Zosano Pharma Corp
Form 10-K
March 12, 2018
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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, 2017

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 No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

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		Accelerated filer
Non-accelerated filer	(do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2017 (the last business day of the registrant s most recently completed second quarter) was approximately $55,132,103.

As of March 1, 2018, the registrant had a total of 1,973,039 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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Zosano Pharma Corporation

Annual Report on Form 10-K

For the Fiscal Year ended December 31, 2017

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this Annual Report) 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, believe, estimate, project, predict, potential, or the negative of those terms, and similar expressions and comp 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 M207;
- our expectations regarding the clinical effectiveness and safety of our product candidates;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- our manufacturing capabilities and strategy, and our ability to establish and maintain relationships with contract manufacturing organizations to expand our manufacturing capacity;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- our intellectual property position and our ability to obtain and maintain intellectual property protection for our product candidates;
- 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 candidates;

the size and growth of the potential markets for our product candidates and the ability to serve those markets;

the rate and degree of market acceptance of any of our product candidates;

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 on Form 10-K.

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

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 M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, for markets where patients remain underserved by existing therapies.

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, for markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, M207. 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 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, or FDA, on M207 s regulatory path has confirmed that one positive pivotal efficacy study, in addition to the required safety study, would be sufficient for approval of M207 for the treatment of migraine.

ZOTRIP Phase 3 Trial Results

The ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of 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 M207 dose demonstrated statistically significant 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	14.3%	41.5%	0.0001
Most bothersome symptom freedom	42.9%	68.3%	0.0009

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 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.

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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

* The p value in 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.

M207 was generally well-tolerated with no serious adverse events, or SAEs, reported in the ZOTRIP study. The most frequently reported adverse event are shown in the following table:

Most Frequent Adverse Events (³4% 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	0.0%	3.8%	5.7%	4.8%
Dizziness	0.0%	1.3%	0.0%	4.8%

M207 Long Term Safety Study

In November 2017, we announced the initiation of enrollment in our long-term safety study for M207 as an acute treatment of migraine (M207-ADAM). M207-ADAM is an open label study evaluating the safety of the 3.8mg dose of M207 in migraine patients who have historically experienced at least two migraines per month. Patients are expected to treat a minimum of two migraines per month, with no maximum treatment limits. The M207-ADAM study will evaluate 150 patients for six months, and 50 patients for a year at approximately 30 sites in the U.S. The study is open-label, with investigator visits at months one, two, three, six, nine and twelve to record adverse events. We may elect to enroll more than the required number of patients to ensure a robust data set, and achievement of evaluable patients at each time point. The primary objective of M207-ADAM is to assess safety of M207 during repeated use over six and twelve months. Other endpoints are electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response.

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, M207. The key elements of our strategy are to:

Develop and commercialize M207. We believe that 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 M207. While we currently intend to develop M207 through FDA approval and commercialization in the United States ourselves, we remain open to opportunities with potential strategic partners to maximize the strategic value of our product and our company.

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Focus on regulatory support and market opportunities for M207. We intend to focus our resources on non-clinical and clinical studies required for NDA filing and, if approved, would support market acceptance and expansion for M207. For example, certain preclinical studies, such as 30 day toxicity studies, are required in order to file an NDA.

Pursue indications outside migraine for external partnering. We have performed initial feasibility studies on a number of compounds, both within CNS and in other therapeutic indications, where rapid drug delivery could provide a therapeutic benefit to patients. For product candidates that are outside the area of migraine, or where a partner can contribute specific expertise, we intend to evaluate collaborations with strategic partners to further the clinical and commercial development of such product candidates. In addition, we continue to explore opportunities to combine a partner s proprietary molecule with our ADAM technology to create new therapeutic options for patients.

M207 for Migraine

The focus of our development efforts is on our product candidate 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 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. According to market data from Symphony Health, triptans constitute over a $4.8 billion market in the United States.

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 M207. Our ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of 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,

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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.

Five hundred and eighty nine 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, 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 3.8 mg 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, M207 was not associated with any SAEs. While the 1.0 mg and 1.9 mg doses of M207 demonstrated statistical significance in pain freedom at two hours, they did not achieve statistical 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	14.3%	41.5%	0.0001
Most bothersome symptom free	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

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 M207-treated groups reported dizziness versus zero subjects in the placebo group, and four (1.2%), subjects across M207-treated groups reported nausea whereas zero subjects in the placebo group reported this event.

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The ZOTRIP trial results demonstrating pain freedom after treating with 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

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

* p-values are nominal because of order of statistical testing

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M207 Long Term Safety Study

In November 2017, we announced enrollment of the first patient in our long-term safety study for M207-ADAM. The M207-ADAM is an open label study evaluating the safety of the 3.8mg dose of M207 in migraine patients who have historically experienced at least two migraines per month. Patients are expected to treat a minimum of two migraines per month, with no maximum treatment limits. The M207-ADAM study will evaluate approximately 150 patients for six months, and approximately 50 patients for a year at approximately 30 sites in the U.S. The study is open-label, with investigator visits at months one, two, three, six, nine and twelve to record adverse events. We expect to have completed enrollment of approximately 100 patients by the end of the first quarter of 2018 and approximately 250 patients by the end of the second quarter of 2018 in order to meet our overall objectives of evaluating repeat use of M207 in 150 subjects for six months and 50 subjects for a year. The primary objective of M207-ADAM is to assess safety of M207 during repeated use over six and twelve months. Other endpoints are electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response. Based on enrollment projections, we anticipate six month safety data will be available around the end of the fourth quarter of 2018 and twelve month safety data around the end of the first quarter of 2019.

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. We intend to pursue product development opportunities that utilize the Section 505(b)(2) regulatory pathway, which may reduce clinical development and regulatory timelines relative to new chemical entity development. 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 3 cm^2 to 6 cm^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 2 cm^2, 3 cm^2 and 6 cm^2 microneedle arrays. In the pivotal trial for M207 we used two 3 cm^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 6 cm^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.

Competition

Competition for our product candidates

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.

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Companies marketing products that treat migraine that may compete with our 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, 2017, our research and development group consisted of 36 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, 2017 and 2016, we incurred $20.2 million and $20.5 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 current good manufacturing practices (cGMP) compliant manufacturing facility in Fremont, California, and believe we have adequate manufacturing capabilities and capacity to produce our ADAM technology for preclinical and Phase 1 and Phase 2 clinical trials of all of our product candidates, and pivotal Phase 3 trials of most of our product candidates. We continue to expand our manufacturing capabilities and have implemented automation of certain processes to further expand our capacity. We expect to produce GMP batches of M207 in the third quarter of 2018. We purchase various components or intermediates of our ADAM technology from third-party vendors, including the titanium foil and formed micro-arrays, 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, 2018, we held exclusive licenses to or owned 28 United States patents and 5 United States patent applications, as well as three Patent Cooperation Treaty patent applications, covering key features of our intracutaneous delivery system, such as formulation, methods of treatment, coating, array design, patch

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anchoring, patch application, delivery, manufacturing and packaging. In December 2017, we received a Notice of Allowance from the U.S. Patent and Trademark Office for our patent application directed to M207 titled Method of Rapidly Achieving Therapeutic Concentrations of Triptans for Treatment of Migraines. This newly-allowed patent application contains claims generated from formulation, preclinical and clinical studies, and highlights the unique aspects of our technologies and their applicability for the treatment of migraine. This application will issue on March 20, 2018, as U.S. Patent No. 9,918,932 and will expire on 2037. In late January 2018, a continuation application was filed from this parent application that will advance the protection for this technology.

We license all of these patents and patent applications, other than an issued US patent and pending US and international applications for D107 and M207 formulation and a new applicator design described below, from ALZA Corporation, or ALZA, on an exclusive basis for all countries. These patents and patent applications are foundational and apply generally to each of our product candidates and their related applicators. 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 intracutaenous 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 four pending United States patent applications, two pending European applications, a pending Patent Cooperation Treaty application covering our single-use applicator and formulations of D107 and zolmitriptan. The D107 patent was issued in November 2015 with an expiration date of 2034. The last of our issued technology platform patents will 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 customers, and have restricted access to our manufacturing facilities and other technology.

We have one registered trademark to Zosano, ZOSANO PHARMA, Reg. No. 3705884 and one pending trademark application for ADAM, App. No. 87525805.

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. In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or the 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 new drug applications (NDAs) warning letters, product recalls, product seizures, total or partial suspension of production or distribution,

injunctions and/or criminal prosecution. We expect each of our product candidates will be subject to review by the FDA as a drug/device combination product under NDA standards. Medical products containing a combination of new drugs, biological products or medical devices are regulated as combination products in the United States. 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

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component, whether a new drug, biologic or device. In order 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 M207 program.

