9,644 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019. A portion of the securities reported for Dr. Xanthopoulos are held by the Xanthopoulos Family Trust, for which Dr. Xanthopoulos may be deemed to exercise voting and investment control.

(13) Consists of: (i) 375 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019; and, (ii) the shares described in footnote 2 above.

(14) Consists of: (i) 1,621,291 shares of common stock; and (ii) 5,015 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019; and (iii) 196,924 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 14, 2019.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Person Transactions

Since January 1, 2017, we have engaged in the following transactions in which the amount involved exceeded or will exceed the lessor of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years with our directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers, and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Real Property Leased with BMR

We have an operating lease with BMR-34790 Ardentech Court LP. Prior to December 2017, BMR was a related party due to its affiliation of BMV Direct and Bruce D. Steel, who served as director of the Company until December 13, 2017, who may have been deemed to have an indirect material interest in our financial relationships with certain of our stockholders based on his association with BMV Direct. As of December 31, 2018, BMR was no longer a related party.

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Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with each of our directors that are broader in scope than the specific indemnification provisions contained in the Delaware General Corporation Law.

Policies and Procedures for Related Person Transactions

Pursuant to the charter of our audit committee, our audit committee is responsible for reviewing and approving in advance any related person transactions. For the purposes of this policy, a "related person transaction" is any transaction between us or our subsidiary and any (a) of our directors or executive officers, (b) nominee for election as a director, (c) person known to us to own more than five percent of any class of our voting securities, or (d) member of the immediate family of any such person, if the nature of such transaction is such that it would be required to be disclosed under Item 404 of Regulation S-K (or any similar successor provision).

In determining whether to approve a related person transaction, the audit committee will consider, among other factors it deems appropriate, whether the related person transaction is on terms no less favorable than terms generally available to an unaffiliated third person under the same or similar circumstances and the extent of the related person's interest in the transaction.

Director Independence

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors has determined that each of Steven Elms, Linda Grais, Kenneth Greathouse, Jay Hagan, Troy Wilson and Kleanthis Xanthopoulos is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Listing Rules and Rule 10A-3 under the Exchange Act, and that John Walker, our President and CEO, is not an "independent director(s)." In making this determination, our board of directors considered the relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining the independence of such directors, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees, which are the only standing committees of our board of directors, operates under a charter that has been approved by our board of directors.

Audit Committee. Reference is made to the disclosure set forth under the caption "Audit Committee" under Item 10 of Part III of this report, which disclosure is incorporated herein by reference.

Compensation Committee. The current members of our compensation committee are Mr. Elms, Mr. Greathouse, and Dr. Xanthopoulos. The compensation committee:

- approves the compensation and benefits of our executive officers;
- reviews and makes recommendations to the board of directors regarding benefit plans and programs for employee compensation; and
- administers our equity compensation plans.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee is comprised entirely of independent directors. The current members of our nominating and corporate governance committee are Mr. Hagan, Dr. Wilson and Dr. Xanthopoulos. The nominating and corporate governance committee:

- identifies individuals qualified to become board members;
- recommends to the board of directors nominations of persons to be elected to the board; and
- advises the board regarding appropriate corporate governance policies and assists the board in achieving them.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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The following table represents aggregate fees billed to us for the years ended December 31, 2018, and 2017, by Marcum LLP, our independent registered public accounting firm:

	2018	2017
Audit fees [1]	$360,733	$200,518
Audit-related fees [2]	—	—
Tax fees [3]	5,000	—
All other fees [4]	—	—
Total fees	$365,733	$200,518

(1) Represents fees for professional services primarily related to the audit of our annual financial statements, the review of our quarterly financial statements; comfort letters, consents and assistance with the review of documents filed with the SEC; and other accounting services necessary to comply with the standards of the Public Company Accounting Oversight Board (United States).

(2) Represents fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under “Audit Fees.”

(3) Represents fees for preparation of federal and state tax returns and for tax advice.

(4) Represents any other fees billed by our principal accountant and not reported under “Audit Fees,” “Audit-related fees,” and “Tax fees.”

Pre-Approval Policies and Procedures

Our audit committee’s pre-approval policies or procedures do not allow our management to engage Marcum LLP to provide any audit, review or attestation services or any permitted non-audit services without specific audit committee pre-approval of the engagement for those services. All of the services provided by Marcum LLP during 2018 and 2017 were pre-approved.

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PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES
(a) The following documents are filed as part of this report:

(1) FINANCIAL STATEMENTS
Financial Statements—See index on page F-1 to Financial Statements on Item 8 of this Annual Report on Form 10-K.

(2) FINANCIAL STATEMENT SCHEDULES
Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) INDEX TO EXHIBITS
EXHIBIT INDEX

Exhibit number	Description
3.1	Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Commission on February 3, 2015)
3.2	Amended and Restated Bylaws of Zosano Pharma Corporation (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed with the Commission on February 3, 2015)
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation, filed on January 24, 2018 (Authorized Share Increase) (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Commission on January 25, 2018).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation, filed on January 24, 2018 (Reverse Stock Split) (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed with the Commission on January 25, 2018).
4.1	Specimen certificate evidencing shares of common stock of Zosano Pharma Corporation (incorporated by reference to Exhibit 4.1 to the registrant's Amendment No. 3 to Registration Statement on Form S-1 filed with the Commission on July 25, 2014)
10.1**	Collaboration, Development and License Agreement, dated January 31, 2014, between Zosano Pharma, Inc. and Novo Nordisk A/S (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.2	Notice of Termination, dated January 27, 2014, of the Amended and Restated License Agreement dated as of April 1, 2012 among Zosano Pharma, Inc. and Asahi Kasei Pharma Corporation (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

10.3	Letter Amendment to Intellectual Property License Agreement, dated February 22, 2011 between ALZA Corporation and Zosano Pharma, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

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10.4**	Intellectual Property License Agreement, dated as of October 5, 2006, between ALZA Corporation and The Macroflux Corporation (incorporated by reference to Exhibit 10.4 to the registrant's Amendment No. 2 to Registration Statement on Form S-1 filed with the Commission on July 17, 2014)
10.5	Lease Agreement, dated May 1, 2007, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.6	First Amendment to Lease, dated June 20, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.7	Second Amendment to Lease, dated October 16, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.8	Third Amendment to Lease, dated April 29, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.12 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.9	Fourth Amendment to Lease, dated July 31, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.13 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.10	Fifth Amendment to Lease, dated April 1, 2012, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.11	Sixth Amendment to Lease, dated as of June 24, 2015, between ZP Opco, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
10.12	Seventh Amendment to Lease, dated as of May 30, 2017, between ZP Opco, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 9, 2017)
10.13	Form of Indemnification Agreement for directors associated with an Investment Fund (incorporated by reference to Exhibit 10.15 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.14	Eighth Amendment to Lease entered into as of May 30, 2018 by and between Zosano Pharma Corporation and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on August 9, 2018).
10.15	Form of Indemnification Agreement for directors not associated with an Investment Fund (incorporated by reference to Exhibit 10.16 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

10.16	Loan and Security Agreement, dated as of June 3, 2014, between Zosano Pharma, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.20 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.17	First Amendment to Loan and Security Agreement, dated as of June 23, 2015, between ZP Opco, Inc., Hercules Technology Growth Capital, Inc. and Hercules Capital Funding Trust 2014-1 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
10.18	Joinder Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.21 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

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10.19	Supplement to Joinder Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation, Hercules Technology Growth Capital, Inc. and Hercules Capital Funding Trust 2014-1 (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
10.20	ZP Holdings, Inc. Pledge Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.22 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.21	Warrant Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.34 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.22	First Amendment to Warrant Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.4 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
10.23#	Warrant Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
10.24#	Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona (incorporated by reference to Exhibit 10.25 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.25#	Amendment to Employment Letter Agreement, dated January 6, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona (incorporated by reference to Exhibit 10.24 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.26#	Amendment No. 2 to Employment Letter Agreement, dated January 16, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona (incorporated by reference to Exhibit 10.23 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.27#	Amendment No. 3 to Employment Letter Agreement, dated May 29, 2015, among ZP Opco, Inc., Zosano Pharma Corporation and Peter Daddona (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on August 13, 2015)
10.28#	Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba (incorporated by reference to Exhibit 10.27 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.29#	Amendment to Employment Letter Agreement, dated December 17, 2013, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba (incorporated by reference to Exhibit 10.26 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.30#	Employment Letter Agreement, dated April 30, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and W. Tso (incorporated by reference to Exhibit 10.17 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

10.31#	Employment Letter Agreement, dated September 7, 2015, among Zosano Pharma Inc., ZP Holding Inc. and Konstantinos Alataris (incorporated by reference to Exhibit 10.29 to the registrant's Annual Report on Form 10-K filed with the Commission on March 29, 2016)
10.32	Amended and Restated Employer Letter Agreement, dated February 3, 2016, among Zosano Pharma Corporation, ZP Opco, Inc. and Konstantinos Alataris (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on February 4, 2016)
10.33	Independent Director Agreement, dated as of March 28, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos (incorporated by reference to Exhibit 10.29 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

