Zosano Pharma Corp
Form 10-K
March 29, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

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 x

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

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

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 x 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 x

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2015 (the last business day of the registrant s most recently completed second quarter) was approximately $36,760,000.

As of March 10, 2016, the registrant had a total of 11,967,895 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 on Form 10-K.

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Zosano Pharma Corporation

Annual Report on Form 10-K

For the Fiscal Year ended December 31, 2015

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Cautionary Note Regarding Forward-Looking Statements

This 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 ZP-PTH, ZP-Glucagon and ZP-Triptan product candidates;
- our expectations regarding the clinical effectiveness 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;
- 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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PART I

Item 1. BUSINESS.

Overview

We are a clinical stage specialty pharmaceutical company that has developed a proprietary transdermal microneedle patch system to deliver our proprietary formulations of existing drugs through the skin for the treatment of a variety of indications. Our microneedle patch system offers rapid onset, consistent drug delivery, improved ease of use and room-temperature stability, benefits that we believe often are unavailable using oral formulations or injections. Our microneedle patch system has the potential to deliver numerous medications for a wide variety of indications in commercially attractive markets. By focusing our development efforts on the delivery of established molecules with known safety and efficacy and premium pricing, we plan to reduce our clinical and regulatory risk and development costs and accelerate our time to commercialization.

Our short-wear-time transdermal patch consists of an array of titanium microneedles that is coated with our proprietary formulation of a previously approved drug and attached to an adhesive patch. When the patch is applied with our hand-held applicator, the microneedles penetrate the skin, resulting in rapid dissolution and absorption of the drug through the capillary bed. We believe our system enables rapid and consistent delivery of the drug, with therapeutic effect typically occurring within 30 minutes or less, and easy and convenient administration. We focus on developing specific formulations of approved drugs to be administered by our microneedle patch system, for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages. We target indications with patient populations that we believe will provide us with an attractive commercial opportunity. Our product candidate is ZP-Triptan, our proprietary formulation of zolmitriptan, one of a class of serotonin receptor agonists known as triptans used for the treatment of migraine. In November 2015, we announced positive results from our Phase 1 clinical trial of our ZP-Triptan patch, which was conducted in healthy human subjects in Australia. The Phase 1 results demonstrated the fast absorption of ZP-Triptan that is a characteristic of our microneedle patch and applicator system, which we believe can potentially translate to fast pain relief. Recent feedback from the United States Food and Drug Administration, or FDA, on ZP-Triptan 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 ZP-Triptan for the treatment of migraine.

In light of these encouraging clinical data and the potential to get to an NDA submission in a relatively short timeframe, we recently made the decision to prioritize our clinical development effort on ZP-Triptan and to suspend further development related to our other product candidates, ZP-PTH and ZP-Glucagon, until such time that we can appropriately fund such development through strategic partnerships or additional financing. While we are considering pursuing clinical development of our ZP-Triptan product candidate to a meaningful milestone, we remain open to opportunities with potential strategic partners to ensure our product candidate will receive the best chance of commercial success.

In connection with our decision to concentrate the clinical development of ZP-Triptan, we recently announced that we would streamline our organization to ensure that we effectively use our funds for this purpose. We implemented a workforce reduction of 24 employees, representing approximately 38% of our total workforce, which we expect to reduce our expenses by approximately $2.0 million, net of severance costs, for fiscal year 2016. We expect to reinvest the savings from the workforce reduction in our ZP-Triptan clinical development program.

Our Strategy

Our goal is to make transdermal drug delivery a standard of care for delivering drugs requiring fast onset. The key elements of our strategy are to:

Pursue indications with high unmet medical need and greater probability of clinical, regulatory and commercial success. We focus on indications in which rapid onset, ease of use and stability offer

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particularly important therapeutic and practical advantages that address unmet needs, that have patient populations large enough to provide us with an attractive commercial opportunity, and where there is currently potential premium pricing.

Maintain focus on effective execution of clinical trials. We believe that timely and efficient execution of our clinical development plans has been critical to our success to date. We intend to continue to maintain, as a primary focus of our efforts, excellence in execution of our clinical development plan for ZP-Triptan while effectively managing our available cash resources.

Build a balanced portfolio of proprietary and partnered programs. We have retained world-wide commercial rights to all of our product candidates. For product candidates that are outside of our immediate and core area of interest, 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. We are continuing our internally funded development efforts with respect to ZP-Triptan, while simultaneously pursuing partnering opportunities for it, as well as our ZP-PTH and ZP-Glucagon programs. We also intend to selectively collaborate with third parties with respect to the delivery of their proprietary drugs using our microneedle patch system.

Continue to refine our next generation drug delivery platform. We believe that each of the currently available methods of drug administration has significant disadvantages. Oral and nasal products are typically characterized by relatively slow onset of action, and the use of injectables can cause discomfort. We intend to continue to refine our next generation microneedle patch system through enhanced portability and improved ease of use.

Our Development Pipeline

We have tested our microneedle patch system in preclinical and clinical proof of concept studies that demonstrated its technical feasibility with approximately thirty compounds, ranging from small molecules to proteins. Based on our research, we believe that our microneedle patch system can be used to deliver treatments for a wide variety of indications beyond those on which we are currently focused, in which our fast onset, room-temperature stability, and ease of use will fill what we believe is a significant unmet need.

The following table summarizes the status of our development programs that we are currently seeking to partner:

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Our Product Candidate Actively in Development

ZP-Triptan for Migraine

The focus of our development efforts is on our product candidate ZP-Triptan, our proprietary formulation of zolmitriptan, one of 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 ZP-Triptan microneedle patch is applied to an individual s upper arm to deliver zolmitriptan to the body, with the objective of providing rapid onset relief from headache symptoms.

Large Market and Attractive Treatment Alternative

According to the Migraine Research Foundation, migraine affects 30 million men, women and children in the United States. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, 63% of migraine patients experience between one and four migraines per month. According to a 2014 study by Global Data Pharma Point, sales of prescriptions for medications indicated for migraine in the United States were approximately $1.9 billion in 2012. Of this amount, $1.1 billion was for triptans.

We believe that each of the currently available methods of administering triptans, including oral, nasal spray, subcutaneous injection and iontophorectic transdermal patch (which is a device that delivers medicine through the skin by a low electrical current), has significant disadvantages. Some migraine patients fail to respond consistently to oral triptans, and oral treatments may be ineffectual for patients who are suffering from the nausea or gastric stasis that can be associated with migraine. Oral, nasal and iontophoretic patch triptan products are also characterized by relatively slow onset of action. Nasal sprays may be unpleasant in taste, and use of injectables can cause discomfort. Because ZP-Triptan has demonstrated fast onset in preclinical studies, does not depend on gastrointestinal absorption, and provides easy, administration, we believe it could provide an attractive alternative to currently marketed triptan products for the treatment of migraine.

Fast Onset Demonstrated

In migraine, time to maximum drug concentration in blood, or T_{max}, closely correlates to speed of onset of pain relief and has also been shown to be correlated with completeness of pain relief and pain freedom over time. Relief at two hours is the standard endpoint used in migraine studies and represents the percentage of patients reporting a reduction of migraine symptoms from a classification of severe or moderate to mild or none within two hours after taking the medication.

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The following table compares T_{max} and pain relief of oral forms, including melts and tablets, and nasal forms of marketed triptans to sumatriptan injection. The data are derived from Prescribing Information for the different formulations of these marketed triptans:

Products Included:

(1) Nasal: Imitrex (sumatriptan), Zomig (zolmitriptan) Oral Melt: Zomig-ZMT (zolmitriptan) Maxalt-MLT (rizatriptan)
(2) Oral Tablets: Imitrex (sumatriptan), Treximet (sumatriptan/naproxen sodium), Zomig (zolmitriptan) Maxalt (rizatriptan), Amerge (naratriptan), Axert (almotriptan), Frova (frovatriptan), Relpax (eletriptan)
(3) Subcutaneous: Sumavel DosePro (sumatriptan injection), Imitrex (sumatriptan injection)
(4) Tmax achieved in Phase 1 clinical trial for ZP-Triptan 3.8 mg
(5) Average Tmax represents overall average of the midpoint of the range for all products.
(6) Average relief at 2 hours represents overall average of the midpoint of the range for all products. Range reflects headache relief data obtained in placebo controlled clinical studies, which include different doses of the same triptan.
(7) In USD millions / Source: IMS Integrated NPA data, Jan Dec 2012.

Phase 1 Clinical Trial Results

In November 2015, we announced positive results from the Phase 1 clinical trial of our ZP-Triptan patch. This Phase 1 clinical trial of ZP-Triptan was conducted in Australia. The objectives of the Phase 1 clinical study were to evaluate the tolerability and pharmacokinetics of the ZP-Triptan patch in healthy volunteers. The crossover study among 20 healthy volunteers tested five doses of ZP-Triptan compared to an oral administration of zolmitriptan and additionally a subcutaneous injection of sumatriptan. ZP-Triptan demonstrated rapid absorption compared to the zolmitriptan tablet. During the first part of the clinical study, the 20 participants were randomized and received the following treatments: a 0.48 mg ZP-Triptan patch, two 0.48 mg ZP-Triptan patches, a 1.9 mg ZP-Triptan patch, a 2.5 mg oral zolmitriptan tablet, and a subcutaneous injection of 6mg of sumatriptan, a common treatment for migraine headaches. During the second and third parts of the study, subjects received higher doses, consisting of two 1.9 mg ZP-Triptan patches and one 3.8 mg ZP-Triptan patch, respectively, for assessment of tolerability and pharmacokinetics.

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ZP-Triptan patch was well-tolerated and rapid absorption was observed which we believe may translate to fast pain relief for migraine patients. The Phase 1 results demonstrating the fast absorption of ZP-Triptan that is characteristic of Zosano s microneedle patch and applicator system are illustrated below:

		C_{max} (SD) ng/ml	T_{max} (range) min	AUC_{0-2hr} (SD) ng/ml hour	AUC_{0-last} (SD) ng/ml hour
A	ZP-Triptan 0.48 mg	1.8 (0.53)	20 (2-30)	2.1 (0.73)	2.8 (1.36)
B	ZP-Triptan 2 x 0.48 mg	3.7 (1.05)	20 (2-30)	4.2 (0.95)	6.5 (1.97)
C	ZP-Triptan 1.9 mg	6.8 (2.75)	20 (2-30)	7.4 (2.53)	12.3 (4.31)
F	ZP-Triptan 2 x 1.9 mg	14.6 (4.46)	17.5 (2-30)	16.4 (5.34)	27.8 (9.93)
G	ZP-Triptan 3.8 mg	22.6 (14.00)	15 (2-30)	19.3 (5.37)	31.7 (8.35)
D	Zolmitriptan 2.5 mg Oral Tablet	3.8 (1.51)	60 (30-240)	4.7 (2.24)	22.2 (10.79)

The concentration-time curve during 0-2 hours for all treatments is displayed in the following table:

All treatments were well tolerated and no significant safety issues were identified. The results for the sumatriptan injection were similar to those reported in previous studies.

We believe that the pharmacokinetic and tolerability results in healthy volunteers show that our ZP-Triptan microneedle patch system could provide considerable clinical advantages over zolmitriptan tablets in the treatment of acute migraine. In this Phase 1 pharmacokinetic study, ZP-Triptan demonstrated rapid absorption and reduced metabolism to the active metabolite with the lowered potential for drug-drug interactions and adverse events via a method that does not depend on gastrointestinal absorption or the discomfort of an injection.