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:

- 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 investigational new drug application (IND) for human clinical testing, which must become effective before human clinical trials in the U.S. may begin and must be updated annually;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication to the FDA s satisfaction;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations; and
- FDA review and 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 and analytical data, 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. We submitted an IND for 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 three sequential phases, but the phases may overlap. The trial protocol and informed consent information for trial subjects in clinical

trials must also be approved by an Institutional Review Board (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 satisfy extensive good clinical practice (GCP) regulations and regulations for informed consent and 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. Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions 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

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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 may request additional information rather than accept the NDA for filing. 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 safe use of the drug. 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. 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 NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA s satisfaction, the FDA will 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.

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

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. 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 products in clinical and

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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. 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.

Hatch-Waxman Act

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, Section 505(b)(2) of the FDCA was enacted, otherwise known as the Hatch-Waxman Amendments. 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. The Hatch-Waxman Amendments permit the applicant to rely 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. 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 the Section 505(b)(2) applicant.

To the extent that the 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. 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 505(b)(2) application. The Section 505(b)(2) 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.

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 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 Section 505(b)(2) NDA by imposing a 30-month automatic statutory injunction, 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 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 Abbreviated New Drug Applications and 505(b)(2) applications containing the protected active

ingredient. The Hatch-Waxman Act also provides three years of 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.

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Pricing and Reimbursement

Sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and 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 are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products 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 products are approved by the FDA, we intend to work with payers to demonstrate the clinical benefits of our products over other delivery modalities to secure adequate and commercially favorable pricing and reimbursement levels.

Other Governmental Regulations, Healthcare Laws and Environmental Matters

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.

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 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.

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. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations, many of which may become more applicable to us if our product candidates are 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.

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.

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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.

Employees

As of December 31, 2017, we had 51 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.

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 will be 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

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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 consolidated financial statements and the related notes thereto.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

The audit report contained in our Annual Report on Form 10-K for the year ended December 31, 2017 contains an explanatory paragraph to the effect that there is doubt about our ability to continue as a going concern.

As of December 31, 2017, we had an accumulated deficit of $225.9 million as well as negative cash flows from operating activities. We will continue to require substantial funds to continue research and development, including clinical trials of our lead product candidate, M207. As noted above, we expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. There is no assurance that such additional funds will be obtained for our ongoing operations and that the Company will succeed in it future operations. Substantial doubt exists about the Company s ability to continue as a going concern. Our audited consolidated financial statements include a going concern disclosure that 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. If the results of our long term safety study do not support regulatory approval and/or market acceptance of M207, it could materially and adversely affect our business, financial condition and results of operation 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, 2017 we incurred a net loss of $29.1 million. As of December 31, 2017, we had an accumulated deficit of $225.9 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, M207. 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 M207 or one of our other product candidates, 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 candidates, which may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or lead product candidates.

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.

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.

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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, such as our March 2017 public offering in which we sold 977,500 million shares of our common stock for aggregate gross proceeds of $29.3 million or under our equity line of credit with Lincoln Park Capital Fund, LLC pursuant to which we may sell up to $35 million of our common stock (subject to certain conditions and limitations) to Lincoln Park, 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 candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings 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 candidates that we would otherwise prefer to develop and market ourselves.

Our loan facility with Hercules Capital, Inc. (Hercules), previously known as Hercules Technology Growth Capital Inc., imposes restrictions on our business, and if we default on our obligations, Hercules would have a right to foreclose on substantially all of our assets, including our intellectual property.

In June 2014, we entered into a loan and security agreement with Hercules Capital, Inc. which provided us $4.0 million in debt financing. In June 2015, we entered into a first amendment to the loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million (Hercules Term Loan). The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance would be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. As of July 1, 2016, we are required to make month installment payments on the principal and interest of the Hercules Term Loan and, if we cannot meet the principal payment requirements under the first amendment to the loan and security agreement, we could be in default. On June 7, 2017, the Company paid a $100,000 legacy end of term charge and in addition, we are obligated to pay a $351,135 end of term charge on the earlier of loan maturity or at the date we prepay the Hercules Term Loan. We may prepay all, but not less than all, of the Hercules Term Loan with no prepayment charge. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties.

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

- incur indebtedness;

create liens on our property;

make payments on any subordinated debt, while the Hercules loan remains outstanding;

make investments in or loans to others;

acquire assets other than in the ordinary course;

dispose of the collateral that secures the Hercules loan;

transfer or sell any assets;

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engage in any transaction that would constitute a change of control; and

change our corporate name, legal form or jurisdiction.

Our indebtedness to Hercules may limit our ability to finance future operations or capital needs or to engage in, expand or pursue our business activities. It may also prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding debt, which may not be desirable or possible.

We have pledged substantially all of our assets, including our intellectual property, to secure our obligations to Hercules under the loan facility under the promissory note. If we default on our obligations prior to repaying this indebtedness, and are unable to obtain a waiver for such default, Hercules would have a right to accelerate our payments under the loan facility or the note, as applicable, and possibly foreclose on the collateral, which would potentially include our intellectual property. Any such action on the part of Hercules 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 M207 or our other product candidates on a commercial scale. The successful commercialization of any of our product candidates will require us to perform a variety of functions, including:

continuing to conduct clinical development of our product candidates;

obtaining required regulatory approvals;

formulating and manufacturing products; 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 products.

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 CANDIDATES

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

We have focused our clinical development efforts on our product candidate, M207. The development and commercialization of M207 and any product candidates 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 candidates;

we may experience delays in regulatory review and approval of product candidates 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;

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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 candidates in the United States and foreign jurisdictions;

potential side effects of our product candidates could delay or prevent commercialization, limit the indications for any approved product candidates, 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 third-party manufacturers;

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;

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 any of our product candidates are safe and effective as a treatment for their respective indications to the satisfaction of the United States Food and Drug Administration, or 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 candidates;

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 products.

If any of these risks materializes, we could experience significant delays or an inability to successfully commercialize our product candidates, which would have a material adverse effect on our business, financial condition and results of operations.

The long-term safety study for M207 is an important next step in the development of M207. If we cannot raise capital, manufacture supply for the safety study, continue to enroll subjects, complete the safety study in a timely manner, or produce results that satisfy FDA requirements, the regulatory approval process could be delayed and our business could be adversely affected.

After receiving positive results from our ZOTRIP Phase 2/3 efficacy trial of M207, the next step in the regulatory approval process is to complete a long-term safety study. We initiated this study in the second half of 2017. To complete the safety study, we will need to raise additional capital to fund the manufacture of sufficient supply of M207 and to continue to enroll subjects in the study. There are no assurances that such additional capital will be available to us on terms that are favorable to us or our existing stockholders or at all. The study will also need to produce results that satisfy FDA requirements. Any failure or setback in completing any of these required steps could require us to delay, limit, reduce or terminate our development of M207. Also, even though we have discussed our development strategy with the FDA on our 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

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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 candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates 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 each of our product candidates 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 Federal Food, Drug and Cosmetic Act (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 candidates, 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 each of our product candidates. The time and financial resources required to obtain FDA approval for our product candidates 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 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 M207 or for any other product candidates 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 candidates, which could materially adversely impact our competitive position and prospects. Even 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 candidates, 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. 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. 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;

unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

slower than expected rates of patient recruitment and enrollment;

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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 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 candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates 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 candidates;

not obtain marketing approval at all;

obtain approval for indications or patient populations that are not as broad as intended or desired;

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 candidates or allow our competitors to bring product candidates to market before we do, and thereby impair our ability to successfully commercialize our product candidates.

The results of our clinical trials may not support the intended use of our products.

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 candidates are 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 filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates 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

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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 candidates are 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 candidates 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 well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the United States population, and the data must be applicable to the United States population and United States medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. 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:

- 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 M207, our other product candidates or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates 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 candidates will ultimately be considered safe for humans and effective for indicated uses by the FDA. The FDA has substantial discretion in

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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 M207 or any other product candidates we develop in the future receive regulatory approval, we may still face future development and regulatory difficulties.

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, current good manufacturing practices, or 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 candidates 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 candidates. 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 candidates for their approved indications, we may be subject to enforcement action for off-label marketing.

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy (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 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

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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 candidates, 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.

We or any of our future partners may choose not to continue developing or commercialize a product or product candidate at any time during development or 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 M207. Currently, we do not have any collaborations with any partners for any of our products. In April 2016, we suspended further development related to our other candidates, Daily B104, Weekly B206 and D107.

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.

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

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

If serious adverse or inappropriate side effects are identified during the clinical trials of our product candidates, we may need to abandon our development of some of these product candidates.

M207 and any other product candidates we develop in the future may have undesirable side effects, or have characteristics that are unexpected.

If any of our product candidates cause serious adverse events or undesirable side effects:

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product candidate;
- 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;
- we may be required to implement a risk minimization action plan, 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;

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 candidates.

Currently, we manufacture our products internally and may encounter manufacturing failures that could impede or delay supply for our clinical trials of our product candidates.