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10.34#	Letter Amendment to Independent Director Agreement, dated July 15, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos (incorporated by reference to Exhibit 10.28 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.35#	ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.30 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.36#	Form of Incentive Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.31 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.37#	Form of Non-Statutory Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.32 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.38#	ZP Holdings, Inc. 2014 Equity and Incentive Plan (incorporated by reference to Exhibit 10.33 to the registrant's Amendment No. 1 to Registration Statement on Form S-1 filed with the Commission on July 16, 2014)
10.39	Zosano Pharma Corporation Amended and Restated 2014 Equity and Incentive Plan (incorporated by reference to Exhibit 10.33 to the registrant's Annual Report on Form 10-K filed with the Commission on March 26, 2015)
10.40	Note Purchase Agreement, dated as of September 9, 2013, among ZP Holdings, Inc., BMV Direct SO LP, BMV Direct SOTRS LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P. and ProQuest Management LLC (incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.41	Form of Subordinated Convertible Promissory Note dated September 9, 2013 (incorporated by reference to Exhibit 4.3 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.42	First Amendment, dated as of June 3, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated September 9, 2013 (incorporated by reference to Exhibit 4.8 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.43	Second Amendment, dated as of September 4, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated September 9, 2013 (incorporated by reference to Exhibit 4.10 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)
10.44	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P., ProQuest Management LLC, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.36 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

10.45	Note Purchase Agreement, dated as of February 26, 2014, among ZP Holdings, Inc., BMV Direct SO LP, BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership (incorporated by reference to Exhibit 4.4 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.46	Form of Subordinated Convertible Promissory Note dated February 26, 2014 (incorporated by reference to Exhibit 4.5 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.47	First Amendment, dated as of June 3, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated February 26, 2014 (incorporated by reference to Exhibit 4.9 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.48	Second Amendment, dated as of September 4, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated February 26, 2014 (incorporated by reference to Exhibit 4.11 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)

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10.49	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.37 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.50	Note Purchase Agreement, dated as of December 2, 2014, among Zosano Pharma Corporation, BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership (incorporated by reference to Exhibit 4.12 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)
10.51	Form of Subordinated Convertible Promissory Note dated December 2, 2014 (incorporated by reference to Exhibit 4.13 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)
10.52	Subordination Agreement, dated as of December 2, 2014, among BMV Direct SOTRS LP, New Enterprise Associates 12, Limited Partnership, ZP Opco, Inc., Zosano Pharma Corporation and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.40 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)
10.53	Letter Agreement, dated January 9, 2015, regarding Subordinated Convertible Promissory Notes dated September 9, 2013, February 26, 2014 and December 2, 2014 (incorporated by reference to Exhibit 4.14 to the registrant's Amendment No. 6 to Registration Statement on Form S-1 filed with the Commission on January 9, 2015)
10.54	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BioMed Realty Holdings, Inc., Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.35 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.55**	Independent Director Agreement, dated as June 23, 2014, between Zosano Pharma Corporation and Troy Wilson (incorporated by reference to Exhibit 10.39 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.56	Collaboration, Development and License Agreement, dated as of November 21, 2014, between ZP Opco, Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.41 to the registrant's Amendment No. 7 to Registration Statement on Form S-1 filed with the Commission on January 20, 2015)
10.57	Amendment No. 1 to Collaboration, Development and License Agreement, dated as of August 11, 2015, between ZP Opco, Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on August 17, 2015)
10.58#	Common Stock Purchase Agreement, dated as of November 21, 2014, between Zosano Pharma Corporation and Eli Lilly and Company (incorporated by reference to Exhibit 10.42 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)
10.59#	Amended and Restated Employment Letter Agreement, dated February 3, 2016, among Zosano Pharma Corporation, ZP Opco, Inc. and Konstantinos Alataris (incorporated by reference to Exhibit 10.1 to the

	registrant's Current Report on Form 8-K filed with the Commission on February 4, 2016)
10.60#	Consulting Agreement between the Company and Georgia Erbez, dated June 15, 2016 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 17, 2016)
10.61	Employment Letter Agreement, dated September 7, 2016, among Zosano Pharma Corporation, ZP Opco, Inc. and Georgia Erbez (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on September 9, 2016)
10.62	Securities Purchase Agreement, dated August 15, 2016, by and among Zosano Pharma Corporation and the Investors defined therein (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on August 16, 2016)
10.63#	Form of Purchase Agreement (incorporated by reference to Exhibit 1.1 to the registrant's Amendment No. 1 to Registration Statement on Form S-1 filed with the Commission on March 13, 2017)

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10.64#	Separation Agreement, dated May 8, 2017, among Zosano Pharma Corporation, ZP Opco, Inc. and Konstantinos Alataris (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on May 9, 2017)
10.65#	Separation Agreement, effective as of May 8, 2017, between ZP Opco, Inc. and Winnie Tso (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the Commission on May 9, 2017)
10.66#	Consulting Agreement, effective as of May 8, 2017, among Zosano Pharma Corporation, ZP Opco, Inc. and John Walker (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K/A filed with the Commission on May 24, 2017)
10.67#	Restricted Stock Agreement, dated May 18, 2017, between Zosano Pharma Corporation and John Walker (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K/A filed with the Commission on May 24, 2017)
10.68#	Employment Letter Agreement, dated as of August 17, 2017 and effective as of August 9, 2017, among Zosano Pharma Corporation, ZP Opco, Inc. and John Walker (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on August 23, 2017)
10.69	Purchase Agreement, dated as of October 20, 2017, by and between Zosano Pharma Corporation and Lincoln Park Capital Fund, LLC. (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on October 23, 2017)
10.70	Registration Rights Agreement, dated as of October 20, 2017, by and between Zosano Pharma Corporation and Lincoln Park Capital Fund, LLC. (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the Commission on October 23, 2017)
10.71#	Separation agreement, dated May 10, 2018, between Zosano Pharma Corporation and Georgia Erbez (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on May 15, 2018).
10.72#	Zosano Pharma Corporation Amended and Restated 2014 Equity and Incentive Plan, as amended May 31, 2018 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 5, 2018).
10.73#	Employment Letter Agreement, dated as of June 7, 2018 between Zosano Pharma Corporation and John Walker (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 12, 2018).
10.74	Purchase Order by and between Zosano Pharma Corporation and Harro Hoflinger Packaging System (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August 6, 2018).
10.75	Warrant to Purchase Stock, dated as of September 25, 2018 (Incorporated by reference to the registrant's current report on Form 8-K filed with the SEC on September 26, 2018).

10.76#	Amended and Restated Employment Agreement dated September 18, 2018 with Donald Kellerman, Pharm D. (Incorporated by reference to the registrant's current report on Form 8-K filed with the SEC on September 24, 2018).
10.77#	Amended and Restated Employment Agreement dated September 18, 2018 with Hayley Lewis (Incorporated by reference to the registrant's current report on Form 8-K filed with the SEC on September 24, 2018).
10.78#	Amended Agreement dated October 15, 2018 with Donald Kellerman, Pharm D. (Incorporated by reference to the registrant's current report on Form 8-K filed with the SEC on October 16, 2018).
10.79#	Amended Agreement dated October 15, 2018 with Hayley Lewis (Incorporated by reference to the registrant's current report on Form 8-K filed with the SEC on October 16, 2018).
10.80#	Employment Agreement dated September 25, 2018 with Greg Kitchener (Incorporated by reference to the registrant's current report on Form 8-K filed with the SEC on October 16, 2018).

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10.81*	Master Lease Agreement, dated September 25, 2018, with Trinity Capital Fund III, L.P. (incorporated by reference to Exhibit 10.6 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on November 15, 2018).
10.82	Manufacturing and Supply Agreement, dated September 25, 2018 with Patheon Manufacturing Services LLC. (Incorporated by reference to the registrant's current report on Form 10-Q filed with the SEC on November 15, 2018).
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Chief Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1†	Certification of Chief Executive Officer and Chief Financial Officer, as required by rules 13a-14(a) and 15d-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith.

**Confidential treatment has been granted as to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

#Management contract or compensatory plan or arrangement.

†The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. FORM 10-K SUMMARY

None.

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SIGNATURES

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

ZOSANO PHARMA
CORPORATION

By: /s/ John P. Walker
John P. Walker
Chief Executive Officer
Date: March 25, 2019

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of John P. Walker and Gregory Kitchener his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his or her name.

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

Signature	Title	Date
/s/ John P. Walker John P. Walker	Chief Executive Officer (Principal Executive Officer)	March 25, 2019
/s/ Gregory Kitchener Gregory Kitchener	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 25, 2019
/s/ Steven A. Elms Steven A. Elms	Director	March 25, 2019
/s/ Lisa S. Grais Linda S. Grais	Director	March 25, 2019
/s/ Kenneth R. Greathouse Kenneth R. Greathouse	Director	March 25, 2019
/s/ Joseph P. Hagan Joseph P. Hagan	Director	March 25, 2019
/s/ Troy Wilson Troy Wilson	Director	March 25, 2019
	Director	

/s/ Kleanthis G. Xanthopoulos
Kleanthis G. Xanthopoulos

March 25, 2019

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December 31, 2018 and 2017
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Zosano Pharma Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Zosano Pharma Corporation (the "Company") as of December 31, 2018 and 2017, the related statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has negative cash flows from operations, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits 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.