Planned Pivotal Efficacy and Safety Trials

We plan to submit an Investigational New Drug (IND) application for ZP-Triptan to the FDA in the second quarter of 2016. Thereafter, we plan to sponsor a U.S. study to evaluate the effectiveness and safety of ZP-Triptan, when used for the acute treatment of migraine.

The first planned study is a multicenter, randomized, placebo-controlled comparison of three doses of ZP-Triptan (1.0 mg, 1.9 mg, and 3.8 mg) and placebo for the treatment of a single migraine attack. The co-primary endpoints for the study are those defined in the October 2014 FDA Draft Guidance Migraine: *Developing Drugs for Acute Treatment* , on pain and most bothersome symptom freedom. Subjects will record their

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migraine symptoms in a patient diary, prior to treatment, and at varying intervals following treatment, out to 48 hours. Safety will be assessed by adverse events reported and other standard safety measures.

While we are considering pursuing clinical development of our ZP-Triptan product candidate to a meaningful milestone, we remain open to opportunities with potential strategic partners to ensure our product candidate will receive the best chance of commercial success.

Our Partnering Product Candidates

Our clinical trials of product candidates ZP-PTH for the treatment of severe osteoporosis and ZP-Glucagon for the treatment of severe hypoglycemia have also yielded promising clinical data. In light of our decision to prioritize ZP-Triptan, we currently are not devoting substantial resources to further clinical development of ZP-PTH and ZP-Glucagon, and are actively seeking partnering opportunities with them. These product candidates and their clinical progress are described below.

ZP-PTH for Osteoporosis

Our product candidate ZP-PTH is our proprietary formulation of teriparatide, a synthetic form of parathyroid hormone, which we refer to as PTH 1-34, or PTH, which regulates serum calcium, to be administered for the treatment of severe osteoporosis. Osteoporosis is a disease primarily affecting post- menopausal women that is characterized by low bone mineral and structural deterioration of bone tissue, which can lead to an increase in bone fractures. According to the World Health Organization and the International Osteoporosis Foundation, a patient has severe osteoporosis when he or she has a T-score $\leq$-2.5 (meaning that the patient has a bone mineral density, or BMD, that is two and a one-half standard deviations below the mean BMD of an ethnically matched thirty-year old man or woman, as applicable), plus one or more fragility fractures.

We believe that the two main types of osteoporosis drugs currently available in the United States, anti- resorptive agents and an anabolic agent, either have shortcomings in efficacy and safety or often times provide patients with a less than optimal treatment administration experience. Our ZP-PTH product candidate is intended to provide a convenient, easy-to-use, room-temperature-stable alternative for osteoporosis patients. We have developed a daily and a weekly dose regimen of ZP-PTH and have successfully completed a Phase 2 clinical trial on Daily ZP-PTH and a Phase 1 clinical trial on Weekly ZP-PTH.

We completed a Phase 2 clinical trial of Daily ZP-PTH in the United States (in connection with which we submitted an investigational new drug application, or IND, to the United States Food and Drug Administration, or FDA), Mexico and Argentina in 2008, and we held End-of-Phase 2 meetings with the FDA and similar meetings with European regulatory authorities in 2009.

In 2013, we completed a Phase 1 clinical trial of our Weekly ZP-PTH in Australia and the study demonstrated pulsatile performance with all six patch doses, which is a significant factor for anabolic efficacy. We had a pre-IND meeting with the FDA in July 2014 and discussed the clinical study design for a planned Phase 2 study.

We believe that we have made significant progress in the clinical development of our ZP-PTH product candidate. We have retained world-wide commercial rights to both Daily ZP-PTH and Weekly ZP-PTH. We intend to evaluate collaboration with strategic partners to further the clinical and commercial development of Daily ZP-PTH and Weekly ZP-PTH.

Large Osteoporosis Market with Significant Unmet Needs

Osteoporosis is a disease characterized by low BMD and structural deterioration of bone tissue, which can lead to an increase in bone fractures. It mainly affects adults age 50 and older. The National Osteoporosis Foundation, or NOF, estimates that approximately nine million adults in the United States have osteoporosis and more than 43 million have low bone mass, placing them at increased risk for osteoporosis and broken bones. In addition, the NOF has estimated that osteoporosis is responsible for more than two million bone fractures in the United States per year resulting in an estimated $19 billion in costs.

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Two main types of osteoporosis drugs are currently available in the United States: anti-resorptive agents and anabolic agents. Anti-resorptive agents act to prevent bone loss by inhibiting the breakdown of bone, whereas anabolic agents stimulate bone formation to build new, high-quality bone. We believe that existing anti-resorptive therapies have shortcomings in efficacy, tolerability and convenience. In part due to these limitations, anabolic agents are generally used as an alternative to anti-resorptive agents. For example, bisphosphonates, the current standard of care and a type of anti-resorptive agent, do not stimulate new bone growth, and have been associated with infrequent but serious adverse events, such as osteonecrosis of the jaw (a bone disease where the jaw bone begins to weaken and die), atrial fibrillation, and anomalous bone fractures, especially of long bones, resulting from frozen bone (a condition that shuts down the body s natural process of bone breakdown and regeneration). We believe that this limitation on their efficacy and safety concerns related to these serious adverse events which may limit their duration of use, has created demand for bone anabolic agents as an alternative to anti-resorptive agents.

The only anabolic agent approved in the United States for the treatment of severe osteoporosis is teriparatide, which is marketed by Eli Lilly & Company, or Lilly, as Forteo®, which must be injected daily and is unstable at room temperature. Based on our 2010 osteoporosis market survey, we estimated that in 2010 only 6% of the treated population of severe osteoporosis patients in the United States received prescriptions for Forteo®. Nevertheless, worldwide sales of Forteo® in 2015 were approximately $1.35 billion. We believe there is significant opportunity for a convenient and easy to use alternative for osteoporosis patients.

Completed Daily ZP-PTH Phase 2 Clinical Development

In 2008, we completed a Phase 2 clinical trial of Daily ZP-PTH. The objective of the study was to determine the safety and efficacy of our microneedle patch system compared to a placebo patch and a subcutaneous teriparatide 20 µg injection in post-menopausal women with osteoporosis. The Daily ZP-PTH Phase 2 clinical trial demonstrated the fast-on, fast-off pharmacokinetic profile we believe is critical for strong anabolic effect, which we believe contributed to the increases in lumbar spine and hip BMD illustrated in the tables immediately below.

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In the tables above, the confidence interval, or CI, means a range of values for a variable of the measure of treatment effect, constructed so that this range has a specified probability of including the true value of the variable. P-value, or p, means the level of marginal significance within a statistical hypothesis test, representing the probability of the occurrence of a given event.

The pharmacokinetic profile for all patch doses showed a faster time to peak concentration and a shorter apparent half-life than the subcutaneous teriparatide 20 µg injection, as illustrated in the following tables:

In terms of safety, the mean serum calcium for all Daily ZP-PTH doses increased moderately, but remained within the normal range. None of the patients discontinued the trial due to hypercalcemia (which is an elevated level of calcium in the blood) or hypercalciuria (which is an elevated level of calcium in the urine), potentially dangerous conditions with cardiovascular risk. During the six months of therapy, there was no clinically significant, or outside the range of normal, hypercalcemia observed and there were no clinically significant changes in liver functions, renal functions, blood counts or electrocardiograms. Also, no antibodies against PTH were detected nor any skin infection observed in any of the Daily ZP-PTH treatment groups.

In summary, the Daily ZP-PTH Phase 2 trial demonstrated that transdermal delivery of PTH using our microneedle patch system increased bone density over six months, and demonstrated:

- a faster T_{MAX}, a higher C_{MAX} and a shorter half-life (critical to the efficacy of an anabolic) observed with the Daily ZP-PTH patch versus Forteo.® T_{MAX} is a measure of the time after administration of a drug when it reaches the highest serum concentration. C_{MAX} is a measure of the peak serum concentration achieved after the drug has been administered; and

- comparable efficacy compared to Forteo® as measured by both six-month spine BMD and six-month hip BMD, even with lower bioavailability versus Forteo®. Bioavailability is the degree and rate at which an administered dose of unchanged drug is absorbed into the body and reaches the blood.

Weekly ZP-PTH Phase 1 Clinical Study

During the fourth quarter of 2013, we commenced a Phase 1 clinical study in healthy post-menopausal women of a single application of one or two Weekly ZP-PTH transdermal patches coated with doses ranging from 60 µg to 160 µg of teriparatide, compared to subcutaneous injections of teriparatide at doses of 20 µg or 57 µg. The design was a single-center, open-label, randomized eight-way crossover study in 32 subjects. Test treatments included single patches of 60 µg, 120 µg, 160 µg doses, two patches of 60 µg (120 µg total PTH), two patches of 90 µg (180 µg total PTH), two patches of 120 µg (240 µg total PTH), and doses of two active injectable comparators: teriparatide 20 µg (Forteo®) by subcutaneous injection, and teriparatide 57 µg

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(Teribone) by subcutaneous injection. The rationale of the patch dose selection was driven by our desire to replicate the demonstrated efficacy of 28 µg and 57 µg subcutaneous injections in studies conducted by Asahi Kasei Pharma Corporation, or Asahi, while adjusting for a higher bio mass index in a Caucasian population.

As indicated by the chart below, showing mean results, the Phase 1 study demonstrated pulsatile performance with all patch doses, which we believe is a significant factor for anabolic efficacy.

Zosano Ph1: Assess Pulsatile Delivery and Adequate Bioavailability

with Patch Doses vs. Injectable (n=32)

The study results also demonstrated:

- The bioavailability of our selected patch doses bracketed the subcutaneous doses of 28 µg and 57 µg, which have proven to be efficacious in reducing fractures in Japanese patients. Our patches illustrated high bioavailability, dose proportionality in ascending doses in the single-patch systems, and dose proportionality in ascending doses in the two-patch systems, enabling us the flexibility of dose selection for future clinical studies; and

- With all weekly doses on one- or two-patch systems, we achieved the desired pulsatile pharmacokinetic profile which we believe is critical for anabolic efficacy. We observed pulsatile pharmacokinetic profile comparable to that in our Daily ZP-PTH Phase 2 study and in our 2008 005 ZP-PTH study.

Patch doses were similarly tolerated when compared to Forteo® and Teribone . The Phase 1 study was conducted in Australia and, as such, was not subject to an IND and was conducted in compliance with applicable Australian regulations.

We had a pre-IND meeting with the FDA, a meeting required for the filing of an investigational new drug application, or IND, in July 2014 to discuss the clinical study design for our Phase 2 and Phase 3 studies of Weekly ZP-PTH.

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Demonstrated 36-Month Stability of ZP-PTH Formulation

The stability of a drug formulation means the extent to which the formulation is able to maintain its physical and chemical properties over time under specified environmental storage conditions. In our internal studies, our Daily ZP-PTH formulation coated on the patch and stored at room temperature in its sealed, nitrogen-filled package retained over 98% of its purity for 12 months and over 97% of its purity after 36 months. By contrast, Forteo® retained less than 87% of its purity after 12 months when stored at room temperature, and less than 95% of its purity after 12 months when under refrigeration (2-8°C).