Any failure in our internal manufacturing operations could cause us to be unable to meet the demand for product candidates for our clinical trials and delay the development or regulatory approval of our product

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candidates. Our internal manufacturing operations may encounter difficulties involving, among other things, material supplies, production yields, regulatory compliance, quality control and quality assurance, and shortages of qualified personnel. Regulatory approval of our product candidates could be impeded, delayed, limited or denied if the FDA does not maintain the approval of our manufacturing processes and facilities.

Difficulties in our manufacturing processes and facilities could result in supply shortfalls of our product candidates, and could delay our preclinical studies, clinical trials and regulatory submissions.

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

We have limited experience manufacturing our product candidates, including M207, and to date have only manufactured our product candidates for our clinical trials. If any of our product candidates are approved, we will need to scale up our own capabilities or contract with third parties to support the production of commercial level quantities of our product candidates, which may require expensive process improvements. If we decide to manufacture commercial quantities of our product candidates ourselves, we will be required to devote substantial resources to the construction or purchase of a commercial scale manufacturing facility, the purchase of manufacturing equipment and hiring additional personnel. 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 are unable to establish a new manufacturing facility or expand our existing manufacturing facilities, purchase equipment, hire adequate personnel to support our manufacturing efforts or implement necessary process improvements, we may be unable to produce commercial materials or meet demand, if any should develop, for our product candidates. Any such failure would have a material adverse effect on our business, financial condition and results of operations.

If we instead decide to contract with third parties to support commercial scale manufacture of our product candidates and we are unable to arrange for such a third-party manufacturing source for any of our product candidates, or fail to do so on commercially reasonable terms, we may not be able to successfully produce, develop and market one or more of our product candidates, or we may be delayed in doing so. Reliance on third-party manufacturers also entails risks to which we would not be subject if we manufactured product candidates 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 candidates 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 authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Contract manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If our third-party manufacturers are unable to successfully scale up the manufacture of any of our product candidates 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 contract manufacturers 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.

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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 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 any of our product candidates are approved, but do 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 candidates 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 candidates 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 candidates not commercially viable. For example, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our product candidates 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 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

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commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of product candidates. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates 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 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 candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights 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 our product candidates or sales of our product candidates, 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 or, if any of our product candidates is approved, our customers demands, each of which could adversely affect our business, financial condition and results of operations.

We rely on third party manufacturers 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.

We rely on third-party manufacturers 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, third party manufacturers may not be able to comply with cGMP, or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates that we may develop.

Any failure or refusal to supply the components for our product candidates or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to fail to fill our purchase orders, the development or commercialization of the affected product candidates 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 and because the expenses relating to the transfer of necessary technology and processes could be significant.

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We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing 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. 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.

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 good clinical practices (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 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 candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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, M207.

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 candidates to market and generate revenue.

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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 candidates 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;

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

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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 our product candidates do not obtain sufficient market share against competitive products, we may not achieve substantial product revenues and our business will suffer.

The markets for our product candidates are characterized by intense competition and rapid technological advances. All of 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 candidates, or may offer comparable performance at a lower cost. If our product candidates fail 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 our M207 product candidate include Alder Biopharmaceuticals, Allergan, Inc., AstraZeneca plc, Biohaven Pharmaceuticals, Eli Lilly & Company, GlaxoSmithKline plc, Promius Pharma, LLC, Teva Pharmaceutical Industries, Inc., and Zogenix, Inc.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our product candidates 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

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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.

Our ability to generate revenues from the sale of our product candidates 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;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (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 and the Republican majorities in both houses of the U.S. Congress have been 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 . Congress may consider other legislation 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 candidates. 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 one of our product candidates 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 one of our product candidates, once approved, market acceptance of the product could be reduced.

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 candidates in clinical trials and the sale of any products 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;

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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 candidates, but we may be unable to obtain commercially reasonable product liability insurance for any product candidates 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.

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 Corporation 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. The occurrence of such events could have a material adverse effect on our business, financial condition and results of operations.

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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 candidates 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 candidates.

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 candidates. 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 products 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 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 laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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 candidates 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. 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 candidates. 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.

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The costs and other requirements associated with prosecution of pending patent applications and maintenance of issued patents are material to us. Bearing these costs and complying with these requirements are essential to procurement and maintenance of patents integral to our product candidates.

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.

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. In addition, 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.

We could be prevented from selling product candidates, 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 any of our product candidates 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.

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;

abandon an infringing product;

redesign our product candidates 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.

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

We intend to pursue regulatory approval of certain of our product candidates, including M207, pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or 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 candidates 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 candidates only to be subject to significant delay and patent litigation before our product candidates 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.

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

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. An adverse result in any litigation 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.

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. 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.

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, or the 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 U.S. Patent and Trademark Office (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.

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The USPTO is currently developing 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. 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.

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 candidates, 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 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

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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;

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;

federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals;

the federal transparency requirements under the ACA require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; 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.

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.

The implementation of the reporting and disclosure obligations of the Physician Payments Sunshine Act/Open Payments provisions of the Patient Protection and Affordable Care Act could adversely affect our business.

An ACA provision, generally referred to as the Physician Payments Sunshine Act or Open Payments Program, has imposed new reporting and disclosure requirements for applicable drug and device manufacturers of covered products and those entities under common ownership that provide assistance and support to the applicable manufacturers, with regard to payments or other transfers of value made to certain practitioners (including physicians, dentists and teaching hospitals), and certain investment/ownership interests held by physicians in the reporting entity. On February 1, 2013, Centers for Medicare & Medicaid Services, or CMS, released the final rule to implement the Physician Payments Sunshine Act.

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The final rule implementing the Physician Payments Sunshine Act is complex, ambiguous, and broad in scope. When and if M207 and any other product candidates we develop in the future are approved, we will within a defined time period become subject to the reporting and disclosure provisions of the Physician Payments Sunshine Act. Accordingly, we will be required to collect and report detailed information regarding certain financial relationships we have with physicians, dentists and teaching hospitals. It is difficult to predict how the new requirements may impact existing relationships among manufacturers, distributors, physicians, dentists and teaching hospitals. The Physician Payments Sunshine Act preempts similar state reporting laws, although we may also be required to continue to report under certain provisions of such state laws. While we expect to have substantially compliant programs and controls in place to comply with the Physician Payments Sunshine Act requirements, our compliance with the new final rule will impose additional costs on us. Additionally, failure to comply with the Physician Payment Sunshine Act may subject the Company to civil monetary penalties.

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

From time to time, legislation is implemented to rein in rising healthcare expenditures. In March 2010, President Obama signed into law the ACA, as amended by the Health Care and Education Reconciliation Act. 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. 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. Congress has also proposed a number of legislative initiatives, including possible repeal of the ACA. At this time, it remains unclear whether there will be any changes made to certain provisions of the ACA or its entirety.

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 and the Republican majorities in both houses of the U.S. Congress have been 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 . Congress may consider other legislation 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 candidates.

If any of our product candidates become 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 products 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

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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 candidates 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 candidates 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 business 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.

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

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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 candidates could be delayed.

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 26, 2018 through March 8, 2018, for example, our stock has traded in a range with a low of $3.61 and a high of $25.70.

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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.

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 the Company s 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, the Company received a letter from the Nasdaq Stock Market, LLC (the Letter) stating that the Company had failed to maintain at least a $1.00 minimum bid price for its common stock (the Minimum Bid Requirement) as required for continued listing of the Company s common stock on the Nasdaq Capital Market. The Company subsequently effected a 1-for-20 reverse stock split of the Company s outstanding common stock and, on February 9, 2018, the Company received a letter from the Director of Nasdaq Listing Qualifications indicating that the Company had regained compliance with the Minimum Bid Requirement under Nasdaq Rule 5550(a)(2).

If, for any reason, Nasdaq should delist the Company s securities from trading on its exchange (including if the Company fails to comply with the Minimum Bid Requirement in the future) and the Company is 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;

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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, or 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 1, 2018 we had 1,973,039 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 are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended (Securities Act). Registration of these shares under the Securities Act would result in the shares becoming 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.

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.

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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, or the 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;

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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.

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, 2019, 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. The Company has an operating lease for its headquarters in Fremont, California. Under the Seventh Amendment, the Company extended the term of the Lease for the Company s 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. On January 25, 2018, we effected a 1-for-20 reverse stock split. The share prices in the table below are shown on a post-split basis. Unless otherwise indicated, all per share amounts have been adjusted for this reverse stock split. The following table sets forth on a per share basis, for the periods indicated, the low and high sale prices of our common stock as reported by the Nasdaq Capital Market.