Marcum LLP
/s/ Marcum LLP

We have served as the Company's auditor since 2012.

Los Angeles, CA
March 25, 2019

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ZOSANO PHARMA CORPORATION
BALANCE SHEETS
(in thousands, except par value and share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$9,140	$11,651
Marketable securities at fair value	13,862	—
Prepaid expenses and other current assets	358	1,742
Total current assets	23,360	13,393
Restricted cash	455	455
Property and equipment, net	11,916	4,152
Other long-term assets	49	—
Total assets	$35,780	$18,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$4,450	$1,511
Accrued compensation	2,092	1,571
Capital lease obligation, current portion	5	—
Build-to-suit obligation, current portion	2,326	—
Secured promissory note (including accrued interest), net of issuance costs	—	6,687
Other accrued liabilities	2,414	688
Total current liabilities	11,287	10,457
Capital lease obligation, long-term portion	18	—
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	4,478	—
Deferred rent	1,287	495
Total liabilities	17,070	10,952
Commitments and contingencies (note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; none issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, $0.0001 par value; 250,000,000 and 100,000,000 shares authorized as of December 31, 2018 and 2017, respectively; 11,973,039 and 1,973,039 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1	—
Additional paid-in capital	279,946	232,922
Accumulated deficit	(261,232)	(225,874)
Accumulated other comprehensive loss	(5)	—
Total stockholders' equity	18,710	7,048
Total liabilities and stockholders' equity	$35,780	$18,000

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

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ZOSANO PHARMA CORPORATION
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2018	2017
Revenue	$ —	$ —
Operating expenses:		
Research and development	25,508	20,118
General and administrative	9,357	8,182
Impairment loss	511	70
Total operating expenses	35,376	28,370
Loss from operations	(35,376)	(28,370)
Other income (expense):		
Interest income	381	75
Interest expense	(379)	(817)
Other income, net	16	7
Loss before provision for income taxes	(35,358)	(29,105)
Provision for income taxes	—	—
Net loss	$ (35,358)	$ (29,105)
Unrealized loss on marketable securities, net of tax	(5)	—
Comprehensive loss	$ (35,363)	$ (29,105)
Net loss per common share – basic and diluted	$ (3.74)	$ (16.82)
Weighted-average common shares outstanding – basic and diluted	9,452,491	1,730,388

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

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ZOSANO PHARMA CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share amount)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2017	840,798	$ —	$ 201,253	$ (196,769)	$ —	$ 4,484
Issuance of common stock in connection with public offering	977,500	—	26,623	—	—	26,623
Issuance of common stock in connection with exercise of warrants	136,301	—	4,041	—	—	4,041
Issuance of common stock in connection with equity line of credit	11,375	—	174	—	—	174
Issuance and release of restricted stock to certain board members as remuneration	2,139	—	—	—	—	—
Issuance of common stock to employees upon the exercise of stock options	4,926	—	139	—	—	139
Stock-based compensation	—	—	692	—	—	692
Net loss	—	—	—	(29,105)	—	(29,105)
Balance at December 31, 2017	1,973,039	—	232,922	(225,874)	—	7,048
Issuance of common stock in connection with public offering	10,000,000	1	45,603	—	—	45,604
Issuance of common stock warrants in connection with build-to-suit obligation	—	—	243	—	—	243
Stock-based compensation	—	—	1,178	—	—	1,178
Unrealized loss on marketable securities	—	—	—	—	(5)	(5)
Net loss	—	—	—	(35,358)	—	(35,358)
Balance at December 31, 2018	11,973,039	$ 1	$ 279,946	$ (261,232)	$ (5)	$ 18,710

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

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ZOSANO PHARMA CORPORATION
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (35,358)	$ (29,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	1,178	692
Deferred rent	936	443
Depreciation	764	2,553
Effective interest on financing obligations	304	51
Capitalized interest	(294)	—
(Accretion) amortization of interest on marketable securities	(131)	2
Impairment loss	511	70
Other	(14)	(8)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	1,208	(1,279)
Accounts payable	98	(34)
Accrued compensation and other accrued liabilities	1,676	(224)
Net cash used in operating activities	(29,122)	(26,839)
Cash flows from investing activities:		
Purchase of marketable securities	(29,788)	(8,280)
Proceeds from maturities of marketable securities	16,050	8,274
Purchase of property and equipment	(5,490)	(1,244)
Proceeds from sale of property and equipment	15	22
Net cash used in investing activities	(19,213)	(1,228)
Cash flows from financing activities:		
Proceeds from public offering of securities, net of commissions, discounts and other offering costs	45,604	26,623
Proceeds from build-to-suit obligation, net of issuance costs	7,570	—
Principal payments made on financing obligations	(6,999)	(5,808)
Payment of term loan end of term charge	(351)	—
Proceeds from exercise of warrants and issuance of common stock	—	4,041
Proceeds from exercise of stock options and issuance of common stock	—	139
Net cash provided by financing activities	45,824	24,995
Net decrease in cash, cash equivalents, and restricted cash	(2,511)	(3,072)
Cash, cash equivalents, and restricted cash at beginning of year	12,106	15,178
Cash, cash equivalents, and restricted cash at end of year	$ 9,595	$ 12,106
Supplemental cash flow information:		
Cash paid for interest	$ 884	$ 865
Cash paid for income taxes	$ 2	$ 2
Non-cash investing activities:		
Acquisition of property and equipment under accounts payable and other accrued liabilities	$ 3,374	$ 144
Issuance of common stock warrants in connection with a build-to-suit obligation	$ 243	$ —
Issuance of common stock in connection with equity line of credit	$ —	$ 174

Property and equipment acquired through capital lease	$ 25	$ —

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

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Zosano Pharma Corporation
Notes to Financial Statements
For the Years Ended December 31, 2018 and 2017

1. Organization

The Company

Zosano Pharma Corporation (the “Company”) is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using its proprietary Adhesive Dermally-Applied Microarray, or ADAM™, technology.

On November 1, 2017, the Company's wholly owned subsidiary, ZP Opco. Inc., through which the Company conducted its primary research and development activities merged with and into Zosano Pharma Corporation, with Zosano Pharma Corporation as the surviving corporation of the merger.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of the accompanying financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

On January 23, 2018, the stockholders approved an increase to the number of authorized shares of the Company’s common stock from 100,000,000 to 250,000,000 shares. On January 23, 2018, the board of directors approved a 1-for-20 reverse stock split of the outstanding common stock, which was effective on January 25, 2018. At the effective time, every twenty shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock. The par value of stock remained unchanged at $0.0001 per share. No fractional shares of the Company's common stock were issued in the reverse stock split, but in lieu thereof, each holder of the Company's common stock who would otherwise have been entitled to a fraction of a share in the reverse stock split received a cash payment. As a result of the reverse stock split, the number of the Company’s outstanding shares of common stock as of January 25, 2018 decreased from 39,460,931 (pre-split) shares to 1,973,039 (post-split) shares. Unless otherwise noted, all share and per share information included in these financial statements have been retroactively adjusted to give effect to the reverse stock split.

The reverse stock split did not affect the number of authorized shares of common stock, which, after giving effect to the authorized share increase, is 250,000,000 shares.

Liquidity and Substantial Doubt in Going Concern

Since inception, the Company has incurred recurring operating losses and negative cash flows from operating activities, and as of December 31, 2018, had an accumulated deficit of $261.2 million. As of December 31, 2018, the Company had approximately $23.0 million in cash, cash equivalents and marketable securities. Presently, the Company does not have sufficient cash, cash equivalents and marketable securities to enable it to fund the anticipated level of operations and meet its obligations as they become due within twelve months following the date of issuance of this Annual Report on Form 10-K. The aforementioned factors raise substantial doubt about the Company’s ability to continue as a going concern for a period of one year from the issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company plans to raise additional funding through financing, a capital offering, a license or collaboration agreement or a combination of such sources of capital. However, there are no assurances that additional funding will be achieved and that the Company will succeed in its future operations. The Company’s inability to obtain required

funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and it may have to cease operations.

The Company will continue to evaluate its timelines, strategic needs, and working capital requirements. There can be no assurance that if the Company attempts to raise additional capital, it will be successful in doing so on terms acceptable to the

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Company, or at all. Further, there can be no assurance that it will be able to gain access and/or be able to execute on securing new sources of funding, new development opportunities, successfully obtain regulatory approvals for and commercialize new products, achieve significant product revenues from its products (if approved), or achieve or sustain profitability in the future.

Segment Reporting

The Company operates in one reportable segment: the development of human pharmaceutical products. All long-lived assets are maintained in the United States, with the exception of $6.2 million of construction-in-progress related to the Company's commercial coating and primary packaging system that is being manufactured in Germany.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents.

As of December 31, 2018 and 2017, the Company had restricted cash of approximately $0.5 million consisting of deposits of $0.3 million to secure its building lease until the end of the lease term, a deposit of approximately $0.1 million to a utility provider and $35,000 to secure corporate purchase cards.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets and as presented as cash, cash equivalents and restricted cash in the statements of cash flows.