Strategic Alliance with Eli Lilly and Company

In November 2014, we entered into a collaboration agreement with Eli Lilly and Company, or Lilly, to develop a formulation of ZP-PTH to be administered daily using our microneedle patch system for the treatment of osteoporosis. Under the terms of the agreement, we granted to Lilly an exclusive, worldwide license to commercialize any ZP-PTH product using our microneedle patch system. We were responsible, at our own expense, for developing Daily ZP-PTH, including clinical, regulatory and manufacturing scale-up activities. Lilly would be responsible, pending successful clinical study outcomes and regulatory approval, for commercialization of our Daily ZP-PTH product. We had the right to terminate the agreement at any time prior to regulatory approval of Daily ZP-PTH in the United States or Japan if we determined that a critical success factor under the agreement was commercially or scientifically unreasonable to achieve and we discontinued development of Daily ZP-PTH.

In September 2015, we terminated the collaboration agreement in accordance with the terms following our determination that it was commercially unreasonable to pursue one of the critical success factors under the agreement, relating to the required timing of worldwide regulatory approval of Daily ZP-PTH by 2019.

As a result of the termination of the agreement, the exclusive, worldwide license that we granted to Lilly terminated and reverted to us, and we will no longer be eligible to receive any milestone or other payments from Lilly. If, prior to August 19, 2019, we decide to resume development of Daily ZP-PTH, then we will be required to notify Lilly and offer to reinstate the collaboration agreement on the same terms or on other mutually agreeable terms.

We also entered into a common stock purchase agreement with Lilly in November 2014 pursuant to which Lilly has purchased $15 million worth of our common stock in a private placement concurrent with the closing of our initial public offering of shares of our common stock, at a price per share equal to the initial public offering price. On January 30, 2015, concurrent with the closing of our initial public offering, we issued and sold 1,363,636 shares of our common stock to Lilly and received net proceeds of $14.5 million pursuant to the common stock purchase agreement. As of December 31, 2015, Lilly beneficially owned more than ten percent of our outstanding common stock.

ZP-Glucagon for Severe Hypoglycemia

Our product candidate ZP-Glucagon is our proprietary formulation of glucagon, a hormone that raises blood glucose levels, intended for the emergency rescue of patients suffering from life-threatening, severe hypoglycemia. Severe hypoglycemia is a complication of diabetes treatment, often caused by insulin overdose, characterized by a very low level of blood glucose that can lead to loss of consciousness, seizure, coma and death. Timely treatment is critical, and may need to be administered to an incapacitated patient in a life- threatening situation by a third party who lacks medical training. We believe that ZP-Glucagon delivered using our microneedle patch system will offer patients and caregivers a simple device providing rapid onset and enhanced ease of use, as well as extended room temperature

stability, compared with the two glucagon products currently marketed in the United States.

In January 2014 we completed a Phase 1 trial that demonstrated faster onset, a higher bioavailability and lower variability (which is the range of the data points from the trial showing the measure of the treatment s

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effect in relation to the mean of the data points) with ZP-Glucagon treatments compared to glucagon injection. The Phase 1 trial was conducted in Australia and, as such, was not subject to an IND and was conducted in compliance with applicable Australian regulations.

In October 2015 we announced positive Phase 2 clinical trial results on our ZP-Glucagon patch program for the treatment of severe hypoglycemia. The objective of our Phase 2 clinical trial in Australia was to evaluate the performance of our ZP-Glucagon patch in Type 1 diabetic patients at 0.5 milligram, or mg, and 1.0 mg doses, with induction of hypoglycemia, in comparison to comparable doses of glucagon administered by intramuscular injection. Both ZP-Glucagon patch doses normalized blood sugar in 100 percent of the subjects. Both patch doses had rapid onset of action and time to glucose response was similar among the two modes of administration. All treatments were well tolerated and no new safety issues were identified.

We believe that we have made significant progress in the clinical development of our ZP-Glucagon product candidate and intend to evaluate strategic opportunities with a corporate partner to further its clinical and commercial development.

Underserved Severe Hypoglycemia Market

Severe hypoglycemia is a life-threatening potential complication of diabetes treatment, for which timely treatment is critical. The current standard of care in a severe hypoglycemic event is administration of glucagon by injection or infusion. The treatment is typically provided by a third party, caregiver or a bystander, as the patient is typically unable to self-administer the drug. Despite the risks involved with hypoglycemia, many insulin-dependent patients do not carry glucagon rescue kits.

There are 21 million diagnosed diabetes patients in the United States, of whom 26% are insulin-dependent. Insulin-dependent patients have on average 1.2 severe hypoglycemic events per year. There are currently two glucagon products marketed in the United States: Glucagon Emergency Kit by Lilly and GlucaGen® by Novo Nordisk. Based on a market survey of the hypoglycemia market commissioned by us in 2013, we estimate that in 2012, sales of these products exceeded $120 million in the United States with units sold at an average wholesale price of $188 per unit, and that the injectable glucagon market is growing at approximately 15% year- over-year, largely driven by ongoing price increases.

The two glucagon products currently marketed in the United States for severe hypoglycemia are both injectables. Due to its chemical constitution, the glucagon molecule is inherently unstable, and both commercially available products require a multi-step reconstitution process prior to use. Reconstitution and injection are typically administered by a third party who may lack medical training.

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We believe that ZP-Glucagon delivered using our microneedle patch system will offer patients and caregivers the benefit of a simple, easy-to-use device with rapid onset, room temperature stability and enhanced portability, benefits that we believe will encourage patients to carry our product as a glucagon rescue kit.

We expect our finished product to be a single-use, disposable, pre-loaded microneedle patch system. We have designed our product to be intuitive and to be administered with a simple press-and-apply action without requiring any cumbersome reconstitution. We intend to introduce a Generation 1 product consisting of our existing 3 cm2 patch and a single use applicator.

The practical advantages afforded by the room-temperature stability of our microneedle patch system, eliminating the need for reconstitution and allowing for immediate administration, may be as important as the therapeutic benefits of rapid onset. We believe that our formulation of ZP-Glucagon, which we have demonstrated is stable for at least six months, will enable us to market ZP-Glucagon as a ready-to-use product. In our most recent stability studies with the formulations of glucagon that we plan to use in our future clinical trials (Formulation C and Formulation D), the formulations demonstrated purity levels in excess of 99% after six months at 40°C, or in excess of 100°F, a temperature significantly higher than room temperature, and consistent with the ambient temperatures that might be encountered in a warm climate by a patient carrying the product in a pocket or purse.

Completed Phase 1 Clinical Trial

In January 2014, we completed a Phase 1 trial of ZP-Glucagon designed to assess relative bioavailability with our microneedle patch system on a 3cm2 patch compared to GlucaGen® administered by intramuscular injection. We compared subjects across multiple application sites with two formulations (formulation C and formulation D) in a single-center, open-label, randomized five-way crossover study using 0.5 mg on both the ZP- Glucagon patch and GlucaGen®. The study included 20 healthy volunteer subjects.

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We achieved a faster onset and a higher bioavailability with each of the ZP-Glucagon treatments vs. the Glucagon intramuscular injection. The pharmacokinetic and pharmacodynamic data are shown in the graphs below. The table below the two graphs shows the data points in the first of the two graphs, and the CV, or coefficient of variation, which represents the variability of the specified data points.

Treatment	AUC last	AUC 30min	AUC 30min (% > IM)	T max (min)	C max (pg/mL)
Glucagon IM Upper arm	1558±685	1106±553		11.8±4.4	2333±1256
	CV 44%	CV 50%			
Patch C Upper arm	1921±551	1724±492	56%	6.9±2.4	5438±1754
	CV 29%	CV 29%			
Patch C Forearm	1669± 473	1441±395	30%	8.1±3.9	4136±1393
	CV 28%	CV 27%			
Patch C Abdomen	1988±769	1664±596	50%	8.4±3.4	4785±1791
	CV 39%	CV 36%			
Patch D Abdomen	1440±667	1270±580	15%	8.5±2.9	3918±2021
	CV 46%	CV 46%			

Note: AUC measured in ng*hr/mL

Completed Phase 2 Clinical Trial

In October 2015, we completed a Phase 2 clinical trial in Australia to evaluate the performance of our ZP-Glucagon product candidate in Type 1 diabetic patients at 0.5 mg and 1.0 mg doses, with induction of hypoglycemia, in comparison to comparable doses of glucagon administered by intramuscular injection, or IM.

The Phase 2 clinical trial investigated the safety and efficacy of ZP-Glucagon in the treatment of insulin- induced hypoglycemia in diabetic patients (as opposed to healthy volunteers, as used in our Phase 1 clinical trial). Based on the higher bioavailability results from our Phase 1 clinical trial, it is possible that we could have a therapeutic patch dose with a coated amount less than 1 mg. Therefore, in our Phase 2 trial, we were testing both a single patch dose of 0.5 mg and two patches of 0.5 mg (total dose of 1.0 mg) compared to 0.5 mg and 1.0 mg of intramuscular injection.

Our Phase 2 clinical trial was a four-way crossover study with 16 diabetic patients, each of whom was administered the following four doses:

One patch of ZP-Glucagon 0.5 mg applied on the upper arm;

Two patches of ZP-Glucagon 0.5 mg applied on the upper arm;

Intramuscular injections of 1.0 mg commercial glucagon; and

Intramuscular injections of 0.5 mg commercial glucagon.

The primary endpoints in this study were as follows:

Time to increase in blood glucose concentration from baseline by 50 mg/dl;

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Blood glucose concentration change from baseline 15 minutes after treatment administration;

Maximal change from baseline in blood glucose concentration; and

Incidence of adverse events.

In October 2015 we announced positive Phase 2 clinical trial results on our ZP-Glucagon patch program for the treatment of severe hypoglycemia when all of our primary endpoints have been met. Our Phase 2 clinical trial results showed:

Both of our 0.5 mg and 1.0 mg ZP-Glucagon patch doses normalized blood sugar in 100 percent of the study subjects;

Both 0.5 mg and 1.0 mg ZP-Glucagon patch doses demonstrated rapid onset of action and time to glucose response was similar among the patch and injection modes of administration;

Maximal plasma concentrations of glucagon for the patch treatments were higher than those of the IM injections. The time to reach the maximum concentration was faster with the patches (7.7 and 10.2 minutes) compared to the IM injections (14.6 and 16.6 minutes); and

All treatments were well tolerated and no new safety issues were identified.

GLP-1 for Type 2 Diabetes

In July 2015, we announced that Novo Nordisk A/S, or Novo Nordisk, notified us of its intention to discontinue the collaboration, development and license agreement that we entered into with Novo Nordisk in January 2014 related to development of a transdermal presentation of select Novo Nordisk glucagon-like peptide-1 (GLP-1) analogues, to be administered once weekly using our microneedle patch system for the treatment of type 2 diabetes. We were notified that Novo Nordisk s decision was related to a strategic prioritization of Novo Nordisk s research portfolio despite continued progress during the collaboration period. Upon the termination of the collaboration agreement, which became effective on October 27, 2015, all

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technology rights licensed to Novo Nordisk related to the field of GLP-1 products reverted to us. We received a non-refundable upfront payment of $1 million upon entering into the collaboration agreement in January 2014. We will no longer be eligible to receive any milestone or other payments from Novo Nordisk.