	High	Low
2017		
First quarter	$ 70.80	$ 15.60
Second quarter	$ 38.60	$ 24.00
Third quarter	$ 28.20	$ 15.20
Fourth quarter	$ 25.80	$ 10.00

	High	Low
2016		
First quarter	$ 56.60	$ 39.00
Second quarter	$ 49.80	$ 20.60
Third quarter	$ 40.00	$ 13.20
Fourth quarter	$ 23.40	$ 9.00

Holders of Common Stock

As of March 1, 2018, there were 17 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. Additionally, our secured term loan facility with Hercules contains covenants that restrict our ability to pay dividends.

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 2017 and 2016 and the balance sheet data as of December 31, 2017 and 2016 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,	
	2017	2016
	(in thousands, except per share data)	
Consolidated Statements of Operations Data:		
Revenue	$ -	$ -
Operating expenses:		
Research and development	20,188	20,457
General and administrative	8,182	8,176
Total operating expenses	28,370	28,633
Loss from operations	(28,370)	(28,633)
Other income (expense):		
Interest expense, net	(742)	(1,192)
Other income (expense), net	7	(7)
Net loss	$ (29,105)	$ (29,832)
Net loss per common share basic and diluted	$ (16.82)	$ (43.36)
Weighted-average common shares outstanding basic and diluted	1,730	688

	December 31,	
	2017	2016
	(in thousands)	
Selected Balance Sheets Data:		
Cash and cash equivalents	$ 11,651	$ 15,003
Working capital	2,936	5,457
Total assets	18,000	20,906
Total promissory note	6,687	12,542
Accumulated deficit	(225,874)	(196,769)
Total stockholders equity	$ 7,049	$ 4,485

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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 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 the Company s 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 twenty 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 twenty. In addition, 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 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 M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, for 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, for markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, M207. M207 is our proprietary formulation of zolmitriptan delivered utilizing our ADAM technology. Zolmitriptan is one of a class of serotonin receptor

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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 M207 is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding GI tract. Feedback from the United States Food and Drug Administration, or FDA, on 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 M207 for the treatment of migraine.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the United States Food and Drug Administration (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 consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. 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 revenue generated and expenses incurred 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 consolidated 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 Jumpstart Our Business Startups Act of 2012, or 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) servicing our collaborative development efforts with other pharmaceutical companies, (ii) furthering our research and development efforts, and (iii) designing and manufacturing our intracutaneous applicator for our clinical and nonclinical studies. 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, fees paid to contract research organizations that

conduct clinical trials on behalf of the Company, and fees paid to contract manufacturing organizations that conduct manufacturing activities on behalf of the Company.

Stock-Based Compensation

We account for its stock-based compensation, recorded as an expense, based on the fair value of the stock- based awards at the grant date that 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 are recognized as expense on

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a straight- line basis over the employee s requisite service period (generally the vesting period), net of estimated forfeitures.

We record the expense attributed to non-employee services paid with stock-based awards based on the estimated fair value of the awards determined using the Black-Scholes option pricing model. The measurement of stock-based compensation for non-employees is subject to re-measurement as the options vest, and the expense is recognized over the period during which services are received.

Financial Operations Overview

General

As of December 31, 2017, we had an accumulated deficit of approximately $225.9 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates 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, pursuant to any partnership that we might pursue.

We expect our research and development expenses and manufacturing expenses related to the development of our 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 2017. We intend to raise such capital through the issuance of additional equity through public or private 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 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.

Debt Financing

We have funded, and will continue to fund, our operations in part through debt financing. In June 2014, we entered into a $4.0 million term loan facility with Hercules Capital, Inc. (Hercules), previously known as Hercules Technology Growth Capital, Inc. In June 2015, we entered into a first amendment to the loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million (the Hercules Term Loan). Upon the execution of the first amendment to the loan and security agreement, we used approximately $11.4 million of the Hercules Term Loan to prepay all amounts owing under the secured promissory note held by BMV Direct SOTRS LP, an affiliate of BioMed Realty Holdings, Inc. The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance will be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. The interest rate on the

secured term loan with Hercules was 7.95% for the years ended December 31, 2017 and 2016. On June 1, 2017, we paid a $100,000 legacy end of term charge and is required to pay an additional $351,135 end of term charge on the earlier of loan maturity or at the date we prepay the Hercules Term Loan. We may prepay all, but not less than all, of the Hercules Term Loan with no prepayment charge. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties.

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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 costs 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 and fees paid to conduct clinical studies, drug formulation, and cost of consumables used in nonclinical 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 contract research organizations (CROs), clinical consultants, clinical trial sites and vendors, including institutional review boards (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 and IT support services.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2017 and 2016, and from our inception to December 31, 2017:

	Year Ended December 31,		For the Period from inception to December 31, 2017
	2017	2016	
		(In thousands)	
Product candidate:			

M207 [1]	$ 15,569	$ 13,281	$ 34,676
Suspended programs [2]	7	126	52,409
Other research projects [3]	173	1,984	12,746
Collaborative development support [4]	-	-	2,630
Unallocated research and development expenses [5]	4,439	5,066	79,573
Total research and development expenses	$ 20,188	$ 20,457	$ 182,034

(1) We initiated our M207 project in September 2013.

(2) In April 2016, we suspended further development related to Daily B104, Weekly B104 and D107.

(3) Our other research projects include programs other than our lead development candidate, M207.

(4) Collaborative development support consists of support services provided to Asahi in 2011 and 2012 and to Novo Nordisk in 2014 and 2015 in connection with our collaboration and license agreements with Asahi and Novo Nordisk.

(5) Unallocated costs include research and development expenses not allocated to a specific program or product candidate, and personnel-related costs prior to the implementation of our timesheet tracking system in 2011.

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The project-specific expenses summarized in the table above include costs directly attributable to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and indirect costs to our product candidates on a project-specific basis, and we include these costs in the project- specific expenses. 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 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 2017, our research and development efforts and resources focused primarily on advancing the development of M207. While we currently intend to continue clinical development of M207 through commercialization in the United States ourselves, we remain open to opportunities with potential strategic partners to ensure 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 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 Sarbanes-Oxley Act.

Other Income and Expense

Interest expense, net. Interest expense, net consists primarily of interest costs related to our short-term borrowings and long-term debt and the amortization of debt discount and issuance costs. Interest expense for the year ended December 31, 2017 and 2016 consisted of accrued interest related to the Hercules Term Loan and the related amortization of debt discount and issuance costs.

Other expense, net. Other expense, net consists of miscellaneous income or expenses that are not included in other categories of the consolidated statement of operations *(See detailed explanations under the next subheading, Results of Operations).*

Results of Operations

Comparison of the year ended December 31, 2017 and 2016

	Year Ended December 31,		Change	
	2017	2016	Amount	%
	(In thousands)			
Research and development	$ 20,188	$ 20,457	$ (269)	(1%)

Research and development expenses decreased approximately $0.3 million, or 1%, for the year ended December 31, 2017 as compared to the year ended December 31, 2016. The decrease was due to lower clinical

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trial costs based on our decision to primarily focus our resources on M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. We also completed our efficacy study in February 2017 and in November 2017, we initiated the required long-term safety study in the development of M207.

General and administrative expenses

	Year Ended December 31,		Change	
	2017	2016	Amount	%
	(In thousands)			
General and administrative	$ 8,182	$ 8,176	$ 6	0%

General and administrative expenses increased slightly by $6,000 for the year ended December 31, 2017 as compared to the same period in 2016.

Other income and expense

	Year Ended December 31,		Change	
	2017	2016	Amount	%
	(In thousands)			
Interest expense, net	$ (742)	$ (1,192)	$ 450	38%
Other income (expense), net	7	(7)	14	200%

Interest expense, net, decreased approximately $0.5 million for the year ended December 31, 2017 as compared to the same period in 2016. Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with the Hercules Loan Agreement. We expect that our interest expense will decrease for 2018 as compared to 2017 as a result of the repayment of the Hercules Loan Agreement in December 2018.

Other expense, net, increased approximately $14,000 for the year ended December 31, 2017 as compared to the same period in 2016. For the year ended December 31, 2017, we recorded a net gain of approximately $9,000 on a sale of equipment. For the year ended December 31, 2016, we recorded a gain of approximately $51,000 on a sale of equipment, offset by a loss in other expenses of approximately $57,000 on the sale of Zosano Inc., a public shell corporation that was a subsidiary of the Company with no operations and no assets.

Income Taxes

As of December 31, 2017, we had net deferred tax assets of $16.9 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, 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, the federal net operating loss carryforwards will begin to expire from 2017 through 2038, and state net operating loss carryforwards will begin to expire in 2018 through 2038.

As of December 31, 2017, we had federal and state research and development credit carryforwards of approximately $0.4 million and $4.6 million, respectively. As of December 31, 2016, we had federal and state research and development credit carryforwards of approximately $0.5 million and $4.2 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

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utilization. We have performed an analysis under Internal Revenue Code Section 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.