	December 31, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$9,140	$ 11,651
Restricted cash	455	455
Total	$9,595	$ 12,106

Marketable Securities

Marketable securities generally consist of debt securities with original maturities greater than 90 days and remaining maturities of less than one year. All of the Company's investments are classified as available-for-sale and carried at fair value based upon quoted market price. The change in unrealized gains and losses is reported as a separate component of other comprehensive loss on the statements of operations and comprehensive loss and as a separate component of stockholders' equity on the balance sheets. Interest income includes interest, dividends, accretion and amortization of purchase premiums and discounts and realized gains and losses on sales of securities, if any. The cost of securities sold is based on the specific-identification method.

The Company monitors its investment portfolio for potential impairment on a quarterly basis. If the carrying amount of an investment in marketable securities exceeds its fair value and the decline in value is determined to be other-than-temporary, the carrying amount of the security is reduced to fair value and a loss is recognized in operating results for the amount of such decline. In order to determine whether a decline in value is other-than-temporary, the Company evaluates, among other factors, the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, and its intent and ability to hold the security to maturity or forecasted recovery.

Fair Value Instruments

The Company records its financial assets and liabilities at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the

inputs used in the valuation methodologies in measuring fair value as follows:
Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.

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Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.
The carrying values of certain assets and liabilities of the Company, such as cash and cash equivalents, accounts receivable, and accounts payable, approximate fair value due to their relatively short maturities. The carrying value of the Company's short-term financial obligations approximates their fair value as the terms of the borrowing are consistent with current market rates and the duration to maturity is short.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company invests its excess cash in money market funds, U.S. treasuries, corporate notes and commercial paper. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. Other than for obligations of the U.S. government, the Company's policy is that no single issuer in the portfolio shall exceed 10% or $1 million, whichever is greater, of the total portfolio at the time of purchase. Bank deposits are held by a single financial institution having a strong credit rating and these deposits may at times be in excess of FDIC insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the balance sheets.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets, which range from three to five years for computer equipment and software, and nine years for manufacturing, laboratory, and office equipment. Leasehold improvements are depreciated over the shorter of the lease term or the estimated useful lives of the respective assets.

The Company records as construction-in-progress ("CIP") property and equipment that has not yet been placed in service for its intended use. All costs prior to a project becoming probable of being constructed are expensed as incurred. After the construction is considered probable, all directly identifiable costs related to an asset are capitalized.

Interest related to construction of assets is capitalized when the financial statement effect of capitalization is material, construction of the asset has begun, and interest is being incurred. Interest capitalization ends at the earlier of the asset being substantially complete and ready for its intended use or when interest costs are no longer being incurred.

When assets are retired or otherwise disposed of, the costs and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statement of operations and comprehensive loss in the period realized.

Impairment of Long-Lived Assets

The Company identifies and records impairment losses on long-lived assets used in operations when events or changes in circumstances indicate that the carrying amount of an asset is likely not recoverable. Recoverability is measured by comparing the fair value to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value.

Deferred Offering Costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through a public or private sale of the Company's common stock. These costs are deferred until the completion of the applicable offering, at which time such costs are reclassified to additional paid-in-capital as a reduction of the proceeds.

Deferred Rent

Rent expense is recognized on a straight-line basis over the non-cancelable term of the Company's operating lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as deferred rent.

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The Company also records lessor-funded lease incentives, such as reimbursable leasehold improvements, as deferred rent, which is amortized as a reduction of rent expense over the non-cancelable term of its operating lease.

Capital Leases

Capital leases are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in property and equipment, net on the balance sheets and depreciated in a manner similar to other property and equipment.

Research and Development Expenses

Research and development costs are charged to expense as incurred and consist of costs related to furthering the Company’s research and development efforts, seeking regulatory approval of its primary drug candidate, Qtrypta™ (M207) and pre-commercialization efforts for Qtrypta™ (M207). Research and development costs include salaries and related employee benefits, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, costs of active pharmaceutical ingredients and raw materials, research and development related overhead expenses, and fees paid to contract manufacturing organizations ("CMO") that conduct manufacturing activities on behalf of the Company.

For the year ended December 31, 2018, the Company incurred research and development costs of approximately $13.9 million in connection with the Company's research and development efforts and approximately $11.6 million in the manufacturing of the Company’s intracutaneous delivery system and facility set-up and technology transfer fees to its commercial manufacturing organizations. For the year ended December 31, 2017, the Company incurred research and development costs of approximately $10.3 million in connection with the Company’s research and development efforts and approximately $9.8 million in the manufacturing of the Company’s intracutaneous delivery system for development of the Company’s product candidate.

Clinical Trial Costs

Clinical trial costs are a component of research and development expenses. The Company expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company accrues clinical trial expenses each reporting period. The Company determines the actual costs through discussions with internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Stock-Based Compensation

The Company has equity incentive plans under which various types of equity-based awards including, but not limited to, non-qualified stock options and restricted stock awards, may be granted to employees, non-employee directors, and non-employee consultants. The Company’s equity incentive plans also allow incentive stock options to be awarded to employees. The Company has also awarded inducement grants to purchase common stock to new employees outside the existing equity compensation plans in accordance with Nasdaq listing rule 5635(c)(4).

For stock options granted to employees and directors, the Company recognizes compensation expense for all stock-based awards based on the estimated grant-date fair values, net of an estimated forfeiture rate. For restricted stock awards to employees, the fair value is based on the closing price of the Company's common stock on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The Company estimates its forfeiture rate based on an analysis of its actual forfeitures and will continue to evaluate the adequacy of the forfeiture rate assumption based on actual forfeitures, analysis of employee turnover, and other related factors.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned.

Warrants

The Company has issued freestanding warrants to purchase shares of common stock in connection with certain debt and a build-to-suit arrangement. The warrants are recorded at fair value using the Black-Scholes option pricing model.

Income Taxes

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The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Financial statement effects of uncertain tax positions are recognized when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. Interest and penalties related to unrecognized tax benefit, if any, will be included within the provision for income tax.

Interest Expense

Interest expense, includes cash and non-cash components with the non-cash components consisting of (i) interest recognized from the amortization of debt discount and issuance costs, which were capitalized on the balance sheets, that are generally derived from cash payments or warrants issued related to financing obligations, (ii) interest recognized from the amortization of purchase option and termination fees related to financing obligations, which were accrued and capitalized on the balance sheet offset by (iii) interest income recognized from the accretion of debt premiums and (iv) interest capitalized for assets constructed for use in operations.

The capitalized amounts related to the debt issuance costs and debt discounts are generally amortized to interest expense over the term of the related debt instruments unless they are attributable to assets constructed for use in operations and are capitalized as construction-in-progress until the asset is substantially complete and ready for its intended use.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, convertible promissory notes, common stock warrants and stock options are considered to be potential dilutive securities but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The following outstanding common stock equivalents were excluded from the computations of diluted net loss per common share for the periods presented as the effect of including such securities would be antidilutive:

	December 31,	
	2018	2017
	(shares)	
Warrants to purchase common stock	274,524	199,524
Options to purchase common stock	1,309,994	118,379
Total	1,584,518	317,903

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In November 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statements of cash flows. The Company adopted this standard effective January 1, 2018, using the retrospective transition approach. Accordingly, as a result of the adoption of this accounting guidance prior period information has been adjusted to include the addition of restricted cash to cash and cash equivalents on the Company’s statements of cash flows.

Recent Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU2018-15, Intangible - Goodwill and Other - Internal-Use Software (Subtopic 350-40), which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract

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with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU2018-15 is effective for the Company in the first quarter of 2020. Early adoption is permitted. ASU2018-15 permits either a prospective or retrospective transition approach. The Company is currently evaluating ASU2018-15 to determine the impact to its financial statements and related disclosures.

In August 2018, the FASB issued ASU2018-13, Fair Value Measurement (Topic 820). The new guidance modifies the disclosure requirements on fair value measurements. ASU2018-13 is effective for the Company beginning in the first quarter of 2020 and must be adopted on a modified retrospective basis, with certain exceptions. Early adoption is permitted. The Company does not expect ASU2018-13 to have a significant impact to its financial statements and disclosures.

In June 2018, the FASB issued ASU2018-07, Compensation - Stock Compensation (Topic 718); Improvements to Nonemployee Share-Based Payment Accounting which aligned certain aspects of share-based payments accounting between employees and non-employees. Specifically, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied and an entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. ASU2018-07 is effective for the Company beginning in the first quarter of 2019. The new standard will not have a significant impact on the Company's financial statements or disclosures.

In June 2016, the FASB issued ASU2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments and in November 2018, issued ASU2018-19, which amended the standard. This new guidance is intended to present credit losses on available for sale debt securities as an allowance rather than as a write-down. Entities are required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. ASU2016-13 is effective for the Company in the first quarter of 2020. The Company is currently evaluating ASU2016-13 and ASU2018-19 to determine the impact to its financial statements and disclosures.