Our Research Programs

Our internal research and development programs involve generic molecules with demonstrated safety and efficacy and a low clinical and regulatory risk relative to new chemical entities, or NCEs. We believe that these programs will have a shorter development time and lower cost to commercialization than typical NCEs. 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 microneedle patch system consists of a 3 to 6 cm^2 array of titanium microneedles approximately 200-350 microns long, coated with a hydrophilic formulation of the relevant drug, and attached to an adhesive patch. The maximum amount of active 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, and, based on our testing, we believe that the maximum amount of zolmitriptan that can be coated on a patch with a 6 cm^2 microneedle array is approximately 3.5 mg. 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 rapid and consistent dissolution and absorption of the drug coating, yet short of the nerve endings in the skin. The typical patch wear time is thirty minutes or less, avoiding skin irritation.

Our drug formulations are dry, hydrophilic formulations and the final packaging contains a desiccant and is purged with nitrogen to remove any traces of moisture and oxygen. These features help provide extended product stability and longer shelf life at room temperature than conventional liquid formulations. We have demonstrated an initial six-month shelf life at up to 40 degrees Celsius for our ZP-Glucagon product candidate.

We have tested our microneedle patch system in preclinical and clinical proof of concept studies that demonstrated its technical feasibility with approximately thirty (30) compounds, ranging from small molecules to proteins. Based on this research, we believe that our microneedle patch system can be used to deliver treatments for a wide variety of indications beyond those on which are currently focused, in which our fast onset, room-temperature stability, and ease of use will fill a significant unmet need.

We intend, independently or through strategic collaborations with others, to explore other potential applications of our microneedle patch system. We anticipate that our internal development programs will focus on delivery of generic drugs, and that we will collaborate with third parties with respect to delivery of their proprietary drugs.

Competition

Competition for our product candidates

The development and commercialization of new products to treat severe osteoporosis, severe hypoglycemia and migraine is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have substantially greater financial, technical and other resources than we do. In addition, many of these companies have longer operating histories and more experience

than us in preclinical and clinical development, manufacturing, regulatory and global commercialization.

Companies marketing products that treat migraine that may compete with our ZP-Triptan product candidate include Teva Pharmaceutical Industries, Inc., Zogenix, Inc., GlaxoSmithKline plc, AstraZeneca plc and Allergan, Inc. Companies marketing or developing products that treat severe osteoporosis that may compete with our ZP-PTH product candidate include Amgen, Inc., Lilly and Radius Health, Inc. Companies marketing products that treat severe hypoglycemia that may compete with our ZP-Glucagon product candidate include Novo Nordisk and Lilly.

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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 (including transdermal microneedle patches), and from alternative formulations and methods of delivery of the drugs on which we have focused, including oral formulations, nasal sprays, transdermal patches, intramuscular and subcutaneous injection and infusion. Such companies include, but are not limited to, 3M Company, Corium International, Inc. and Pantec Biosolutions AG.

Research and Development

As of December 31, 2015, our research and development organization consisted of 56 employees, located in our headquarters in Fremont, California. Our research and development organization was reduced to 27 employees after the workforce reduction initiative implemented on March 24, 2016. Our research and development staff is focused primarily on development of our ZP-Triptan product candidate. They have broad knowledge and skills in a range of disciplines applicable to formulation of drugs and the design and manufacture of our microneedle patch system. Our research and development group has particular expertise in two areas critical to our success: developing drug formulations that can be delivered using our microneedle patch system and optimizing the system to deliver those drugs.

The goals of our research and development efforts are to identify and develop drugs that can be delivered using our microneedle patch system and optimize the system to deliver those drugs. In the years ended December 31, 2015 and 2014, we incurred $20.4 million and $11.0 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, or cGMP, compliant manufacturing facility in Fremont, California, and believe we have adequate manufacturing capabilities and capacity to produce our microneedle patch system 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. In order to expand our manufacturing capabilities for large scale production, we are exploring both internal and outsourced manufacturing and supply alternatives. We purchase various components or intermediates of our microneedle patch system from third-party vendors, including the metal 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. All of these components and intermediaries are available from multiple sources. We also outsource the manufacturing of our applicators.

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

Once a microneedle array is completed, we attach it to an inner ring housing the adhesive backing layer, which we purchase from a third party manufacturer. This is performed at our facility using a semi-automatic assembly process. We apply the drug formulation to the microneedle array by a contact process whereby the titanium needles are dipped in a liquid drug formulation until the specified amount of drug is applied to the microneedle array. We then attach an outer ring to the assembly using a mechanical press fit on the same equipment used for coating the microneedle array. The outer ring is made from a polymer material, which is readily available from multiple suppliers. We then insert the

patch assembly into the primary packaging, which is purged with nitrogen for longer shelf life. We perform substantially all product testing in-house.

We intend to explore alliances with contract manufacturing organizations, or CMOs, to expand our manufacturing capacity as we believe this will be critical to support the late-stage development, launch and commercial production of our product candidates.

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Intellectual Property

We regard our technology as proprietary. 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 further 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 December 31, 2015, we held exclusive licenses to or owned 26 United States patents and six United States patent applications, as well as numerous foreign counterpart patents and patent applications (including two Patent Cooperation Treaty patent applications), covering key features of our microneedle patch system, such as formulation, coating, array design, patch anchoring, patch application, delivery, manufacturing and packaging.

We license all of these patents and patent applications, other than an issued patent for Glucagon formulation and new applicator design application 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 transdermal microneedle patch system. We are also responsible for commercializing our transdermal microneedle patch 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-teens 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 two United States patent applications and two Patent Cooperation Treaty patent applications covering our single-use applicator and formulation of ZP-Glucagon. The ZP-Glucagon 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 believe that the long life of our patent portfolio may make collaborating with us particularly attractive for third parties seeking to extend the lifecycle of profitable drugs nearing the expiration of their patent protection.

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.

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, or 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

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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 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 ZP-Triptan program. We have had ongoing discussions with the FDA on ZP-Glucagon.

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, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or 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 to the FDA in connection with our Phase 2 trial of Daily ZP-PTH in 2008, but we have not

submitted an IND to the FDA for ZP-Glucagon. We are planning to submit an IND on ZP-Triptan in connection with our planned Phase 2 efficacy study in 2016. We cannot be sure that submission of an IND will result in the FDA allowing clinical trial to begin.

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 study, 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 study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board, or IRB, for each institution where the trials will be conducted, and each IRB must monitor the study until completion. Study subjects must sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy extensive good clinical practice, or 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

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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 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 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 approved risk evaluation and mitigation strategies, or 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

Often times, 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

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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 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 ANDAs 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

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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.

Pricing and Reimbursement

In the United States and internationally, 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 payors 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 and receive a high reimbursement per unit for the currently marketed injectable form. We intend to commercialize our products at prices competitive to those of the currently marketed injectables, thereby securing support of the payors.

There is no legislation at the EU level governing the pricing and reimbursement of medicinal products in the EU. As a result, the competent authorities of each of the EU Member States have adopted individual strategies regulating the pricing and reimbursement of medicinal products in their territory. These strategies often vary widely in nature, scope and application. However, a major element that they have in common is an increased move towards reduction in the reimbursement price of medicinal products, a reduction in the number and type of products selected for reimbursement and an increased preference for generic products over innovative products. These efforts have mostly been executed through these countries existing price-control methodologies. The government of the United Kingdom, while continuing for now to utilize its established Pharmaceutical Pricing Reimbursement Scheme approach, has announced its intentions to phasing in, by 2014, a new value-based pricing approach, at least for new product introductions. Under this approach, in a complete departure from established methodologies, reimbursement levels of each drug will be explicitly based on an assessment of value, looking at the benefits for the patient, unmet need, therapeutic innovation, and benefit to society as a whole. It is increasingly common in many EU Member States for Marketing Authorization Holders to be required to demonstrate the pharmaco-economic superiority of their products as compared to products already subject to assessment and reimbursement in specific countries. In order for drugs to be evaluated positively under such criteria, pharmaceutical companies may need to re-examine, and consider altering, a number of traditional functions relating to the selection, study, and management of drugs, whether currently marketed, under development, or being evaluated as candidates for research and/or development. All such cost containment efforts by the payors in US and overseas are likely to support our competitive pricing model.

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.

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

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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.

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, 2015, we had 67 employees, 9 of whom held doctorate degrees in their respective scientific and pharmaceutical fields. As of March 25, 2016, we had a total of 39 employees, which includes the effect of the workforce reduction. We make extensive use of third party contractors, consultants and advisors to perform many of our present activities.

Corporate Information

We were incorporated under the laws of the State of Delaware as ZP Holdings, Inc. in January 2012, and changed our name to Zosano Pharma Corporation in June 2014. Our business was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006. We were originally incorporated under the name The Macroflux Corporation, and changed our name to Zosano Pharma, Inc. in 2007 following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of ZP Holdings was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of ZP Holdings. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc. 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

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, 2015 we incurred a net loss of $28.4 million. As of December 31, 2015, we had an accumulated deficit of $166.9 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 candidates, ZP-PTH, ZP-Glucagon and ZP-Triptan. 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 one or more of our 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. For the year ended December 31, 2015, we had total revenue of $0.3 million. Substantially all of our revenue since inception has resulted from payments by collaboration partners. 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. However, adequate and additional funding may not be available to us on acceptable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends on our common stock.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our research programs or drug candidates or grant licenses on terms that may not be favorable to us.

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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 Technology Growth Capital, Inc., or Hercules, 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 Technology Growth Capital, Inc. (Hercules) 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 (the Hercules Term Loan). 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 will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date we prepay the Hercules Term Loan and 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 subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. 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;

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.

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We have limited operating history.

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 our products 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 organizing our company, acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our products. In addition, our previous strategic partnership with Asahi, which terminated in January 2014, has accounted for substantially all of our revenues to date. As a result, investors have a limited operating history on which to evaluate the merits of an investment in our common stock.

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

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 ZP-Triptan 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.

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 development efforts on three product candidates, ZP-Triptan, ZP-PTH, and ZP-Glucagon,, and currently are advancing only ZP-Triptan in further clinical development. The development and commercialization of each of these product candidates 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 drug, require the establishment of a risk evaluation and mitigation strategy, or REMS, or cause an approved drug 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, or CMOs, to supply or manufacture our products;

we depend on contract research organizations, or CROs, 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 drug candidates, which would have a material adverse effect on our business, financial condition and results of operations.

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.

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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 as anticipated, 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. As an organization, we have conducted only one Phase 2 clinical trial in 2008, have not conducted a Phase 3 clinical trial before, have limited experience in preparing and submitting regulatory filings, and have not previously submitted an NDA for any product candidate. We also have had limited interactions with the FDA, and have not discussed our clinical trial designs or implementation with the FDA for our ZP-Glucagon. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission of other product candidate we are developing.

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 or timely 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. We estimate that clinical trials of Weekly ZP-PTH will take more than four years to complete, and ZP-Glucagon and ZP-Triptan will each take two or more years to complete. Furthermore, failure of any 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;

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.

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If we are required to conduct additional clinical trials or other testing of our drug 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 or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our drug 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 the drug 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 drugs 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 our product claims.

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product claims. 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 and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While members of our management team have experience in designing clinical trials, our company has 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.