Refer to Note 11. Income Taxes, for discussions on the impact of the Tax Cuts and Jobs Act (the 2017 Tax Act) which was enacted in December 2017.

Liquidity and Capital Resources

As of December 31, 2017, we had an accumulated deficit of $225.9 million as well as negative cash flows from operating activities. Presently, we do not have sufficient cash resources to meet our plans in the next twelve months from issuance of these financial statements. We will continue to require substantial funds to continue research and development, including clinical trials of M207 and any future product candidates. Management s plans in order to meet its operating cash flow requirements include financing activities such as public or private offerings of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate sources. Accordingly, on December 22, 2017, we filed a registration statement with the SEC for the offer and sale of our common stock. 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. 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.

Our accumulated deficit, negative cash flows and insufficient cash resources raise substantial doubt regarding the Company s ability to continue as a going concern. There are no assurances that additional funding will be achieved and that we will succeed in our future operations. 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 our license and collaboration agreements. We have incurred recurring operating losses and negative cash flows from operating activities since inception, and as of December 31, 2017, had an accumulated deficit of $225.9 million. We expect to incur additional losses in the future to conduct research and development of our M207 product candidate and to conduct pre-commercialization manufacturing activities.

In accordance with ASU No. 2014-15 Presentation of Financial Statements Going Concern (Subtopic 205-40), our management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company s ability to continue as a going concern within one year after the date that the financial statements are issued.

As of December 31, 2017, we had approximately $11.7 million in cash and cash equivalents. Presently, we do not have sufficient cash resources to meet our obligations as they become due within one year after the issuance date of

this filing.

We will continue to require additional financing to develop our product candidates and fund our operations. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate partners, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our

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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, costs, and results of our clinical trials;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- 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 candidates;
- our ability to draw funds from our loan and security agreement; 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 to others technologies or clinical product candidates or programs, if any, that we would prefer to develop and commercialize ourselves. This raises substantial doubt about our ability to continue as a going concern. As of December 31, 2017, we had an accumulated deficit of $225.9 million and we do not have sufficient cash resources to meet our plans in the next twelve months following the issuance of these financial statements.

The following table shows a summary of our cash flows for the years ended December 31, 2017 and 2016:

	2017	2016
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (27,119)	$ (25,686)
Investing activities	(1,228)	30,272
Financing activities	24,995	3,771
Net (decrease) in cash and cash equivalents	$ (3,352)	$ 8,357

Operating Cash Flow: Net cash used in operating activities was $27.1 million and $25.7 million for the years ended December 31, 2017 and 2016, respectively. 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. Net cash used in 2016 was primarily the result of clinical and non-clinical development costs of the ZOTRIP trial, personnel costs related to hiring key personnel with critical manufacturing know-how to ramp up our production of clinical trial material of our Phase 2 and Phase 3 clinical trials, professional fees and administrative expenses incurred in the course of continuing

operations.

Investing Cash Flow: Net cash used by investing activities was $1.2 million for the year ended December 31, 2017, and net cash provided by investing activities was $30.3 million for the year ended December 31, 2016. Net cash used by investing activities during 2017 was mostly the result of purchases of property and equipment. Net cash provided by investing activities during 2016 resulted primarily from $30.2 million in proceeds from maturities of our investments in marketable securities.

Financing Cash Flow: Net cash provided by financing activities was $25.0 million and $3.8 million for the years ended December 31, 2017 and 2016, respectively. Net cash provided by financing activities for 2017 was primarily due to proceeds from a registered public offering of $26.6 million, net of underwriter s discounts,

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commissions, and offering expenses 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. Net cash generated from financing activities during 2016 included $6.6 million of net proceeds from our private investment in public equity (PIPE) financing, partially offset by $2.9 million in repayment of loan principal and accrued interest to Hercules.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2017:

	Payment Due by Period				
	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Contractual Obligations					
Short and long-term debt obligations (including interest) [1]	$ 6,947	$ 6,947	$ -	$ -	$ -
Operating lease obligations [2]	12,204	1,558	3,561	7,085	-
Total contractual obligations	$ 19,151	$ 8,505	$ 3,561	$ 7,085	$ -

(1) Short and long-term debt obligations

Secured financing with Hercules

In June 2014, we entered into a loan and security agreement with Hercules Capital Inc. for a $4.0 million term loan facility. In June 2015, we entered into a first amendment to the loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million. Upon the execution of the first amendment to the loan and security agreement, we used approximately $11.4 million of the Hercules Term Loan to prepay all amounts owing under the secured promissory note held by BMV Direct SOTRS LP, an affiliate of BioMed Realty Holdings, Inc.

The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance will be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. In addition, we paid a $100,000 legacy end of term charge on June 1, 2017 and is required to pay a $351,135 end of term charge on the earlier of loan maturity or at the date we prepay the Hercules Term Loan. We may prepay all, but not less than all, of Hercules Term Loan with no prepayment charge. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties.

The loan and security agreement with Hercules contains customary conditions related to borrowing, events of default, and covenants, including covenants limiting our ability to dispose of collateralized assets, undergo a change of

control, incur debt or incur liens, subject to certain exceptions. The loan and security agreement also requires us to comply with certain basic affirmative covenants, such as maintenance of financial records, insurance and prompt payment of taxes.

(2) Operating leases

We have an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings and related party, for its office, research and development, and manufacturing facilities in Fremont, California. On June 6, 2017, we entered into the seventh amendment to the existing lease (Seventh Amendment), effective as of May 30, 2017.

Under the Seventh Amendment, we extended the term of the Lease for our headquarters in Fremont, California through August 31, 2024, with an option to further extend the lease for an additional 65 months,

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subject to certain terms and conditions. We agreed to pay a monthly base rent of $136,191 for the period commencing September 1, 2017, and ending on August 31, 2018, with an increase on September 1, 2018, and annual increases on September 1 of each subsequent year until the lease year beginning September 1, 2023. The Seventh Amendment also provides for rent abatements, subject to certain conditions, totaling $275,552 and certain tenant improvements to be completed at the Landlord s expense (not to exceed $975,000 or, under certain conditions, $1,100,000). We may incur additional expenses under the lease in connection with roof repairs that will be treated as additional rent and paid over the term of the lease.

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 to the accompanying condensed consolidated 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. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. We had cash and cash equivalents of $11.7 million and $15.0 million as of December 31, 2017 and 2016, respectively, which consist of bank deposits and money market funds. Any interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, a hypothetical immediate 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

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 Business Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. 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, 2017, our Chief Executive Officer and our Chief Business Officer and Chief Financial Officer concluded that, as of such date, our

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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 Business Officer and 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 Business Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017 based on the guidelines established *in Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). 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, 2017. 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 were no changes in our internal control over financial reporting during the fourth fiscal quarter of the annual reporting period ended December 31, 2017 that have 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.

Item 9B. OTHER INFORMATION

None.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Directors and Key Employees

Our executive officers, directors and key employees, their positions and their ages as of March 1, 2018 are set forth below:

Name	Age	Position
John P. Walker	69	President, Chief Executive Officer, and Director
Kenneth R. Greathouse (1) (3)	65	Director
Joseph Jay P. Hagan (1) (2)	49	Director
Troy Wilson, Ph.D., J.D. (1) (2) (3)	49	Director
Kleanthis G. Xanthopoulos, Ph.D. (2) (3)	59	Director
Georgia L. Erbez	51	Chief Business Officer and Chief Financial Officer
Donald Kellerman, PharmD	63	VP Clinical Development and Medical Affairs
Hayley Lewis	42	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 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 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.

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

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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 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 President and Chief Executive Officer and a member of the board of managers of Avidity Biosciences LLC, a private biopharmaceutical company, since November 2012 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 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 Chairman 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.

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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. 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.

Georgia L. Erbez has served as our Chief Business Officer since September 2016 and Interim Chief Financial Officer since May 2017. Ms. Erbez also served as our Interim Chief Financial Officer from June 2016 until May 2017. From May 2016 until September 2016, Ms. Erbez served as Senior Vice President and Chief Financial Officer of Revolution Medicines, a drug development company. From November 2015 to March 2016, Ms. Erbez served as Executive Vice President and Chief Financial Officer of Asterias Biotherapeutics, a development stage biotechnology company, and from September 2012 to November 2014, Mr. Erbez served as Chief Financial Officer, Secretary and Treasurer of Raptor Pharmaceutical Corp., a commercial-stage biopharmaceutical company. Prior to Raptor, from March 2008 to September 2012, Ms. Erbez was a founder and Managing Director of Beal Advisors, a boutique investment bank providing advisory and capital acquisition services to emerging growth companies. Ms. Erbez also served as Managing Director and Consultant at Collins Stewart LLC from April 2011 to January 2012. From 2005 to 2008, Ms. Erbez was a Senior Vice President in the life sciences investment banking group at Jefferies & Co. From 1998 to 2002, she was with the healthcare investment banking group at Cowen and Co., most recently as Director. From 1997 to 1998, Ms. Erbez was an associate at Hambrecht & Quist, where she provided investment banking services to life sciences companies and healthcare services. From July 1989 to January 1997, Ms. Erbez was with Alex Brown & Sons in the healthcare investment banking group, where she focused on life sciences, medical technology and healthcare services companies. Ms. Erbez currently serves as a member of the board of directors of Artelo Biosciences, a public biotechnology company. Ms. Erbez holds a B.A. in International Relations with an emphasis in Economics from the University of California at Davis.