In February 2016, the FASB issued authoritative guidance under ASU2016-02, Leases (Topic 842). ASU2016-02 requires lessees to recognize right-of-use assets and lease liabilities for most leases on the balance sheet and to provide expanded disclosures about leasing arrangements. ASU2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company will adopt this guidance effective January 1, 2019 using the optional transition method and will not restate comparative periods. The Company's assessment of the impact of the adoption of this standard is substantially complete and will result in the recognition of right-of-use assets of approximately $6.4 million and lease liabilities of approximately $7.8 million with no material impact to the statement of operations and comprehensive loss. Additionally, the Company will no longer have a deferred rent liability of approximately $1.4 million.

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3. Cash Equivalents and Marketable Securities

The following is a summary of the Company's cash equivalents and marketable securities measured at fair value on a recurring basis:

		Fair value Measurements		
	Total	Quoted prices in active market Level I	Significant other observable inputs Level II	Significant unobservable inputs Level III
	(in thousands)			
As of December 31, 2018:				
Money market funds	$4,830	$4,830	$ —	$ —
Commercial paper	1,497	—	1,497	—
Corporate notes and bonds	6,989	—	6,989	—
U.S. treasuries	8,375	8,375	—	—
Total	$21,691	$13,205	$ 8,486	$ —
Classified as:				
Cash equivalents	$7,829			
Marketable securities at fair value	13,862			
Total	$21,691			

		Fair value Measurements		
	Total	Quoted prices in active market Level I	Significant other observable inputs Level II	Significant unobservable inputs Level III
	(in thousands)			
As of December 31, 2017:				
Money market funds	$6,414	$6,414	$ —	$ —
U.S. government agencies	650	—	650	—
Total	$7,064	$6,414	$ 650	$ —
Classified as:				
Cash equivalents	$7,064			

The company did not transfer any marketable securities measured at fair value on a recurring basis to or from Level 1 and Level 2 during the years ended December 31, 2018 and 2017.

The following is a summary of the unrealized positions for available-for-sale fixed-maturity debt securities disaggregated by class of instrument:

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	December 31, 2018 (in thousands)			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$4,830	$ —	$ —	$4,830
Commercial paper	1,497	—	—	1,497
Corporate notes and bonds	6,994	—	(5)	6,989
U.S. treasuries	8,375	—	—	8,375
Total	$21,696	$ —	$ (5)	$21,691

	December 31, 2017 (in thousands)			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$6,414	—	—	6,414
U.S. government agency bonds	650	—	—	650
Total	$7,064	$ —	$ —	$7,064

As of December 31, 2018, the maximum contractual maturity of the Company's available-for-sale investments was within five months. The Company does not intend to sell the investments that are in an unrealized loss position, and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. The Company has determined that the gross unrealized losses on its available-for-sale investments as of December 31, 2018 were temporary in nature.

4. Property and Equipment

The following summarizes the Company's property and equipment for each of the periods presented:

	December 31, 2018	December 31, 2017
	(in thousands)	
Leasehold improvements	$16,690	$ 15,660
Manufacturing equipment	10,387	10,387
Laboratory and office equipment	1,434	1,159
Computer equipment and software	206	209
Construction-in-progress	9,558	2,351
	38,275	29,766
Less: accumulated depreciation	(26,359)	(25,614)
Total	$11,916	$ 4,152

Depreciation expense was approximately $0.8 million and $2.6 million for the years ended December 31, 2018 and 2017, respectively. The decrease in depreciation expense in 2018 as compared to 2017 was a result of certain leasehold improvements becoming fully depreciated in 2017.

The gross property and equipment and accumulated depreciation presented in the above table include property under capital lease and the related accumulated amortization, respectively. Property under capital lease is comprised of office equipment. Capital lease assets included in property and equipment in the balance sheets were $24,000 and zero at December 31, 2018 and 2017, respectively. Accumulated amortization on the property under capital lease was

insignificant at December 31, 2018 and 2017.

At December 31, 2018, construction-in-progress included $6.2 million of an asset relating to the build-to-suit arrangement for construction of the Company's commercial coating and primary packaging system, of which capitalized construction period interest was $0.3 million (See Note 7. Debt Financing).

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Impairment

The Company evaluates its long-lived assets for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets is measured by a comparison of the carrying amount of the asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Previously, the Company discontinued its D107 research and development program, and concluded that the D107 related assets could be repurposed. In 2018, the Company performed an impairment analysis of the D107 related assets to determine fair value based on highest and best use. The Company concluded that only certain of these assets would be able to be repurposed for other research and development projects. As a result, the Company determined the fair value based on its highest and best use and that for certain D107 related assets, the carrying value of the assets was not entirely recoverable and the fair value, which was calculated using the market or cost approach depending on the specific asset, was lower than the carrying value. Accordingly, the Company recorded an impairment loss of approximately $0.4 million for D107 related assets.

In 2018, the Company defined its manufacturing strategy for Qtrypta™ (M207), resulting in the decision to use CMOs for future clinical supply and commercial product production. As a result of this strategy, the Company entered into a drug delivery and supply agreement with a new supplier to design and manufacture the Company's next generation applicator, obsoleting custom manufacturing equipment that had been used to manufacture the Company's current applicator. The Company performed an impairment analysis of the manufacturing equipment assets to determine fair value based on highest and best use. The Company concluded that due to the custom nature of the assets that they could not be repurposed and that there was not a secondary market for the assets. As a result, the Company determined the fair value was not entirely recoverable and the fair value, which was calculated using the market or cost approach depending on the specific asset, was lower than the carrying value. Accordingly, the Company recorded an impairment loss of approximately $0.1 million for custom manufacturing assets.
For the year ended December 31, 2017, the Company recognized $0.1 million of impairment losses, primarily related to laboratory equipment with no current or future utility to the Company.

5. Other Accrued Liabilities

The following summarizes the Company's other accrued liabilities for each of the periods presented:

	December 31,	December 31,
	2018	2017
	(in thousands)	
Contract manufacturing	$834	$ —
Pre-clinical and clinical study	483	88
Construction-in-progress obligations	395	45
Accrued taxes	187	—
Professional service fees	112	377
Other	403	178
Total	$2,414	$ 688

6. Capital Lease Obligation

The Company leases certain equipment under a non-cancelable agreement, that was accounted for as a capital lease and expires in 2022. The effective interest rate on this lease is 25%. The scheduled lease payments of the capital lease obligation for each year ending December 31 were as follows (in thousands):

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Year	
2019	$10
2020	10
2021	10
2022	4
	34
Less: amount representing interest	(11)
Total	$23

Capital lease obligation, current	$5
Capital lease obligation, long-term	18
Total	$23

7. Debt Financing

Build-to-Suit Obligation with Trinity

In September 2018, the Company entered into a build-to-suit arrangement with Trinity Capital Fund III, L.P., ("Trinity") in order to obtain financing for the third party construction of the Company's commercial coating and primary packaging system (the "Equipment"), expected to be completed in the second quarter of 2020. Under the agreement, Trinity will make available to the Company $14.0 million for equipment costs and associated soft costs ("Total Cost"), with an initial drawdown of $5.0 million and additional drawdowns in increments of not less than $0.5 million, until March 30, 2020. At March 30, 2020, any unused portion of the $14.0 million will be subject to a non-utilization fee equal to 3% of the unused amount. In consideration of the financing arrangement, as collateral, the Company granted Trinity a first-priority lien and security interest in substantially all the Company's assets.

The Company determined that it is the deemed owner, for financial reporting purposes, of the Equipment during the construction period due to its involvement in and its obligations related to the construction of the Equipment. Accordingly, construction costs incurred were recorded as construction-in-progress, a component of property and equipment on the balance sheet and the Trinity financing obligation was recorded as a build-to-suit obligation on the balance sheet.

Under the financing arrangement, each individual drawdown represents a separate financing arrangement with its own 36-month-term and stated interest rate. Each drawdown is non-cancelable, with no prepayment options. Each drawdown has embedded optional purchase options to (i) extend the term for an additional three months, with the option to purchase the equipment at 4% of the Total Cost, which is equal to the drawdown amount, following the end of such extended term, or (ii) purchase the equipment at 12% of the Total Cost, which is equal to the drawdown amount, at the end of the 36-month-term. The Company intends to exercise the optional purchase option of 12% at the end of each 36-month-term ("Purchase Option Fee"). The transfer of title from Trinity to the Company will occur at the end of the final 36-month-term, provided that the purchase option was executed and the Purchase Option Fee was paid in full at the end of each 36-month-term. Failure to pay any of the Purchase Option Fees will result in Trinity retaining title to the Equipment and the Company paying a 6% restocking fee.

In September 2018, upon commencement of this arrangement, the Company drew its first drawdown of $5.0 million, of which $2.7 million was for the Company’s commercial coating and primary packaging system, $2.0 million was used to extinguish an existing loan (see below), and the remaining $0.3 million was withheld by Trinity for interim interest and a security deposit that will be applied to the final monthly payment. The monthly loan payment is $160,000, with a stated and effective interest rate of 9.43% and 26.28%, respectively. The Purchase Option Fee of $0.6 million was recorded as a discount to the principal balance. The first drawdown of $5.0 million matures on

October 1, 2021.