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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. For example, our Phase 1 and Phase 2 clinical trials on ZP-Glucagon as well as our Phase 1 clinical trial on ZP-Triptan were all conducted in Australia.

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 study 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 trials, which would be costly and time-consuming and delay or permanently halt our development of a product candidates. 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 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 any of our product candidates, including ZP-Triptan, ZP-PTH, and ZP-Glucagon 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 research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review. Delays in obtaining regulatory approvals may:

delay commercialization of, and our ability to derive product revenues from, our products;

impose costly procedures on us; and

diminish any competitive advantages that we may otherwise enjoy.

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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 our product candidates 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 candidate. The FDA closely regulates the post- approval marketing and promotion of drugs and drug delivery devices to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers communications regarding off-label use and, if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing 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. The FDA currently requires a REMS for Forteo® and will likely require a post-approval REMS for Weekly ZP-PTH.

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 the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. 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. Similar requirements exist in many of these areas in other countries.

In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling. If we receive marketing approval for our products, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to

have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several

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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 our 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.

Although we have three product candidates in clinical stage development, we currently do not have any products approved for sale and currently are focusing our clinical development efforts on only one of them, ZP-Triptan.

At any time, we or our partners 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 a competing product, or changes in or failure to comply with applicable regulatory requirements. For example, we were a party to a collaboration agreement with Eli Lilly and Company to develop one or more microneedle patch products to administer Daily ZP-PTH. In September 2015, this relationship with Eli Lilly was terminated. 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 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 our partnership agreement with that party.

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.

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The commercialization of large dose products using our microneedle patch system may be dependent on the development of different size patches and/or different designs for our patch applicator. If we are not successful in implementing these developments in the time frames we expect, the commercialization of products that would benefit from such developments may be delayed and, as a result, our results of operations may be adversely affected.

Our microneedle patch system can be used to deliver numerous medications for a wide variety of indications. Our ability to successfully commercialize any given drug product using our microneedle patch system may be dependent on large scale development of different patch sizes or different designs for our patch applicator. Delays in the development of different size patches and/or different designs for our patch applicator, may adversely affect our business, financial condition and results of operations.

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 transdermal 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 candidates.

All of our product candidates are still in preclinical or clinical development. Our products 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;

- 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 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;

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

we may be subject to limitations on how we promote the product;

sales of the product may decrease significantly;

regulatory authorities may require us to take our approved product 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 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 products.

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We manufacture our products internally and may encounter manufacturing failures that could impede or delay supply for our clinical trials or 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 candidates. Our internal manufacturing operations may encounter difficulties involving, among other things, 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.

In addition, once approved, we plan to manufacture our products for commercial sale internally. We have no experience producing our microneedle patch system in commercial quantities, which would require additional manufacturing equipment and space. Upon commercialization, there will be a need for additional infrastructure at our Fremont manufacturing facility and there will be additional regulatory requirements for the aseptic manufacturing required by the FDA for commercialization.

Difficulties could result in commercial supply shortfalls of our products, delay in the commercial launch of any of our product candidates, if approved, delay in our preclinical studies, clinical trials and regulatory submissions, or the recall or withdrawal of our products from the market.

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 our products will depend upon their acceptance by the medical community, including physicians, patients and health care payors. 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 payors.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors 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 payors on the benefits of our product candidates may require significant resources and may never be successful.

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

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;

longer accounts receivable collection times;

longer lead times for shipping;

language barriers for technical training;

reduced protection of intellectual property rights in some foreign countries;

foreign currency exchange rate fluctuations; and

interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

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RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

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 expenses. We currently are seeking to collaborate with third parties for the development and potential commercialization of all three of our product candidates.

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 on certain terms 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 the development of a particular product candidate, reduce or delay its development or one or more of our other development programs, delay its 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 product revenue.

We use customized equipment to coat and package our microneedle patch system, making us vulnerable to production and supply problems that could negatively impact our sales.

We presently use customized equipment for the coating and packaging of our microneedle patch system. Because of the customized nature of our equipment, and the fact that we rely on third parties to manufacture our equipment, if the 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 our customers demands, which could adversely affect our business, financial condition and results of operations.

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

We are actively seeking to form 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 strategies, 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 that competes, either directly or indirectly, with our product candidate;

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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;

a collaboration partner may exercise a contractual right to terminate a strategic alliance;

if a collaboration partner terminates a strategic alliance agreement, then we will not be eligible to receive milestone or royalty payments under such agreement.

We have limited experience manufacturing our proposed products.

We have limited experience manufacturing our product candidates. If we are unable to establish a new manufacturing facility or expand existing manufacturing facilities, we may be unable to produce commercial materials or meet demand, if any should develop, for our products. Any such failure could delay or prevent our development of any product candidates and would have a material adverse effect on 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 active pharmaceutical ingredients, or 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 or products that we may develop.

Any failure or refusal to supply the components for our 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 products or 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.

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 conduct our clinical trials. In addition, we rely on other third parties, such as clinical data management organizations, medical institutions and clinical

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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 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. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or 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 drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates.

RISKS RELATED TO MARKETING AND SALE OF OUR PRODUCTS

We have no experience selling, marketing or distributing products and have limited internal capability 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 to the sales and marketing of our proposed products. Although we intend to develop a targeted commercial infrastructure to market and distribute our proprietary products that we have not exclusively licensed to others, our future success may depend, in part, on our ability to enter into and maintain collaborative relationships to provide such capabilities, on the collaborators strategic interest in the product candidates under development and on such collaborators ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of any approved products. However, 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 proposed products, 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.

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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 products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product 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.

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 transdermal delivery companies, in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business.

Our ability to generate product revenues will be diminished if we are unable to obtain third party coverage and adequate levels of reimbursement for any approved product.

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 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. 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

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FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such drug. 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 such 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 products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

costs of related litigation;

substantial monetary awards to patients or other claimants;

decreased demand for an approved product and loss of revenue;

impairment of our business reputation;

diversion of management and scientific resources from our business operations; and

the inability to commercialize an approved product.

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 for products 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 products 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 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

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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 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.

Our failure to obtain and maintain patent protection for our technology and our products 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 products may be adversely affected.

Our commercial success is significantly dependent on intellectual property related to our product 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 products.

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 products. 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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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 products. 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.

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 proposed product offerings.

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 candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product.

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

In addition to our patented technology and products, 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 products 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

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

We intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for 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 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 drug 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 drug product or the FDA s prior findings of safety and effectiveness for a previously approved drug 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 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 drug product that involves patents referenced in the

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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 only to be subject to significant delay and patent litigation before our product may be commercialized, if at all.

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

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

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

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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, or the USPTO, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

The USPTO is 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.

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RISKS RELATED TO LEGISLATION AND ADMINISTRATIVE ACTIONS

Our relationships with customers and third-party payors 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 payors 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 payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute 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 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 Patient Protection and Affordable Care Act, or the ACA, requires 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 payors, 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.

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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.

The final rule implementing the Physician Payments Sunshine Act is complex, ambiguous, and broad in scope. When and if our product candidates become 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 includes 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 establishes 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. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. Most recently, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which may result in such changes as aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, starting in 2013. The full impact on our business of the ACA and the Budget Control Act is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would

affect the pharmaceutical industry generally.

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If any of our products becomes subject to a product 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 products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products 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 drug candidate to other available therapies. If reimbursement of our drugs 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.

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

We are highly dependent on our chief executive officer and our chief financial officer. We do not have key person life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales 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 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

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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

An active trading market for our common stock may not develop or be sustained following our recently completed initial public offering.

There can be no assurance that our common stock will be actively traded in the future. Although our common stock is listed on The NASDAQ Capital Market, a consistent active trading market has not existed for our common stock and, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. 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. 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 products 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 addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies whose shares trade in the stock market. In the past, stockholders have initiated class action lawsuits against pharmaceutical and

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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.

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 and the venture capital funds affiliated with two of our current directors, sell substantial amounts of our common stock in the public market, 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 10, 2016, we had 11,967,895 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 (the 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, or the 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.

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.

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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 approximately 65% 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 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, and are leased under a seven-year property rental agreement that commenced in 2012. 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 has been publicly traded and listed on The NASDAQ Select Global Market under the symbol ZSAN since our initial public offering, or IPO, of our common stock on January 27, 2015. Prior to that time, there was no public market for our common stock. 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 Global Select Market.

	High	Low
2015		
First Quarter (from January 27, 2015)	$ 11.67	$ 9.01
Second Quarter	$ 10.69	$ 7.25
Third Quarter	$ 9.61	$ 3.96
Fourth Quarter	$ 3.88	$ 2.24

Holders of Common Stock

As of March 10, 2016, there were 35 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 Technology Growth Capital, Inc., or Hercules, contains covenants that restrict our ability to pay dividends.

Performance Graph

This graph is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Zosano Pharma Inc., under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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The following graph shows the cumulative total stockholder return of an investment of $100 in cash on January 27, 2015 (the first day of trading of our common stock), through December 31, 2015 for (i) our common stock, (ii) the Russell 2000 Index (U.S.) and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

Recent Sale of Unregistered Securities; Issuer Purchases of Equity Securities

From January 1, 2015 through December 31, 2015, we did not issue any securities in a transaction that was not registered under the Securities Act that has not been previously disclosed in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Use of Proceeds

On January 30, 2015, we consummated the closing of our initial public offering of common stock pursuant to our Registration Statement on Form S-1 (File No. 333-196983), as amended, which was declared effective by the Securities and Exchange Commission, or SEC, on January 26, 2015. The managing underwriters for the offering were Ladenburg Thalmann & Co. Inc. and Roth Capital Partners, LLC, or Roth.

We issued and sold a total of 4,610,000 shares of common stock in our initial public offering (comprising 4,500,000 shares of common stock plus an additional 110,000 shares of common stock pursuant to the underwriters partial exercise of their option to purchase up to an additional 675,000 shares of common stock to cover overallotments), at an initial public offering price of $11.00 per share. The aggregate sale price for all shares sold by us in the offering was $50.7 million, resulting in net proceeds to us of approximately $45.5 million after deducting underwriting discounts and commissions and estimated offering expenses paid or payable by us of approximately $5.2 million. Neither any underwriting discounts and commissions, nor any offering expenses, nor any of the net proceeds of the offering were paid, directly or indirectly, to our directors or officers, to persons owning ten percent or more of any class of our equity securities, or to their associates, or to any of our

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affiliates. However, Theodore D. Roth, the President and an associated person of Roth, is also a director of BioMed Realty Trust, Inc., and BioMed Realty Trust, Inc. is as an affiliate of BioMed Ventures, which is a beneficial owner of in excess of ten percent of our outstanding capital stock.