Donald Kellerman, Pharm.D. has served as our Vice President of Clinical Operations 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

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labeling changes for the neurology and pain 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 2017 our directors, executive officers and ten-percent stockholders complied with all applicable Section 16(a) filing requirements.

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 Mr. Greathouse, Mr. Hagan and Dr. Wilson. Our board of directors has determined that Mr. Greathouse, 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.

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Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information regarding compensation earned by our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer who served as executive officers as of December 31, 2017. We refer to these individuals as our named executive officers.

	Year	Salary	Bonus (1)	Stock Awards (5)	Fair Value of Option Awards (4)	Other	Total
John P. Walker	2017	141,923	-	82,200 (6)	220,710 (7)	76,290 (10)	521,123
President and Chief Executive Officer (2)	2016	-	-	19,999 (8)	26,868 (9)	39,516 (11)	86,383
Georgia Erbez	2017	350,000	-	-	-	-	350,000
Chief Business Officer and Chief Financial Officer (3)	2016	110,160	41,300	-	143,161	99,536 (12)	394,157
Donald Kellerman	2017	331,200	-	-	-	-	331,200
Vice President Clinical Development and Medical Affairs	2016	297,083	90,000	-	98,742	-	485,825
Konstantinos Alataris	2017	165,998	-	-	-	296,185 (14)	462,183
President and Chief Executive Officer (13)	2016	449,148	191,250	-	385,808	-	1,026,206

(1) The amounts reported in this column for 2016 represent cash bonuses awarded in respect to 2016 and paid in March 2017. 2016 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 amount of 2017 bonuses has not been determined as of the date of this Annual Report on Form 10-K. It is expected that the amount of these bonuses will be determined in the first quarter of 2018.

(2) Mr. Walker served as a consultant as 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.

(3) Ms. Erbez joined the Company as Chief Business Officer on September 7, 2016.

(4) Represents the aggregate grant date fair value of option awards granted in fiscal year 2016 and 2017 and in accordance with ASC718, *Compensation-Stock Compensation.* (See Note 9 Stock-Based Compensation)

(5) Represents the aggregate grant date fair value of stock awards granted in fiscal year 2016 and 2017 and in accordance with ASC718, *Compensation-Stock Compensation.* (See Note 9 Stock-Based Compensation)

(6) Represents restricted shares of the Company s common stock awarded to Mr. Walker on May 18, 2017 for his services as Interim Chief Executive Officer.

(7) Represents the fair value of option awards granted for fiscal year 2017 to Mr. Walker for his services as our President and Chief Executive Officer.

(8) Represented restricted shares of the Company s common stock awarded to Mr. Walker on May 04, 2016 for his services as a non-employee director.

(9) Represents the fair value of option awards granted for fiscal year 2016 to Mr. Walker for his services as non-employee director.

(10) 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, respectively.

(11) Represents fees paid to Mr. Walker in cash for his services as a non-employee director during 2016.

(12) Represents consulting fees paid.

(13) Dr. Alataris employment with the Company terminated on May 8, 2017. He was succeeded as our President and Chief Executive Officer by Mr. Walker.

(14) Represents severance and vacation payout.

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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 board of directors has historically determined our executives compensation. Our compensation committee typically has reviewed and discussed management s proposed compensation with the Chief Executive Officer for all executives other than our Chief Executive Officer. Based on those discussions and its discretion, the compensation committee then has recommended the compensation for each executive officer. Our board of directors, without members of management present, has discussed the compensation committee s recommendations and ultimately approved the compensation of our executive officers. Effective upon the closing of our initial public offering in January 2015, our compensation committee is responsible for approving the compensation and benefits of our executive officers.

We have a formal employment agreement with John P. Walker, our President and Chief Executive Officer. We also have executed employment offer letters with Georgia Erbez, our Chief Business Officer and Chief Financial Officer, and with Donald Kellerman, our Vice President, Clinical Development. We had a formal employment agreement with Konstantinos Alataris, our former Chief Executive Officer, until Dr. Alataris s employment terminated with the Company on May 8, 2017.

Mr. Walker s employment agreement provides for an initial base salary of $360,000, subject to increase from time to time. Mr. Walker is eligible for a bonus in an amount determined by the board of directors in its discretion based on his performance and the performance of the Company against certain goals to be established annually. Ms. Erbez s employment letter agreement provides for an initial base salary of $350,000, subject to increase from time to time. Ms. Erbez joined the Company on September 7, 2016. Ms. Erbez employment letter agreement provides for a target annual bonus of 40% of her annual base salary, to be determined by the board of directors in its discretion after consideration of a proposal from the CEO based on company performance against goals established annually by the compensation committee, as well as the Company s then prevailing cash position. Mr. Kellerman s employment offer letter agreement provides for an initial base salary of $265,000. At the end of 2017, Dr. Kellerman s annual base salary was $331,200. Dr. Kellerman s employment offer letter provides for a targeted bonus of 30% of his annual base salary, to be awarded and paid in accordance with the terms of the Company s bonus program adopted by our Compensation Committee in February 2015 and based on achievement of company performance and individual goals and other factors deemed relevant by our Compensation Committee.

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.

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Outstanding Equity Awards at Year-End

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2017. The number of 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.

	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Option Exercise Price ($)	Option Expiration Date	Option Grant Date
John P. Walker	-	15,000 (1)	$ 19.80	8/9/2027	8/9/2017
	1,500	- (2)	$ 11.40	11/2/2026	11/2/2016
	340	- (2)	$ 42.20	5/4/2026	5/4/2016
Georgia Erbez	3,937	8,663 (3)	$ 15.40	9/7/2026	9/7/2016
Donald Kellerman	2,437	6,563 (3)	$ 11.40	11/2/2026	11/2/2016
	749	- (4)	$ 51.40	3/29/2026	3/29/2016
	262	338 (1)	$ 51.40	3/29/2026	3/29/2016
	750	750 (1)	$ 45.20	12/15/2025	12/15/2015
Konstantinos Alataris (5)	-	-	$ -	-	-

(1) This option became exercisable for 25% of the underlying shares on the first anniversary of the grant date, and thereafter becomes exercisable for the remaining underlying shares in equal monthly installments over three years, resulting in the option being exercisable for 100% of the underlying shares on the fourth anniversary of the grant date.

(2) This option becomes exercisable on the corresponding day of each monthly anniversary for which this Option is exercisable so that the Option was vested on the first anniversary of the vesting start date.

(3) This option becomes exercisable on the first anniversary of the date of vesting start date for 25% of the total number of option shares and becomes exercisable on the corresponding day of each month thereafter for an additional 1/48th of the total number of option shares, so that the stock option is fully vested on the fourth anniversary of the vesting start date; provided, however, that 25% of the total option shares (in addition to any then-vested option shares) shall vest if the holder is terminated without cause or resigns for good reason (as these terms are defined in the holder s employment agreement); provided, further, that 100% of any then unvested option shares shall vest if the holder is terminated without cause or resigns for good reason within one year after a change in control (as defined in the holder s employment agreement).

(4) This option became exercisable on April 10, 2017 the corresponding day that each pivotal milestone, grant tranche, was declared achieved by Compensation Committee.

(5) Dr. Alataris s employment with the Company terminated on May 8, 2017. His unvested options were forfeited as of the date of his resignation, and any vested options expired three months following his resignation.

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 of 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 month 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,

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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.

Pursuant to the terms of Ms. Erbez s employment agreement, if the Company terminates Ms. Erbez other than for cause, or in the event of her resignation for good reason, then, for the six-month period following such termination of her employment, the Company will continue to pay Ms. Erbez her base salary and provide her with group medical, dental and vision insurance. In addition, the vesting schedule for any outstanding stock options held by Ms. Erbez on the date of termination will automatically accelerate so that 25% of any then unvested option shares will immediately become exercisable upon such termination. If, during the one-year period following a change in control of our Company, either we terminate Ms. Erbez s employment without cause or Ms. Erbez resigns for good reason, then she shall be entitled to receive a lump sum severance payment equal to twelve months of her base salary and a lump sum payment equal to the total cost of projected premiums for group medical, dental and vision insurance for a period of twelve months. In such event, the vesting schedule for any outstanding stock options held by Ms. Erbez will automatically accelerate so that 100% of the total option shares will immediately become exercisable upon such termination.