In connection with the build-to-suit arrangement, the Company issued common stock warrants ("Trinity Warrants") for a total of 75,000 shares of common stock at an exercise price of $3.59 per share. The Trinity Warrants expire on September 25, 2025. Proceeds allocated to the Trinity Warrants based on their relative fair value approximated $243,000 and were recorded as a discount to the initial $5.0 million drawdown under the Trinity financing arrangement and are being amortized as interest over the term of the September 2018 drawdown.

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In December 2018, the Company drew a second drawdown of $2.8 million, of which $2.6 million was for the Company's commercial coating and primary packaging system, and the remaining $0.2 million was withheld by Trinity for interim interest, the first monthly payment and a security deposit that will be applied to the final monthly payment. The monthly loan payment is approximately $90,000 with a stated and effective interest rate of 9.68% and 19.58%, respectively. The Purchase Option Fee of approximately $0.3 million was recorded as a discount to the principal balance. The second drawdown of $2.8 million matures on January 1, 2022.

As of December 31, 2018, the Company had an aggregate commercial coating and primary packaging system CIP balance of $6.2 million that included $0.3 million of interest related to its build-to-suit obligation, of which $37,000 was attributable to the Trinity Warrants; and a net build-to-suit obligation of $6.8 million. As of December 31, 2018, $6.2 million remains available to the Company under the Trinity build-to-suit arrangement.

The following is a summary of the Company's build-to-suit obligation as of December 31, 2018 (in thousands):

Build-to-suit obligation principal amount	$7,120
Build-to-suit obligation Purchase Option Fees	936
Less: Unamortized Purchase Option Fees	(845)
Unamortized fair value of free-standing warrants	(207)
Unamortized debt discount	(178)
Unamortized debt issuance costs	(22)
Build-to-suit obligation, net of debt issuance costs and discount	$6,804
Build-to-suit obligation, current portion	$2,326
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	4,478
Build-to-suit obligation, net of debt issuance costs and discount	$6,804

Future minimum payments on the Company's build-to-suit obligation, including payment of principal and interest and Purchase Option Fees for each year ending December 31 were as follows (in thousands):

Year	Principal	Interest	Purchase Option Fees
	(in thousands)		
2019	$2,326	$ 583	$ —
2020	2,632	367	—
2021	2,162	107	936
Total	$7,120	$ 1,057	$ 936

Senior Secured Term Loan with Hercules

In June 2014 and June 2015, the Company entered into a loan and security agreement and the first amendment to the loan and security agreement, respectively, with Hercules Capital, Inc. ("Hercules"). Hercules provided the Company a $15.0 million term loan ("Hercules Term Loan") of which equal installment payments of principal and interest were due monthly, with a scheduled maturity date of December 1, 2018. The Hercules Term Loan bore interest at a variable rate equal to the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. On June 1, 2017, the Company paid a $0.1 million legacy end of term charge. On September 25, 2018, the Company paid all its outstanding obligations under the Hercules Term Loan, including an end of term charge of approximately $0.4 million. The gain on extinguishment of the Hercules Term Loan was insignificant.

8. Stockholders' Equity

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On January 24, 2018, the Company amended its certificate of incorporation to increase the number of shares of common stock authorized for issuance from 100,000,000 to 250,000,000. On January 25, 2018, the Company effected a 1-for-20 reverse stock split of its outstanding common stock.

Public Offering - March 2017

On March 22, 2017, the Company completed a registered public offering of 977,500 shares of common stock at a price of $30.00 per share, which included the exercise in full by the underwriters of their over-allotment option to purchase up to 127,500 additional shares of common stock. The total proceeds from the offering were $26.6 million, net of underwriter’s discounts and commissions and offering expenses.

Public Offering - April 2018

On April 3, 2018, the Company completed a registered public offering of 10,000,000 shares of common stock at a price of $5.00 per share. The total proceeds from the offering were approximately $45.6 million, net of underwriter's discounts and commissions and offering expenses.

Equity Line of Credit

On October 20, 2017, the Company entered into a purchase agreement and a registration rights agreement with an accredited investor, Lincoln Park Capital LLC ("Lincoln Park"), providing for the purchase of up to $35.0 million worth of the Company’s common stock over a 30-month-term that commenced on November 21, 2017 ("Equity Line of Credit").

Under the terms and subject to the conditions of the Equity Line of Credit, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $35.0 million worth of shares of the Company’s common stock. The Company’s board of directors reserved 392,104 shares for issuance pursuant to the Equity Line of Credit (inclusive of commitment shares). On October 20, 2017, the Company issued 11,375 shares of its common stock, as initial commitment shares, to Lincoln Park with a fair value of $15.30 per share. The value of the commitment shares and professional service fees to secure the Equity Line of Credit were recorded as deferred financing costs and are being amortized as interest expense over the term of the Equity Line of Credit, as there is no guarantee that additional shares will be sold under the Equity Line of Credit. Deferred financing costs of $0.2 million and $0.3 million were recorded in prepaid expenses and other current assets and long-term assets in the accompanying balance sheets as of December 31, 2018 and 2017, respectively.

The Company will issue, pro rata, up to an additional 11,375 shares of its common stock as additional commitment shares to Lincoln Park in connection with any additional purchases. Such future sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company’s option, over the 30-month-term of the Equity Line of Credit. No sales of common stock have been made under the Equity Line of Credit as of December 31, 2018.

Private Investment in Public Equity (“PIPE”) – August 2016

On August 15, 2016, the Company entered into a Securities Purchase Agreement (“Purchase Agreement”) between the Company and certain investors, including members of the Company’s board of directors and executive management, pursuant to which the Company sold and issued shares of common stock and warrants to purchase shares of common stock for aggregate gross proceeds of $7.5 million. Costs related to the offering were $0.9 million. Pursuant to the Purchase Agreement, the Company sold 239,997 common shares at $26.40 per common share. Additionally, 480,000 warrants were sold, at a price of $2.50 per warrant. Each warrant grants the holder the right to purchase one share of the Company’s common stock. The Company granted 239,997 Series A Warrants, which expired in August 2017. The Company granted 239,997 Series B Warrants, which have a per share exercise price of $31.00 and expire in August 2021. Certain of the Company's board of director and executive officers purchased an aggregate of 13,771 shares of common stock and an aggregate of 27,542 warrants in this offering at the same price as the other investors. As of December 31, 2018, 195,906 warrants, which were issued in conjunction with the PIPE, remain outstanding.

Hercules Warrants

In connection with the Company’s entry into the Hercules Term Loan in June 2014, the Company issued Hercules warrants to purchase 1,583 shares of the Company’s common stock at an exercise price of $176.80 per share.

In June 2015, when the Company entered into the first amendment to the Hercules Term Loan, the Company issued Hercules warrants to purchase 2,035 shares of the Company's common stock at an exercise price of $147.40 per share.
Trinity Warrants

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In connection with its build-to-suit arrangement, the Company issued the Trinity Warrants for a total of 75,000 shares of common stock at an exercise price of $3.59 per share. The Trinity Warrants expire on September 25, 2025. Proceeds allocated to the Trinity Warrants based on their relative fair value approximated $0.2 million and were recorded as a discount to the initial $5.0 million drawdown under the Trinity financing arrangement and are being amortized over the 36-month-term of the September 2018 drawdown.

The following warrants were issued and outstanding as of December 31, 2018:

	Warrants Outstanding as of December 31, 2017	Warrants Issued	Warrants Exercised	Warrants Expired	Warrants Outstanding as of December 31, 2018	Exercise Price	Expiration Date
PIPE Financing - Series B	195,906	—	—	—	195,906	$31.00	8/19/2021
Hercules - June 2014	1,583	—	—	—	1,583	$176.80	1/27/2020
Hercules - June 2015	2,035	—	—	—	2,035	$147.40	6/23/2020
Trinity - September 2018	—	75,000	—	—	75,000	$3.59	9/25/2025
Total	199,524	75,000	—	—	274,524		

Each warrant grants the holder the right to purchase one share of common stock. Equity warrants are recorded at their relative fair market value in the stockholders' equity section of the balance sheet. The Company's equity warrants can only be settled through the issuance of shares and do not have any anti-dilution or price reset provision.

9. Commitments and Contingencies

Operating Leases

The Company has a non-cancelable operating lease with BMR-34790 Ardentech Court LP ("BMR") for office, research and development, and manufacturing facilities in Fremont, California. Prior to December 2017, BMR was a related party due to its affiliation with Bruce D. Steel, who served as director of the Company until December 13, 2017. As of December 31, 2018, BMR was no longer a related party.

On June 6, 2017, the Company entered into the seventh amendment to the existing lease ("Seventh Amendment"), effective as of May 30, 2017, that extended the term of the lease through August 31, 2024, with an option to further extend the lease for an additional 60 months, subject to certain terms and conditions. The Company agreed to pay a monthly base rent of approximately $136,000 for the period commencing September 1, 2017, and ending on August 31, 2018, with annual increases on September 1 of each subsequent year until the lease year beginning September 1, 2023. The Seventh Amendment also provided for rent abatements, subject to certain conditions, totaling $0.3 million and certain tenant improvements to be completed at the landlord's expense of approximately $1.0 million by May 30, 2018.

The Company entered into the eighth amendment to the existing lease effective as of May 30, 2018, which extended the deadline for the Company to cause certain tenant improvements to be completed at the landlord's expense to September 30, 2018.