Through December 31, 2015, we used approximately $11.8 million of the net offering proceeds to fund continued advancement of our ZP-Triptan, ZP-Glucagon, and Daily ZP-PTH product candidates, approximately $1.3 million to service our debt obligation with Hercules, approximately $0.9 million to expand and enhance our manufacturing capabilities, and approximately $11.1 million for working capital and other general corporate purposes. We expect to use the remaining net proceeds from our initial public offering to continue to advance the product candidates described in 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 2015 and 2014 and the balance sheet data as of December 31, 2015 and 2014 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,	
	2015	2014
	(in thousands, except per share data)	
Consolidated Statements of Operations Data:		
Revenue:		
License fees revenue	$ 170	$ 1,955
Collaborative development support services	143	906
Total revenue	313	2,861
Operating expenses:		
Cost of license fees revenue	-	100
Research and development	20,366	10,953
General and administrative	6,315	4,420
Total operating expenses	26,681	15,473
Loss from operations	(26,368)	(12,612)
Other income (expenses):		
Interest expense, net	(1,564)	(1,848)
Other expense	(97)	(93)
Warrant revaluation income (expense)	48	(185)
Gain on debt forgiveness	-	497
Loss on debt extinguishment	(446)	-
Net loss	(28,427)	(14,241)
Unrealized holding loss on marketable securities, net of tax effect	(46)	-
Comprehensive loss	$ (28,473)	$ (14,241)
Net loss per common share basic and diluted	$ (2.49)	$ (2.78)
Weighted-average shares used in computing net loss per common share basic and diluted	11,414	5,128

	December 31,	
	2015	**2014**
	(in thousands)	
Selected Balance Sheets Data:		
Cash, cash equivalents and marketable securities	$ 36,933	$ 1,214
Working capital (deficit)	30,391	(11,719)
Total assets	45,337	13,343
Short-term and long-term debt	15,270	22,061
Accumulated deficit	(166,891)	(138,464)
Total stockholders equity (deficit)	26,502	(13,401)

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

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

Overview

We are a clinical stage specialty pharmaceutical company that has developed a proprietary transdermal microneedle patch system to deliver drug formulations through the skin for the treatment of a variety of indications. Our microneedle patch system offers rapid onset, consistent drug delivery, improved ease of use and room-temperature stability, benefits that we believe often are unavailable using oral formulations or injections. Our microneedle patch system has the potential to deliver numerous medications for a wide variety of indications in commercially attractive markets. By focusing our development efforts on the delivery of established molecules with known safety and efficacy and premium pricing, we plan to reduce our clinical and regulatory risk and development costs and accelerate our time to commercialization.

During 2015, our clinical development efforts were focused on three product candidates: ZP-PTH, for the treatment of severe osteoporosis, ZP-Glucagon, for the treatment of severe hypoglycemia, and ZP-Triptan, for the treatment of migraine. These product candidates are generic drugs specifically formulated to be administered by our microneedle patch system, and are proposed treatments for indications in which we believe rapid onset, ease of use and stability offer particularly important therapeutic and practical advantages, and have patient populations that we believe will provide us with an attractive commercial opportunity.

We recently made the decision to prioritize our clinical development effort on ZP-Triptan and to suspend further development related to our other product candidates, ZP-PTH and ZP-Glucagon, until such time that we can appropriately fund such development through strategic partnerships or additional financing. While we are considering pursuing clinical development of our ZP-Triptan product candidate to a meaningful milestone, we remain open to opportunities with potential strategic partners to ensure our product candidate will receive the best chance of commercial success.

ZP-Triptan is our proprietary formulation of zolmitriptan, one of a class of serotonin receptor agonists known as triptans used for the treatment of migraine. In November 2015, we announced positive results from our Phase 1 clinical trial of our ZP-Triptan patch, which was conducted in healthy human subjects in Australia. The Phase 1 results demonstrated the fast absorption of ZP-Triptan that is a characteristic of our microneedle patch and applicator system, which we believe can potentially translate to fast pain relief.

In connection with our decision to concentrate on the clinical development of ZP-Triptan, we recently announced that we would streamline our organization to ensure that we effectively use our funds for this purpose. We implemented a workforce reduction of 24 employees, representing approximately 38% of our total workforce, which we expect to reduce our expenses by approximately $2.0 million, net of severance costs, for fiscal year 2016. We expect to reinvest the savings from the workforce reduction in our ZP-Triptan clinical development program.

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, or FDA, or equivalent foreign regulatory bodies, to market and sell one or more of our product candidates. Accordingly, our success depends not only on the development, but also on our ability to finance the development, of these products. We will require substantial additional funding to complete development and seek regulatory approval for these products. Additionally, we

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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.

In November 2014, we entered into a collaboration and license agreement with Eli Lilly and Company, or Lilly, to develop one or more ZP-PTH microneedle patch products, with the initial product candidate being Daily ZP-PTH, a daily administration of ZP-PTH. Under the terms of the agreement, we granted to Lilly an exclusive, worldwide license to commercialize ZP-PTH in all dosing frequencies, including Daily ZP-PTH. On September 28, 2015, we terminated the collaboration agreement in accordance with its terms following our determination that it is commercially unreasonable to pursue one of the critical success factors under the collaboration agreement, relating to worldwide regulatory approval of Daily ZP-PTH by 2019. As a result of the termination of the collaboration agreement, the exclusive, worldwide license that we granted to Lilly terminated and reverted to us, and we will no longer be eligible to receive any milestone or other payments from Lilly.

In January 2014, we entered into an agreement with Novo Nordisk A/S, or Novo Nordisk, to develop a new transdermal formulation of semaglutide, an investigational proprietary human GLP-1 (Glucagon-Like Peptide-1) analogue, to be administered once a week using our microneedle patch system for the treatment of type 2 diabetes. In July 2015, we announced that Novo Nordisk A/S, or Novo Nordisk, has notified us of its intention to discontinue the collaboration. We were notified that Novo Nordisk s decision was related to a strategic prioritization of Novo Nordisk s research portfolio despite continued progress during the collaboration period. Upon the termination of the collaboration agreement, which became effective on October 27, 2015, all technology rights licensed to Novo Nordisk related to the field of GLP-1 products reverted to us. We received a non-refundable upfront payment of $1 million upon entering into the collaboration agreement in January 2014. We will no longer be eligible to receive any milestone or other payments from Novo Nordisk.

For the immediate future, our efforts and resources will be focused primarily on advancing our product candidate ZP-Triptan through clinical development, and raising capital to continue our clinical and commercial success. In addition to developing our own product candidate ZP-Triptan, we are actively seeking opportunities to evaluate collaboration with strategic partners to further the clinical and commercial development of our other product candidates. We also intend to selectively collaborate with other biopharmaceutical companies to explore other therapeutic uses for our microneedle patch system.

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.

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Revenue recognition

To date, we have not generated any revenue from product sales and do not expect to do so until one of our product candidates receives approval from the FDA. The only revenue we have generated to date has been revenue generated from collaboration and license agreements for the development of our technology for proposed indications utilizing our microneedle patch system. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under our collaboration arrangements and royalties on sales of product candidates if they are successfully approved and commercialized.

Our performance obligations under the collaborations may include the transfer or license of intellectual property rights, provision of research and development services and related materials, and participation on development and/or commercialization committees with the collaboration partners. We make judgments that affect the periods over which we recognize revenue. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

We adopted an accounting standard that provides guidance on revenue recognition using the milestone method. Payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on our partner s performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Accordingly, we have not recorded any milestone revenue on our consolidated financial statements as the contingent payments received did not meet the definition of milestone revenue.

Amounts related to research and development services are recognized as the related services or activities are performed, in accordance with the contract terms. Payments to us are typically based on the number of full- time equivalent personnel assigned to the collaboration project and the related research and development expenditures incurred.

Accrued research and development and manufacturing expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;

- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and

periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development and manufacturing expenses that we accrue include:

fees paid to contract research organizations, or CROs, and other service providers in connection with nonclinical studies and clinical trials;

fees paid to investigative sites in connection with clinical trials;

fees paid to contract manufacturing organizations, or CMOs, in connection with the production of nonclinical study and clinical trial materials; and

professional service fees for consulting and related services.

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We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with research institutions and CROs that conduct and manage nonclinical and clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under these contracts often depend on factors such as the successful enrollment of patients and the completion of certain clinical trial milestones. Our service providers invoice us in arrears for services performed. In accruing clinical costs, we estimate the time period over which patient enrollment will be completed and the progress of patient enrollment through completion in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the number of patients enrolled or the costs of patient enrollment, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued clinical trial expenses after a reporting period. However, due to the nature of the estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Stock-based compensation

We account for our stock-based compensation in accordance with ASC 718, Compensation Stock Compensation. ASC 718 establishes accounting for stock-based awards exchanged for employee services. Under the fair value recognition provisions of ASC 718, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service/vesting period. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the use of highly subjective assumptions, including the expected life of the stock-based awards and stock price volatility.

We account for stock-based compensation to non-employees in accordance with the recognition provisions of ASC 505-50, Equity-Based Payments to Non-Employees, using a fair value approach. The fair value of these awards is subject to re-measurement over the vesting period at each reporting date based upon the valuation of our common stock at that time.

Our stock-based compensation expense for stock options is estimated at the grant date based on the award s fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite service period. The Black-Scholes option pricing model requires various highly judgmental assumptions including expected volatility and expected term. The expected volatility is based on the historical stock volatilities of several of our publicly listed peers over a period equal to the expected terms of the options as we do not have a sufficient trading history to use the volatility of our own common stock. To estimate the expected term, we have opted to use the simplified method which is the use of the midpoint of the vesting term and the contractual term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. We estimate the forfeiture rate based on historical experience and our expectations regarding future pre-vesting termination behavior of employees. To the extent our actual forfeiture rate is different from our estimate, stock-based compensation expense is adjusted accordingly.

Prior to our initial public offering, or IPO, of common stock in January 2015, our board of directors, with the assistance of management and independent consultants, performed fair value analyses based on information available to us at the time of grant to determine the fair value of the shares of our common stock that underlie options granted

by the board of directors. For option grants made on dates for which there was no contemporaneous valuation to utilize in setting the exercise price of options to purchase shares of our common stock, and given the absence of an active market for our common stock prior to our IPO, our board of directors determined the fair value of our common stock on the date of grant using significant judgment and taking into account numerous factors, including product development progress since the last valuation of the Company and that the grants involved illiquid securities in a private company.

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Financial Operations Overview

General

As of December 31, 2015, we had an accumulated deficit of approximately $166.9 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. Our collaboration agreements with Novo Nordisk and Lilly have been terminated.

We expect our research and development expenses and manufacturing expenses related to clinical trials of our ZP-Triptan product candidate to increase as we continue to advance this program through clinical development. However, our other research and development and manufacturing expenses will decrease in 2016 due to the suspension of our material development efforts related to ZP-PTH and ZP-Glucagon. 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.

In addition to the proceeds received upon the closing of our initial public offering and concurrent private placement in January 2015, additional capital will be required to undertake our planned research and development activities and to meet our operating requirements beyond 2016. 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 delay or reduce the scope of our ZP-Triptan program, out-license intellectual property rights to our transdermal 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. During 2014, we funded our operations predominantly through debt arrangements with certain related parties and with Hercules Technology Growth Capital, or Hercules. In February 2014, we sold $2.5 million of convertible promissory notes and in December 2014, we sold an additional $1.3 million of convertible promissory notes to related parties participating in the debt financing. The convertible promissory notes were unsecured, subordinated notes and accrued simple interest at the rate of 8% per annum. The principal and all unpaid and accrued interest on each of the convertible promissory notes automatically converted into shares of our common stock upon the closing of our initial public offering on January 30, 2015, at a conversion price equal to $9.35 per share (or 85% of our initial public offering price of $11.00 per share).

In June 2014, we entered into a $4 million term loan facility with Hercules. 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%. In addition, we will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date we prepay the Hercules Term Loan and a $351,135 end of term charge on the earlier of loan maturity or at the date we

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prepay the Hercules Term Loan. We may prepay all, but not less than all, of the Hercules Term Loan subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. 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.