Dr. Alataris, our former Chief Executive Officer, resigned from the Company on May 8, 2017. Pursuant to the terms of Dr. Alataris s separation agreement. Dr. Alataris received continuation of his base salary as of the date of termination and COBRA continuation coverage for the six-month period following his resignation. In addition, any vested options held by Dr. Alataris remained exercisable for a period of three months following his resignation.

Director Compensation

Each of our independent directors receives compensation as follows:

- for serving as a member of our board of directors, an annual cash retainer of $35,000 and an annual grant of a non-statutory stock option to purchase a number of shares of our common stock equal to approximately 0.0555% of our then outstanding common stock on a fully-diluted basis (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 annual cash retainer of $10,000; for serving as the chairperson of the compensation committee of the board of directors, an annual cash retainer of $7,000; and for serving as the chairperson of the nominating and corporate governance committee of the board of directors, an annual cash retainer of $7,000.

The cash fees described above are paid in monthly installments, in arrears. 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 2017. For information concerning the compensation paid to Mr. Walker, see Summary Compensation Table above.

	Fees Earned or Paid in Cash	Option Awards [1]	Total
Kenneth R. Greathouse [2]	$ 8,562	$ 37,494	$ 46,056
Joseph Jay P. Hagan	45,000	-	45,000
Bruce D. Steel [3]	-	-	-
Troy Wilson, Ph.D., J.D.	42,000	-	42,000
Kleanthis G. Xanthopoulos, Ph.D.	42,000	-	42,000

(1) Represents the aggregate grant date fair value of stock options and restricted stock awards granted in fiscal year 2017 in accordance with *ASC 718, Compensation-Stock Compensation*. For information regarding the assumptions used in calculating these amounts, see Note 9. Stock-Based Compensation included in this Annual Report.

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(2) On October 3, 2017, our board of directors appointed Kenneth R. Greathouse to our board of directors to serve as an independent Class II director.
(3) Only our independent directors receive compensation for service on the board of directors. While he served as a director, Mr. Steel was not an independent director as defined under Rule 5605(a)(2) of the Nasdaq Listing Rules. Effective December 13, 2017, Mr. Steel resigned as a Class II director.

Our nonemployee directors listed in the table above held outstanding stock awards and options, as follows:

	Number of Shares Outstanding in Restricted Stock Awards	Number of Shares Subject to Outstanding Options
Kenneth R. Greathouse		3,000
Joseph Jay P. Hagan	-	2,400
Bruce D. Steel (1)	-	-
Troy Wilson, Ph.D., J.D.	150	2,415
Kleanthis G. Xanthopoulos, Ph.D.	300	2,415

(1) Effective December 13, 2017, Mr. Steel resigned as a Class II director.

Compensation Committee Interlocks and Insider Participation

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 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 information regarding the securities authorized for issuance as of December 31, 2017 under our equity compensation plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	99,029	$ 25.33	29,571
Equity compensation plans not approved by security holders	19,350 [(1)]	$ 19.12	-
Total	118,379		29,571

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(1) Represents 12,600 shares granted as an inducement grant to our Chief Business Officer and Chief Financial Officer and 6,750 shares granted to other employees as inducement material to their acceptance of employment, in accordance with the inducement grant exception under Nasdaq Rule 5635(c)(4). The inducement grants were granted outside of the equity compensation plans approved by security holders and 15,100 shares granted as inducement grants were registered with the Registration Statement filed on Form S-8 on June 5, 2017.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to beneficial ownership of our common stock, as of February 16, 2018 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 16, 2018 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 1,973,039 shares of our common stock outstanding as of February 16, 2018.

Name of Beneficial Owner [1]	Total Shares Beneficially Owned	Percentage	
5%+ Stockholders			
Amzak Capital Management, LLC and affiliates [2]	263,491	13.35	%
980 North Federal Highway; Suite 315			

Boca Raton, FL 33432			
BMV Direct SOTRS LP [3]	122,121	6.19	%
17190 Bernardo Center Drive			
San Diego, CA 92128			
Atlantic Trust Group, LLC [4]	103,132	5.23	%
Directors and Named Executive Officers:			
John P. Walker [5]	14,036		*
Georgia Erbez [6]	13,161		*
Donald Kellerman, Ph.D. [7]	6,703		*
Kenneth Greathouse [8]	10,000		*
Joseph Jay P. Hagan [9]	1,991		*
Troy Wilson, Ph.D., J.D. [10]	2,476		*
Kleanthis Xanthopoulos, Ph.D. [11]	4,307		
Konstantinos Alataris [12] [13]	19,107		
Current Directors and Executive Officers as a Group (8 persons) [14]	58,323	2.91	%

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* 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 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/A filed with the SEC on March 28, 2017. Includes 257,590 shares of common stock outstanding owned by the Amzak Capital Management, LLC and 5,901 shares of common stock owned by Michael D. Kazma. In addition to these shares, Amzak Capital Management, LLC owns 63,750 shares subject to warrants. These warrants provide the holder may not exercise them to the extent doing so would result in it owning in excess of 9.99% of the outstanding shares of common stock of Zosano. Given the current ownership percentage exceeds the limitation, Amzak Capital Management is prevented from exercising said warrants. Michael D. Kazma and Gerry Kazma may be deemed to share voting and investment power with respect to the securities held by Amzak. The address of the principal business office of each reporting person is 980 N. Federal Highway, Suite 315, Boca Raton, FL 33432.

(3) Based on the information disclosed in the Schedule 13G filed by BioMed Realty Trust, Inc., with the SEC on January 19, 2016, BMV Direct SO LP holds 27,272 shares of common stock and BMV Direct SOTRS LP holds 94,849 shares of common stock. The sole general partner of BMV Direct SOTRS LP is BioMed Realty Holding, Inc. the sole stockholder of BioMed Realty Holdings, Inc. and the sole general partner of BMV Direct SO LP is BioMed Realty, L.P. The sole general partner of BioMed Realty, L.P. is BioMed Realty Trust, Inc. BioMed Realty Trust, Inc. has sole voting and dispositive power with respect to the shares directly held by BMV Direct SOTRS LP and BMV Direct SO LP Bruce D. Steel is a limited partner with a variable economic interest in each of BMV Direct SOTRS LP and BMV Direct SP LP. Mr. Steel disclaims beneficial ownership in the shares directly held by each of BMV Direct SOTRS LP and BMV Direct LP except to the extent of his pecuniary interest therin. The address of the principal business office of each reporting person is 17190 Bernardo Center Drive, San Diego, California 92128.

(4) Based on the information disclosed in the Schedule 13G/A filed by Atlantic Trust Group, LLC with the SEC on February 13, 2018, Atlantic Trust Group, LLC has sole power to vote or to direct the vote, and to dispose or to direct the disposition of 103,132 shares of common stock. The address of the principal business office of the reporting person is 3290 Northside Parkway, 7th Floor, Atlanta, GA 30327.

(5) Consists of: (i) 9,011 shares of common stock; (ii) 3,185 shares of common stock issuable upon exercise of outstanding warrant exercisable within the 60-day period following February 16, 2018, and (iii) 1,840 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 16, 2018.

(6) Consists of: (i) 5,787 shares of common stock, (ii) 2,387 shares of common stock issuable upon exercise of outstanding warrants exercisable within 60-day period following February 16, 2018 and (iii) 4,987 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 16, 2018.

(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 January 22, 2018 and (iii) 5,111 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following

February 16, 2018.

(8) Consists of 10,000 shares of common stock.

(9) Consists of 1,991 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 16, 2018.

(10) Consists of : (i) 150 shares of common stock and (ii) 2,326 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 16, 2018.

(11) 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 16, 2018 and (ii) 2,415 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 16, 2018. 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.

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(12) Dr. Alataris s employment with the Company terminated on May 8, 2017. He was succeeded as our President and Chief Executive Officer by Mr. Walker.

(13) Consists of: (i) 12,738 shares of common stock held by The Alataris Family Trust and (ii) 6,369 shares of common stock issuable upon exercise of outstanding warrants exercisable within the 60-day period following February 16, 2018. Dr. Alataris, the trustee of The Alataris Family Trust, may be deemed to have investment discretion and voting power over the securities held by The Alataris Family Trust.

(14) Consists of: (i) 27,078 shares of common stock, (ii) 7,402 shares of common stock issuable upon exercise of outstanding warrants exercisable within the 60-day period following February 16, 2018 and (iii) 23,843 shares of common stock issuable upon exercise of outstanding options exercisable within the 60-day period following February 16, 2018.