The Company incurred additional expense of approximately $0.4 million under the lease in connection with roof repairs that are treated as additional rent and paid over the term of the lease.

The Company records rent expense under the lease on a straight-line basis over the term of the lease. The difference between the actual lease payments and the expense recognized under the lease, along with the unamortized tenant improvement allowances, resulted in a net deferred rent liability of approximately $1.4 million and $0.5 million as of December 31, 2018 and 2017, respectively.

For the years ended December 31, 2018 and 2017, rent expense under operating leases was $1.6 million and $1.2 million, respectively.

As of December 31, 2018, future minimum payments under all non-cancelable operating leases for each year ending December 31 were as follows (in thousands):

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Year	
2019	$1,762
2020	1,815
2021	1,863
2022	1,914
2023 and thereafter	3,310
Total	$10,664

Employment Arrangements

The Company has entered into employment agreements with some of its executive officers. Generally, the terms of these agreements provide for base salary, health care coverage, annual bonus and stock options. In addition, if the Company terminates the officer other than for cause, death, or disability, or if the officer terminates his or her employment with the Company for good cause, the officer shall be entitled to receive certain severance compensation and benefits as described in each such agreement as well as automatic acceleration of vesting, at a certain percentage (25% or 100%), of their unvested stock options and other equity awards on the date of such termination.

The employment agreements with the Company’s Chief Executive Offer ("CEO") and Chief Financial Officer ("CFO") provide for the payment of base salary and healthcare coverage if the Company terminates their employment other than for cause or in the event of their resignation for good reason. Under the terms of his employment agreement, the CEO is entitled to receive base salary for twelve months, healthcare coverage for twelve months, and an amount equal to the amount of the annual bonus awarded to him in the calendar year prior to such termination. Under the terms of his employment agreement, the CFO is entitled to receive base salary for six months and payment or reimbursement for healthcare coverage for up to six months. The employment agreements with both the CEO and CFO also provide for the automatic acceleration of vesting of 25% of their unvested stock options and other equity awards on the date of such termination.

During the one-year period following a change in control of the Company, if the Company terminates the CEO or CFO without cause or if the CEO or CFO resign for good reason, the CEO and CFO are entitled to receive additional compensation. In the event of such termination, the CEO is entitled to receive a lump sum severance payment equal to 24 months of base salary, a lump sum payment equal to 229.56% of projected premiums for group medical, dental and vision insurance coverage for 24 months, and an amount equal to the amount of the annual bonus awarded to him in the calendar year prior to such termination. The CFO is entitled to receive a lump sum severance payment equal to twelve months of base salary, payment or reimbursement for healthcare coverage for up to twelve months, and an amount equal to the bonus he earned for the preceding fiscal year. In addition, the employment agreements with both the CEO and CFO provide for the automatic acceleration of vesting of 100% of their unvested stock options and other equity awards on the date of such termination.

The Company also has employment agreements with its Vice President of Clinical Development and Medical Affairs ("VPCDMA") and Senior Vice President of Operations ("SVPO"). The agreements provide for the continuation of payment of base salary for six months and payment or reimbursements for healthcare coverage for up to six months in the event of termination of their employment with the Company without cause or their resignation for good reason. The employment agreements also provide for the automatic acceleration of vesting of 25% of their unvested stock options and other equity awards on the date of such termination. If such termination or resignation occurs during the one-year period following a change in control of the Company, the VOCDMA and SVPO are entitled to receive lump sum severance payments equal to 12 months of base salary, payment or reimbursement for healthcare coverage for up to twelve months and an amount equal to their bonus, if any, earned for the immediately proceeding year. In addition, the employment agreements provide for the automatic acceleration of vesting of 100% of their unvested stock options and other equity awards on the date of such termination.

Equipment Purchase Commitments

In May 2018, the Company entered into a purchase order with an equipment manufacturer to purchase a commercial coating and primary packaging machine for the production of its product candidate, Qtrypta™ (M207), for an aggregate purchase price of $12.2 million. The terms of the purchase commitment are contingent upon performance of certain milestones. The Company anticipates that the obligation will be paid over an 18 month period. As of December 31, 2018, the Company had made payments totaling $3.0 million.

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During 2018, the Company also entered into agreements with equipment manufacturers to produce its patch assembly machine and its applicator and retainer machinery. The aggregate purchase price of this equipment is $3.5 million of which $0.9 million was paid in 2018.

Contract Manufacturing Organizations

In September 2018, the Company entered into a manufacturing and supply agreement with a contract manufacturing organization to provide services related to the manufacture and commercialization of Qtrypta™ (M207). During the term of the agreement, the CMO will provide services related to processing, packaging, labeling and storing Qtrypta™ (M207), in addition to other services such as stability testing, quality control and assurance, and waste disposal.

The agreement calls for annual fees of $1.0 million in 2019 escalating to $14.0 million in 2024, to be paid in equal monthly installments. Beginning in 2020, the annual fee includes the production of a defined number of units with an option to purchase additional units at a defined price. The agreement contains negotiated representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the agreement continues until the seventh anniversary of the date on which the Company receives New Drug Application approval of Qtrypta™ (M207) in the United States.

The Company may elect to terminate the agreement at any time prior to certain regulatory approvals or if such regulatory approval is withdrawn under certain circumstances. Upon termination of the contract, the Company would incur cancellation fees of 50% of the annual fee due in the year that the contract is terminated, estimated to be between $1.0 million and $1.4 million, and costs to remove the Company's equipment and restore the CMO's facility to its original condition. The Company or the CMO may terminate the agreement for the other’s uncured material breach, uncured force majeure or bankruptcy or insolvency-related events.

At December 31, 2018, the Company had entered into agreements with CMOs for the construction of dedicated manufacturing space and technology transfer fees of $4.1 million of which $0.2 million had been paid.

Indemnification and Guarantees

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company’s request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2018.

Legal Proceedings

The Company is not party to any material pending legal proceedings. However, it may from time to time become involved in litigation relating to claims arising in the ordinary course of business.

10. Stock-Based Compensation

The 2012 Stock Incentive Plan

The 2012 Stock Incentive Plan ("2012 Plan") provided for the granting of stock options and restricted stock awards to employees, directors and consultants of the Company. Options granted under the 2012 Plan were either incentive stock options or nonqualified stock options. Incentive stock options were granted only to Company employees. Nonqualified stock options were granted to Company employees, outside directors and consultants. Options and awards under the 2012 Plan were granted for periods of up to ten years. Employee options granted by the Company generally vest over four years. In connection with the Company’s initial public offering of its common stock, the

Company’s board of directors terminated the 2012 Plan effective as of January 27, 2015 and no further awards were issued under the 2012 Plan. However, any awards outstanding under the 2012 Plan at January 27, 2015 continue to be governed by the terms of the 2012 Plan.

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The Amended and Restated 2014 Equity and Incentive Plan

The Amended and Restated 2014 Equity and Incentive Plan ("2014 Plan") provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company's common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of December 31, 2018, the Company had reserved 1,348,173 shares of its common stock for issuance under the 2014 Plan, subject to automatic annual increases as set forth in the plan. Options and awards under the 2014 Plan may be granted for periods of up to ten years. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions and the right of repurchase by the Company of unvested shares as determined by its board of directors. As of December 31, 2018, the Company had 55,799 shares available for grant under the 2014 Plan. During the year ended December 31, 2018, the Company granted stock options to purchase 131,000 shares of common stock to non-employee directors.

The following table summarizes option and award activity, excluding inducement grants, for the fiscal years ended December 31, 2017 and 2018:

	Shares Available for Grant	Outstanding Number of Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at January 1, 2017	2,826	79,657	$ 38.51	5.62	
Additional shares reserved	52,950	—	$ —		
Options granted	(55,210)	55,210	$ 17.43		
Options exercised	—	(4,926)	$ 27.94		
Options canceled/forfeited/expired	30,912	(30,912)	$ 39.10		
Restricted stock award granted	(3,000)	—	$ —		
Restricted stock award forfeited	1,334	—	$ —		
Shares expired under 2012 Plan	(241)	—	$ —		
Balance at December 31, 2017	29,571	99,029	$ 25.33	8.46	
Additional shares reserved	1,225,223	—	$ —		
Options granted	(1,212,200)	1,212,200	$ 4.24		
Options canceled/forfeited/expired	15,072	(15,072)	$ 12.38		
Shares expired under 2012 Plan	(1,867)	—	$ —		
Balance at December 31, 2018	55,799	1,296,157	$ 5.75	9.23	$ —
Exercisable at December 31, 2018		225,138	$ 10.43	8.83	$ —
Vested or expected to vest at December 31, 2018		1,195,711	$ 5.86	9.22	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company's common stock for in-the-money options at December 31, 2018.