Revenue

Our revenue to date has been generated primarily from non-refundable license fee payments and reimbursements for research and development expenses under our prior collaboration and license agreements with Asahi Kasei Pharma Corporation, or Asahi, and our prior collaboration, development and license agreement with Novo Nordisk. Through December 31, 2015, we had received a non-refundable upfront license fee payment of $1.0 million from Novo Nordisk under the collaboration, development and license agreement, which was recorded as deferred revenue. Based on Novo Nordisk s notification to us in July 2015 of its intention to discontinue the collaboration agreement, we have recognized the remaining deferred revenue under this collaboration agreement in 2015. Reimbursements from Novo Nordisk for development support services and out-of-pocket expenses in connection with the collaboration agreement were recognized as service revenue when service was rendered and cost of material was incurred. As a result of the termination of the agreement, the collaboration with Novo Nordisk will no longer be a source of revenue for us. Through December 31, 2014, we had received an aggregate of $16.5 million under the license agreement with Asahi, which was terminated in January 2014.

Cost of license fees revenue

We are a party to an intellectual property license agreement dated October 5, 2006, as amended, with ALZA Corporation, or ALZA, under which we license certain patents and patent applications from ALZA on an exclusive basis worldwide. Cost of license fees revenue represents our payment obligations to ALZA under the intellectual property license agreement. Under the terms of the agreement, we are obligated to pay ALZA royalties on sales of products by us 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 royalties on sales by our sublicensees of such products. We are also obligated to pay ALZA a percentage of non-royalty revenue, defined as upfront payments, milestone payments and all other considerations (other than royalties), that we receive from our sublicensees on third party products where no generic equivalent is available to the public. Pursuant to the agreement with ALZA, we made a $0.1 million payment to ALZA in 2014 for the upfront license fee we received upon execution of the collaboration agreement with Novo Nordisk in January 2014. We have not made, nor were we obligated to make, payment to ALZA in 2015.

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:

- employee-related expenses, which include salaries, benefits and stock-based compensation;

fees paid to contract research organizations, or CROs, clinical consultants, clinical trial sites and vendors, including institutional review boards, or 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;

expenses related to the purchase of active pharmaceutical ingredients and raw materials for the production of our transdermal microneedle patch system, including fees paid to contract manufacturing organizations, or CMOs;

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fees paid to conduct nonclinical 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, 2015 and 2014, and from our inception to December 31, 2015:

	Year Ended December 31,		For the Period from inception to December 31, 2015
	2015	2014	
		(In thousands)	
Product candidate:			
ZP-PTH [1]	$ 5,753	$ 598	$ 44,486
ZP-Glucagon [2]	3,536	1,228	7,790
ZP-Triptan [3]	4,425	1,259	5,826
Collaborative development support [4]	117	631	2,630
Other research projects [5]	978	1,570	10,589
Unallocated research and development expenses [6]	5,557	5,667	70,068
Total research and development expenses	$ 20,366	$ 10,953	$ 141,389

(1) We completed a Phase 2 clinical trial of Daily ZP-PTH in 2008. Our research and development involving PTH was primarily focused on our Weekly ZP-PTH program during 2013 and 2014. In connection with our former collaboration agreement with Lilly, our spending in 2015 was exclusively focused on Daily ZP-PTH.

(2) Spending to date on ZP-Glucagon reflects spending since project initiation in the third quarter of 2012.

(3) We initiated our product development on ZP-Triptan in September 2013.

(4) Collaborative development support includes 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, respectively.

(5) Our other research projects include our research and development efforts on compounds other than our product candidates and projects in connection with potential partnership and collaboration development.

(6) 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.

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 our future collaborative partner may only be interested in applying our technology in the development and advancement of their own product candidates, as we have previously experienced.

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For the immediate future, our research and development efforts and resources will be focused primarily on advancing our product candidate ZP-Triptan through clinical development. While we are planning to pursue clinical development of our ZP-Triptan product candidate to a meaningful milestone, we remain open to opportunities with potential strategic partners to ensure our product candidate 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. As a result, we expect research and development expenses related to programs other than ZP-Triptan to decline, beginning the second quarter of 2016. We cannot forecast with any degree of certainty which of our 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 the uncertainties discussed above, 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 newly public company, we expect our general and administrative expenses to increase as we will need 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 (expense)

Interest expense, net. Interest expense, net of interest income, 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, 2015 consists of accrued interest on the related parties convertible promissory notes, which was converted to equity upon the closing of our IPO, accrued interest on the BMR Note, which was repaid in full in June 2015, as well as accrued and paid interest related to the Hercules Term Loan and the related amortization of debt discount and issuance costs. Interest expense for the year ended December 31, 2014 consists of accrued interest on the related parties convertible promissory notes, accrued interest on the BMR Note, and accrued interest related to the Hercules Term Loan, as well as related amortization of debt discount and issuance costs.

Other income (expense). Other income or expense consists of certain miscellaneous income or expenses that are not included in other categories of the consolidated statement of operations.

Warrant revaluation. Warrant revaluation income or expense resulted from the re-measurement of our common stock warrant liability issued in connection with the Hercules Term Loan. We record changes to the fair value of the common stock warrants as income or loss at each balance sheet date until they are exercised, reclassified, expired or converted into shares of our common stock.

Gain on debt forgiveness. In March 2014 and pursuant to the provisions of our joint venture termination agreement with Asahi, we recorded a one-time gain of $0.5 million in 2014 on debt forgiveness resulting from the cancellation of ZP Group LLC s revolving line of credit with Asahi Kasei Pharma USA.

Loss on debt extinguishment. Loss on debt extinguishment was related to the restructuring and consolidation of our outstanding debt in June 2015. In June 2015, we amended our loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million. The amended Hercules Term Loan has substantially

different terms than the original loan and in accordance with U.S. GAAP, the original debt was considered extinguished. We accounted for the extinguishment based on the relative fair value of the loan and recorded a loss on debt extinguishment of $0.4 million in 2015.

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Results of Operations

Comparison of the year ended December 31, 2015 and 2014

Revenue

	Year Ended December 31,		Change	
	2015	2014	Amount	%
	(In thousands)			
Revenue				
License fee revenue	$ 170	$ 1,955	$ (1,785)	-91%
Collaborative development support services	143	906	(763)	-84%
Total revenue	$ 313	$ 2,861	$ (2,548)	-89%

Total revenue decreased $2.5 million, or 89%, for the year ended December 31, 2015 as compared to the year ended December 31, 2014. The decrease was primarily due to the $1.1 million of contract revenue we earned in 2014 under our license agreement with Asahi that did not recur in 2015 as a result of the termination of the license agreement, and an approximately $1.5 million reduction in license fee revenue and related development support service revenue upon completion of the feasibility study and conclusion of work under our now terminated collaboration agreement with Novo Nordisk.

Cost of license fees revenue

	Year Ended December 31,		Change	
	2015	2014	Amount	%
	(In thousands)			
Cost of license fees revenue	$ -	$ 100	$ (100)	-100%

Cost of license fees revenue represents our payment obligations under our intellectual property license agreement with ALZA. There was no cost of license fees revenue for the year ended December 31, 2015. Cost of license fee revenue for the year ended December 31, 2014 was $0.1 million due to the royalty payment to ALZA attributable to our receipt of a $1.0 million license fee from Novo Nordisk upon execution of the collaboration and license agreement in January 2014.

Research and development expenses

	Year Ended December 31,		Change	
	2015	2014	Amount	%
	(In thousands)			
Research and development	$ 20,366	$ 10,953	$ 9,413	86%

Research and development expenses increased $9.4 million, or 86% for the year ended December 31, 2015 as compared to the year ended December 31, 2014. Of this increase, $5.8 million was due to Daily ZP-PTH Phase 3 GMP manufacturing preparation and patient preference study conducted in connection with our then collaboration with Lilly, $3.1 million was due to ZP-Triptan Phase 1 clinical trial and related preclinical toxicology studies, $2.3 million was due to ZP-Glucagon Phase 2 clinical trial, partially offset by a $0.6 million reduction in spending on our Weekly ZP-PTH program and a $1.2 million reduction in spending on our other research and development projects. For the immediate future, our research and development efforts and resources will be focused primarily on advancing our product candidate ZP-Triptan through clinical development. While we are planning to pursue clinical development of our ZP-Triptan product candidate to a meaningful milestone, we remain open to opportunities with potential strategic partners to ensure our product candidate 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.

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General and administrative expenses

	Year Ended December 31,		Change	
	2015	2014	Amount	%
	(In thousands)			
General and administrative	$ 6,315	$ 4,420	$ 1,895	43%

General and administrative expenses increased $1.9 million, or 43%, for the year ended December 31, 2015 as compared to the same period in 2014. The increase was primarily due to approximately $1.2 million related to compliance, infrastructure and insurance expenses to support our operations as a public company and $0.7 million related to additional general and administrative personnel costs in support of our expanded research and development operations.

Other expenses

	Year Ended December 31,		Change	
	2015	2014	Amount	%
	(In thousands)			
Interest expense, net	$ 1,564	$ 1,848	$ (284)	-15%
Other expense	97	93	4	4%
Warrant revaluation (income) expense	(48)	185	(233)	-126%
Gain on debt forgiveness	-	(497)	(497)	-100%
Loss on debt extinguishment	446	-	446	100%

Interest expense, net, decreased $0.3 million for the year ended December 31, 2015 as compared to the same period in 2014. The decrease in interest expense was primarily due to savings from the restructuring of our term loan with Hercules in June 2015 at a lower interest rate.

For the year ended December 31, 2015, we recorded other expense of approximately $97,000 as compared to other expense of approximately $93,000 for the same period in 2014. Other expense for the year ended December 31, 2015 consisted of an impairment charge on our long-term investment in Zosano, Inc., a public shell corporation, partially offset by income related to the recovery of prior year property damage claim received from an insurance company. Other expense for the year ended December 31, 2014 was primarily related to the fair value of the 31,250 shares of common stock that we issued to BMV Direct SOTRS LP in June 2014 as an inducement for its subordination of the BMR Note to the Hercules Term Loan.

Warrant revaluation income or expense resulted from the re-measurement of our common stock warrant liability issued in connection with the Hercules Term Loan. We record changes to the fair value of the common stock warrants as income or loss at each balance sheet date until they are exercised, reclassified, expired or converted into shares of our common stock. Warrant revaluation income/expense changed by $0.2 million as a result of changes in fair value of our common stock.

The gain on debt forgiveness of $0.5 million in 2014 was due to a one-time transaction in March 2014 resulting from the cancellation of ZP Group LLC s revolving line of credit with Asahi Kasei Pharma USA, pursuant to the provisions

of our joint venture termination agreement with Asahi.

Loss on debt extinguishment was related to the restructuring and consolidation of our outstanding debt in June 2015. The amended Hercules Term Loan has substantially different terms than the original loan and the original debt was considered extinguished. We accounted for the extinguishment based on the relative fair value of the loan and recorded a loss on debt extinguishment of $0.4 million in 2015.