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

Related Person Transactions

Since January 1, 2016, we have engaged in the following transactions 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 Lease with BMR

We have an operating lease with BMR-34790 Ardentech Court LP, which is an affiliate of BMV Direct SOTRS LP and BMV Direct SO LP, for a 55,000 square foot facility in Fremont, California, where we operate our manufacturing operations and house our engineering, research and development and administrative employees. For the years ended December 31, 2017 and 2016, we recorded rent expense for BMR-34790 Ardentech Court LP in the amount of approximately $1.2 million and $0.6 million, respectively. In June 2017, we further amended the lease to extend the term through August 31, 2024, with an option to further extend the term an additional 60 months, subject to certain terms and conditions. We agreed to pay a monthly base rent of $136,191 for the period commencing September 1, 2017 and ending on August 31, 2018, with an increase on September 1, 2018 and annual increases on September 1st of each subsequent year until the lease year beginning September 1, 2023. The June 2017 amendment also provides for rent abatements, subject to certain conditions, totaling $275,552 and certain tenant improvements to be completed at the Landlord s expense (not to exceed $975,000 or, under certain conditions, $1,100,000).

Interests of Directors in our Financial Relationships

Bruce D. Steel, who served as director of the Company until December 13, 2017, may be deemed to have an indirect material interest in our financial relationships with certain of our stockholders based on his association with such stockholders. Mr. Steel is a limited partner with a variable economic interest in each of BMV Direct SOTRS LP and BMV Direct SO LP, which entitles him to a percentage of certain distributions of these entities. Mr. Steel does not have voting or dispositive control of either of these entities. Mr. Steel disclaims beneficial ownership in our securities directly held by these entities except to the extent of his pecuniary interest therein.

Private Investment in Public Equity (PIPE)

In August 2016, the Company entered into a securities purchase agreement, or Purchase Agreement, between the Company and certain purchasers, 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, the closing price per share on August 15, 2016, for gross proceeds of $6.3 million. Additionally, 480,000 warrants were sold, at a price of $2.50 per warrant, for gross proceeds of $1.2 million. Each warrant grants the holder the right to purchase one share of our common stock. The Company granted 239,997 Series A

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warrants and 239,997 Series B warrants. The Series A warrants are no longer exercisable as of August 2017. The Series B warrants have a per share exercise price of $31.00 and will expire five years from the date of issuance, August 19, 2016. Certain of our directors and executive officers purchased an aggregate of 13,771 shares of common stock and an aggregate of 27,544 warrants in this offering at the same price as the other investors.

Name	Common Stock Purchased in Private Placement	Warrants Purchased in Private Placement	Aggregate Purchase Price
The Alataris Family Trust	6,369	12,738	$ 200,001
John Walker	3,185	6,370	100,009
Georgia Erbez	2,387	4,774	74,968
Donald J. Kellerman	796	1,592	24,994
Hayley Lewis	238	476	7,497
Kleanthis G. Xanthopoulos, Ph.D.	796	1,592	24,994

Pursuant to the Purchase Agreement, we agreed to register the resale of the shares of the common stock that we issued and any common stock issuable upon the exercise of the warrants that we issued in the private placement. In connection with the PIPE transaction, we filed a registration statement, Form S-3, with the U.S. Securities and Exchange Commission, or SEC, registering the resale of these shares of common stock and shares of common stock issuable upon exercise of the warrants. The registration statement was declared effective by the SEC on September 23, 2016.

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 take into account, 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 his background, employment and affiliations, including family relationships, our board of directors has determined that each of 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 each of Bruce Steel, while he was serving as our director, and John Walker, our President and CEO, was not an independent director. 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.

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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. Our compensation committee is comprised entirely of independent directors. The current members of our compensation committee are Mr. Greathouse, Dr. Wilson and Dr. Xanthopoulos, and each of whom is an independent director. 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

The following table represents aggregate fees billed to us for the years ended December 31, 2017, and 2016, by Marcum LLP, our independent registered public accounting firm:

	2017	2016

Audit fees [1]	$ 200,518	$ 128,130
Audit-related fees [2]	-	-
Tax fees [3]	-	-
All other fees [4]	-	-
Total fees	$ 200,518	$ 128,130

(1) Represents fees for professional services primarily related to the audit of our annual consolidated financial statements, the review of our quarterly consolidated 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. There were no audit-related fees for services rendered during 2017 and 2016.

(3) Represents fees for preparation of federal and state tax returns and for tax advice. There were no tax fees for services rendered during 2017 and 2016.

(4) Represents any other fees billed by our principal accountant and not reported under Audit Fees, Audit-related fees, and Tax fees. There were no All other fees rendered during 2017 and 2016.

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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 2017 and 2016 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 Consolidated 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 consolidated 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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number	**Description**
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	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)
10.15	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)

10.16	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)
10.17	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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number	Description
10.18	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)
10.19	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)
10.20	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)
10.21	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)
10.22	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)
10.23#	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)
10.24#	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)
10.25#	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)
10.26#	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)
10.27#	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)
10.28#	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)
10.29#	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)

10.30#	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)
10.31#	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)

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number	Description
10.32	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)
10.33	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)
10.34#	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)
10.35#	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)
10.36#	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)
10.37#	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)
10.38#	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)
10.39	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)
10.40	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)
10.41	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)
10.42	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)
10.43	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)
10.44	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)

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Exhibit number	Description
10.45	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)
10.46	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)
10.47	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)
10.48	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)
10.49	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)
10.50	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)
10.51	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)
10.52	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)
10.53	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)
10.54	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)
10.55**	

	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)
10.56	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)

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Exhibit number	Description
10.57	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)
10.58#	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)
10.59#	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)
10.60#	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)
10.61	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)
10.62	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)
10.63#	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)
10.64#	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)
10.65#	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)
10.66#	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)
10.67#	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)
10.68	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)

10.69	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)
23.1*	Consent of Independent Registered Public Accounting Firm

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Exhibit

number	Description
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 12, 2018

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 12, 2018
/s/ Georgia L. Erbez **Georgia L. Erbez**	Chief Business Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2018
/s/ Kenneth R. Greathouse **Kenneth R. Greathouse**	Director	March 12, 2018
/s/ Joseph P. Hagan **Joseph P. Hagan**	Director	March 12, 2018
/s/ Troy Wilson **Troy Wilson**	Director	March 12, 2018
/s/ Kleanthis G. Xanthopoulos **Kleanthis G. Xanthopoulos**	Director	March 12, 2018

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Zosano Pharma Corporation

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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 consolidated balance sheets of Zosano Pharma Corporation (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders equity and cash flows for each of the two years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph Going Concern

The accompanying consolidated 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 consolidated 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 12, 2018

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ZOSANO PHARMA CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share amounts)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,651	$ 15,003
Prepaid expenses and other current assets	1,742	273
Total current assets	13,393	15,276
Restricted cash	35	35
Property and equipment, net	4,152	5,455
Other long-term assets	420	140
Total assets	$ 18,000	$ 20,906
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,511	$ 1,445
Accrued compensation	1,571	1,377
Secured promissory note (including accrued interest), net of issuance costs, current portion	6,687	5,992
Other accrued liabilities	688	1,005
Total current liabilities	10,457	9,819
Deferred rent	495	52
Secured promissory note (including accrued interest), net of issuance costs	-	6,550
Total liabilities	10,952	16,421
Commitments and contingencies (note 8)		
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares and none authorized; none issued and outstanding as of December 31, 2017 and 2016, respectively	-	-
Common stock, $0.0001 par value; 250,000,000 shares authorized as of December 31, 2017 and 2016; 1,973,039 and 840,799 shares issued and outstanding as of December 31, 2017 and 2016, respectively	-	-
Additional paid-in capital	232,922	201,254

Accumulated deficit	(225,874)	(196,769)
Stockholders equity	7,048	4,485
Total liabilities and stockholders equity	$ 18,000	$ 20,906

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

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ZOSANO PHARMA CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Year Ended December 31,	
	2017	**2016**
Revenue	$ -	$ -
Operating expenses:		
Research and development	20,188	20,457
General and administrative	8,182	8,176
Total operating expenses	28,370	28,633
Loss from operations	(28,370)	(28,633)
Other income (expense):		
Interest expense, net	(742)	(1,192)
Other income (expense), net	7	(7)
Loss before provision for income taxes	(29,105)	(29,832)
Provision for income taxes	-	-
Net loss	$ (29,105)	$ (29,832)
Net loss per common share basic and diluted	$ (16.82)	$ (43.36)
Weighted-average common shares outstanding basic and diluted	1,730	688

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

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ZOSANO PHARMA CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands)

	Common Stock				Accumulated Other Comprehensive	
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Income (Loss)	Total Stockholders Equity (Deficit)
Balance at December 31, 2015	598	$ -	$ 193,439	$ (166,891)	$ (46)	$ 26,502
Issuance of common stock in connection with PIPE offering in August 2016, net of issuance costs	240	-	6,643	-	-	6,643
Redemption of common stock upon cashless exercise of stock options	(5)	-	(1)	-	-	(1)
Issuance of common stock upon the exercise of stock options	7	-	5	-	-	5
Stock-based compensation	-	-	1,168	-	-	1,168
Net loss	-	-	-			