Inducement Grants

The Company has also awarded inducement grants to purchase common stock to new employees outside the existing equity compensation plans in accordance with Nasdaq listing rule 5635(c)(4). Such options vest at a rate of 25% of the shares on the first anniversary of the commencement of such employee's employment with the Company, and then one forty-eighth (1/48) of the shares monthly thereafter subject to such employee's continued service. The following table summarizes the Company's inducement grant stock option activities:

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	Outstanding Number of Shares	Weighted-Average Exercise Price per Share	Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at January 1, 2017	12,600	$ 15.40	9.68	
Options granted	6,750	$ 26.06		
Balance at December 31, 2017	19,350	$ 19.12	8.91	
Options granted	—	$ —		
Options canceled/forfeited/expired	(5,513)	$ 15.40		
Balance at December 31, 2018	13,837	$ 20.60	4.52	$ —
Exercisable at December 31, 2018	10,007	$ 18.47	3.05	$ —
Vested or expected to vest at December 31, 2018	13,562	$ 20.48	4.44	$ —

The following summarizes the composition of stock options outstanding and exercisable within the approved stock option plans, excluding inducement grants, as of December 31, 2018:

	Options Outstanding			Options Exercisable	
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$3.45 - $4.00	132,500	9.80	$ 3.90	—	$ —
$4.24 - $4.24	937,637	9.29	$ 4.24	156,409	$ 4.24
$4.27 - $181.00	224,470	8.70	$ 11.93	67,338	$ 21.18
$182.60 - $182.60	150	6.32	$ 182.60	137	$ 182.60
$185.80 - $185.80	1,400	6.39	$ 185.80	1,254	$ 185.80

The weighted-average grant-date fair value of options and awards granted within the approved stock option plans during the years ended December 31, 2018 and 2017 were $4.24 and $17.43, respectively. The total fair value of options and awards that vested during the years ended December 31, 2018 and 2017 were $1.0 million and $0.4 million, respectively.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Research and development	$ 529	$ 266
General and administrative	649	426
Total	$ 1,178	$ 692

At December 31, 2018, the Company had $3.5 million of total unrecognized stock-based compensation, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 3.27 years.

The Company’s stock-based compensation expense for stock options is estimated at the grant date based on the award’s fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite

service period. The Black-Scholes option pricing model requires various highly judgmental assumptions including expected volatility and expected term. The expected volatility is based on the historical stock volatilities of several of the Company's publicly listed peers over a period equal to the expected terms of the options as the Company does not have sufficient trading history to use the volatility of its own common stock. To estimate the expected term, the Company has opted to use the simplified method which is the use of the midpoint of the vesting term and the contractual term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. In addition, the Company estimates the forfeiture rate based on historical experience and its expectations regarding future

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pre-vesting termination behavior of employees. To the extent that the actual forfeiture rate is different from this estimate, stock-based compensation expense is adjusted accordingly.

The following table presents the weighted-average assumptions for the Black-Scholes option-pricing model used in determining the fair value of options granted to employees:

	Year Ended December 31,	
	2018	2017
Dividend yield	—%	—%
Risk-free interest rate	2.46% - 3.11%	1.90% – 2.25%
Expected volatility	89%	89%
Expected term (years)	6.08	6.08
Estimated forfeiture % rate	6.50%	6.50%

11. Severance

In May 2018, the Company's Chief Business and Financial Officer resigned. Pursuant to the terms of a separation agreement, the Company agreed to pay severance totaling approximately $0.2 million, including base salary and benefit continuation coverage, for six months and accelerated 25% of the unvested portion of her outstanding equity awards. Additionally, her vested options remain exercisable for a period of eighteen months following her resignation. As of December 31, 2018, the Company had paid substantially all severance related to this arrangement.

In May 2017, the President and Chief Executive Officer of the Company resigned. Pursuant to the terms of a separation agreement, the Company paid total severance payments and continuation of benefits of approximately $0.3 million.

12. Income Taxes

The Company has incurred cumulative net operating losses ("NOL") since inception and, consequently, has not recorded any income tax expense for the years ended December 31, 2018 and 2017 due to its net operating loss position.

The reconciliation of the federal statutory income tax rate to the Company’s effective tax rate is as follows:

	Year Ended December 31,	
	2018	2017
Federal statutory tax rate [1]	(21.0)%	(34.0)%
State statutory tax rate, net of federal benefit	(7.0)	(5.8)
Change in effective tax rate	—	18.1
Derecognition due to Section 382 and 383	25.4	30.2
Stock-based compensation	0.5	1.1
Permanent items	3.0	(2.5)
Change in valuation allowance	(0.9)	(7.1)
Total	—%	—%

(1) In December 2017, the United States government enacted tax reform legislation that reduced the U.S. federal statutory tax rate to 21 percent.

Deferred income taxes 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. As of December 31, 2018 and 2017, the Company had net deferred tax assets of $16.5 million and $16.9 million, respectively. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance

decreased by approximately $0.3 million and $2.0 million during the years ended December 31, 2018 and 2017, respectively.

Significant components of the Company’s net deferred tax assets and liabilities are as follows:

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	December 31,	
	2018	2017
	(in thousands)	
Net operating loss carryforwards	$10,942	$12,226
Research and development credits	3,657	3,245
Depreciation and amortization	729	640
Accruals	569	507
Deferred rent	400	113
Stock-based compensation	213	98
Capital loss carryforward	23	23
Other	2	1
Net deferred tax assets	16,535	16,853
Valuation allowance	(16,535)	(16,853)
Total	$—	$—

As of December 31, 2018, the Company had federal net operating loss carryforwards of approximately $41.1 million and state net operating loss carryforwards of approximately $33.2 million. As of December 31, 2017, the Company had federal net operating loss carryforwards of approximately $43.8 million and state net operating loss carryforwards of approximately $43.5 million. If not utilized, certain of the federal net operating loss carryforwards will expire beginning in 2026, and state net operating loss carryforwards will expire beginning in 2028.

If the Company experiences a greater than 50 percentage point aggregate change in ownership over a 3-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company's stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. As of December 31, 2018, the Company determined that ownership changes occurred on February 26, 2014, November 30, 2015, March 22, 2017 and April 3, 2018. As a result of the ownership changes, approximately $220.5 million and $196.6 million of the NOLs will expire unutilized for federal and California purposes, respectively. As of December 31, 2018, the Company has derecognized NOL related deferred tax assets in the tax affected amounts of $46.3 million and $13.7 million for federal and California purposes, respectively. The ability of the Company to use its remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

In December 2017, the U.S. government enacted the Tax Reform Act. The Tax Reform Act includes, but is not limited to, reducing the U.S federal corporate tax rate to 21 percent, allowing federal net operating losses generated after December 2017 to be carried over indefinitely and creating a new limitation on deductible interest expense.

In February 2018, the SEC staff issued SAB 118 which provided guidance on accounting for the tax effects of the Tax Reform Act. SAB 118 provided a measurement period should not extend beyond one year from the Tax Reform Act enactment date for companies to complete the accounting related to the Tax Reform Act under ASC 740, Income Taxes. The Company completed its assessment of the accounting impact resulting from the Tax Reform Act in the fourth quarter of 2018 and determined there was no adjustment to the Company's financial statements.

As of December 31, 2018, the Company had federal and state research and development credit carryforwards of approximately $0.6 million and $5.1 million, respectively. As of December 31, 2017, the Company had federal and state research and development credit carryforwards of approximately $0.4 million and $4.6 million, respectively. If not utilized, the federal tax credits will begin to expire in 2026 and state tax credits currently do not expire. Research and development credits are subject to IRC section 383. In the event of a change in ownership as defined by this code section, the usage of the credits may be limited. As a result of the previously mentioned ownership changes, the Company has derecognized approximately $5.1 million of gross federal research and development credit-related deferred tax assets due to the Section 383 limitation as of December 31, 2018. The Company has not derecognized

any of the California research and development credit-related deferred tax assets because the credits do not expire.
Uncertain Income Tax Positions

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The Company only recognizes tax benefits if it is more likely than not that they will be sustained upon audit by the relevant tax authority based upon their technical merits. An uncertain tax position is not recognized if it has less than a 50% likelihood of being sustained.

The Company had approximately $1.1 million of unrecognized tax benefits as of December 31, 2018 and approximately $1.0 million of unrecognized tax benefits as of December 31, 2017. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits reduce the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months. A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Balance at the beginning of year	$ 1,006	$ 943
Decrease related to prior year tax positions	(77)	—
Increase related to current year tax positions	199	63
Balance at the end of year	$ 1,128	$ 1,006

As of December 31, 2018 and 2017, the Company had not recognized any tax-related interest or penalties in its financial statements. Interest and penalties related to unrecognized tax benefits would be included as income tax expense in the Company’s statements of operations.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is not currently under audit by the Internal Revenue Service or any other similar state, local, or foreign authority. All tax years remain open to examination by major taxing jurisdictions to which the Company is subject.

13. Employee Benefit Plan

The Company has established a 401(k) tax-deferred savings plan (the "401(k) Plan"), which permits participants to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. The Company is responsible for administrative costs of the 401(k) Plan. The Company may, at its discretion, make matching contributions to the 401(k) Plan. No employer contributions have been made to date.

14. Subsequent Event

In February 2019, the Company entered into an amendment to its May 2018 purchase order with the manufacturer of its commercial coating and primary packaging system for the production of its product candidate, Qtrypta™ (M207). The purchase order increased the aggregate purchase price from $12.2 million to $13.5 million.