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Income Taxes

As of December 31, 2015, we had net deferred tax assets of $75.8 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, 2015, we had federal net operating loss carryforwards of approximately $172.7 million and state net operating loss carryforwards of approximately $169.6 million. If not utilized, the federal net operating loss carryforwards will begin to expire in 2026 and state net operating loss carryforwards will begin to expire in 2016. Utilization of net operating loss carryforward 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 before utilization. We have not performed an analysis under Internal Revenue Code Section 382 to determine whether our net operating loss carryforwards will be subject to annual limitation.

As of December 31, 2015, we had federal and state research and development credit carryforwards of approximately $4.0 million and $4.0 million, respectively. As of December 31, 2014, we had federal and state research and development credit carryforwards of approximately $3.5 million and $3.6 million, respectively. If not utilized, the federal tax credits will begin to expire in 2026 and state tax credits currently do not expire.

Liquidity and Capital Resources

Since our inception in October 2006, we have funded our operations primarily through private placements of our preferred stock, 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, 2015, had an accumulated deficit of $166.9 million. We expect to incur additional losses in the future to conduct research and development of our ZP-Triptan product candidate and to conduct pre-commercialization manufacturing activities.

As of December 31, 2015, we had approximately $36.9 million in cash, cash equivalents and marketable security. We believe our existing cash, cash equivalents and marketable securities will be sufficient to sustain operations for at least the next 12 months from the date of this report based on our existing business plan and enable us to complete certain of our clinical trials as currently projected.

We will continue to require additional financing to develop our product candidates and fund operating losses. 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 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;

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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 delay, reduce, or terminate our ZP-Triptan development program and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

The following table shows a summary of our cash flows for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (24,155)	$ (10,915)
Investing activities	(30,946)	(1,133)
Financing activities	60,533	7,349
Net increase (decrease) in cash and cash equivalents	$ 5,432	$ (4,699)

Operating Cash Flow: Net cash used in operating activities was $24.2 million and $10.9 million for the years ended December 31, 2015 and 2014, respectively. Net cash used during 2015 was primarily the result of clinical and non-clinical development costs, personnel costs related to the hiring of key personnel with critical manufacturing know-how to ramp up our production of clinical trial materials in preparation of our planned Phase 2 and 3 clinical trials for our ZP-PTH, ZP-Glucagon and ZP-Triptan clinical programs, professional fees and administrative expenses incurred in the course of continuing operation. Net cash used in 2014 was primarily the result of personnel-related costs, clinical trial costs, and professional fees and administrative expenses.

Investing Cash Flow: Net cash used in investing activities was $30.9 million and $1.1 million for the years ended December 31, 2015 and 2014, respectively. Net cash used in investing activities during 2015 was primarily due the purchase of $42.6 million of marketable securities for investment, partially offset by maturities of $12.1 million of our investments in marketable securities. Net cash used in investing activities during 2014 included the purchase of manufacturing equipment to support the clinical trial material production of our transdermal microneedle patch.

Financing Cash Flow: Net cash provided by financing activities was $60.5 million and $7.3 million for the years ended December 31, 2015 and 2014, respectively. Net cash generated from financing activities during 2015 included approximately $60.3 million of net proceeds from our initial public offering of securities and concurrent private placement with Eli Lilly. Net cash generated from financing activities during 2014 included $3.9 million of net proceeds from our debt financing with Hercules and $3.8 million from the issuance of our convertible bridge notes to certain of our existing investors.

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Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2015:

	Payment Due by Period				
	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Short and long-term debt obligations (including interest) [1]	$ 17,673	$ 3,924	$ 13,749	$ -	$ -
Operating lease obligations [2]	2,078	626	1,288	164	-
Purchase commitments	-	-	-	-	-
Total contractual obligations	$ 19,751	$ 4,550	$ 15,037	$ 164	$ -

(1) Short and long-term debt obligations
Secured financing with Hercules

In June 2014, we entered into a loan and security agreement with Hercules Technology Growth Capital 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 (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%. In addition, we will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date we prepay the Hercules Term Loan and 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 subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. 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, for our office, research and development, and manufacturing facilities in Fremont, California. We entered into a fifth amendment to the lease in April 2012 which extended the lease term through March 2019 and provided a reduction in annual rents due to a potential reduction of premises from a recapturable premises clause. In June 2015, we entered into a sixth amendment to the lease, pursuant to which the landlord s option to recapture a specified portion of the leased premises (comprising approximately 29,348 square feet of the approximate total 55,588 square feet of leased premises) has been suspended. We had the option until December 31, 2015 to extend the term of the lease. As of December 31, 2015, we did not elect the option afforded under the sixth amendment and as a result, conditions under the fifth amendment remain in effect.

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In addition to the operating lease for our facility, we have other non-cancelable operating leases with various vendors for our copiers and water system.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, *Leases*. Under the new guidance, lessees will be required to recognize substantially all leases on the balance sheet as a right-of-use asset and recognize a corresponding lease liability. The accounting applied by a lessor is largely unchanged from that applied under previous U.S. GAAP. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2018. We are currently evaluating the impact of this accounting standard.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, which amends the guidance in U.S. GAAP on the classification and measurement of financial instruments. Changes to the current guidance primarily affect the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. The guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are currently evaluating the impact of this accounting standard.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes*. The amendment to ASC740 eliminates the requirement that an entity must separate deferred income tax assets and liabilities between current and noncurrent amounts on a classified balance sheet. Rather, deferred tax assets and liabilities will be presented as noncurrent under the new standard. This ASU is effective for fiscal years beginning after December 31, 2016 and early adoption is permitted. We early adopted this standard on a prospective basis in the fourth quarter of fiscal 2015. Prior periods were not retrospectively adjusted upon adoption.

In April 2015, the FASB issued Accounting Standards Update (ASU) 2015-03, *Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. The guidance changes the presentation of debt issuance costs in financial statements. ASU 2015-03 requires an entity to present such costs in the balance sheet as a direct deduction from the related debt liability rather than an asset. Amortization of the costs will continue to be reported as interest expense. ASU 2015-03 is effective for annual reporting periods beginning after December 15, 2015 with early adoption permitted. We elected to adopt ASU 2015-03 as of June 30, 2015 and the adoption has no impact on our financial position or results of operations.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. This new accounting standard requires management to evaluate whether there are conditions or events that raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact of this accounting standard.

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standard Updated (ASU), No. 2014-09, *Revenue from Contracts with Customers*. This ASU outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the

ASU by one year to December 15, 2017 for fiscal years, and interim periods, beginning after that date. Early adoption is permitted, but not before the original effective date (annual periods beginning after December 15, 2016). We are currently evaluating the impact of this accounting standard.

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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 $6.6 million and $1.2 million as of December 31, 2015 and 2014, 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 Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. 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, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and 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 Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015 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 generally accepted accounting principles in the United States, or U.S. GAAP.

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Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2015. 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

As previously disclosed in our 2014 Annual Report on Form 10-K, in order to remediate the material weakness identified for the year ended December 31, 2013, we implemented a number of measures to strengthen our internal controls over financial reporting. Management has implemented the following measures during 2015:

- we recruited and hired additional accounting staff with technical expertise to ensure the proper application of U.S. GAAP, and expect to continue to enhance our financial reporting systems;
- we have implemented policies and procedures and enhanced our review of complex accounting transactions to ensure consistent application of U.S. GAAP and enhanced internal control over financial reporting; and
- we have increased the level of preparation and review of our financial statements, and in connection therewith, we have implemented additional control procedures as part of our quarter and year-end close processes as well as adding resources in connection with our review of key financial estimates, including fixed assets control procedures, stock-based compensation expense, and indebtedness.

In addition, we have implemented new purchasing management and adopted a new treasury policy and procedures to complement and enhance existing internal controls. Further, we have revised our procedures on equity awards administration practices.

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 24, 2016 are set forth below:

Name	Age	Position(s)
Bruce D. Steel	49	Chairman of Board of Directors
Joseph P. Hagan (1) (2) (3)	47	Director
Troy Wilson (1) (2) (3)	47	Director
Kleanthis G. Xanthopoulos (1) (2) (3)	57	Director
Konstantinos Alataris	46	President, Chief Executive Officer and Chief Operating Officer
Winnie W. Tso	54	Chief Financial Officer

(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:

Bruce D. Steel has served as a member of our board of directors since April 2012. Mr. Steel is currently the Managing Director of BioMed Ventures, the strategic investment arm of BioMed Realty Trust. Previously, Mr. Steel served as the Chief Executive Officer of Rincon Pharmaceuticals, Inc. and, between 2008 and 2010, as the Chief Business Officer of Anaphore, Inc. Mr. Steel received his Bachelor of Arts from Dartmouth College and his M.B.A. from the Marshall School of Business at the University of Southern California. Mr. Steel also holds the designation of Chartered Financial Analyst. We believe that Mr. Steel s deep knowledge of the life-sciences industry as well as his executive level experience at various companies qualify him to serve as a member of our board of directors.

Joseph P. Hagan has served as a member of our board of director since May 2015. Mr. Hagan has served as Regulus Chief Operating Officer, Principal Financial Officer and Principal Accounting Officer since January 2016. From 2011 to December 2015, Mr. Hagan served as Orexigen s Chief Business & Financial Officer. From May 2009 to June 2011, Mr. Hagan served as Orexigen s Senior Vice President, Corporate Development, Strategy and Communications. Prior to Orexigen, Mr. Hagan worked at Amgen, from September 1998 to April 2008, where he served in various senior business development roles, including founder and Managing Director of Amgen Ventures. Prior to starting the

Amgen Ventures fund, Mr. Hagan was Head of Corporate Development at Amgen, leading such notable transactions as the acquisition of Immunex and Tularik and the spinouts of Novatrone and Relypsa, as well as numerous other business development efforts totaling over $15 billion in value. Before joining Amgen, Mr. Hagan spent five years in the bioengineering labs at Genzyme and Advance Tissue Sciences. He received an M.B.A. from Northwestern University and a B.S. in Physiology and Neuroscience from the University of California, San Diego.

Troy Wilson 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 NanoMedicines 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 LLC, 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

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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 has served as a member of our board of directors since April 2013. Dr. Xanthopoulos was the President and Chief Executive Officer and a member of the board of directors of Regulus Therapeutics Inc. until June 2015, having joined Regulus in 2007. Dr. Xanthopoulos is also currently chairman of the board of directors of Apricus Biosciences, Inc., a public company, a member of the board of directors of Biotechnology Industry Organization (BIO) and Senté Inc., and is a member of the executive board of BIOCOM, Southern California s life science industry association. Prior to joining Regulus, Dr. Xanthopoulos was a managing director of Enterprise Partners Venture Capital. Dr. Xanthopoulos co-founded and served as President and Chief Executive Officer of Anadys Pharmaceuticals from its inception in 2000 to 2006, and remained a Director until its acquisition by Roche in 2011. Dr. Xanthopoulos was Vice President at Aurora Biosciences, which was acquired by Vertex Pharmaceuticals, 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. Previously, 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, 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. We believe that Dr. Xanthopoulous 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.

Konstantinos Alataris has served as our President, Chief Executive Officer and Chief Operating Officer since January 2016 and has been a member of our board of directors since February 2016. Previously, Dr. Alataris served as Zosano s President and Chief Operating Officer. Dr. Alataris was the founder and held the roles of President, Chief Executive Officer and Chief Commercial Officer with Nevro Corp. (NYSE:NVRO), a company that developed an innovative, evidenced-based neuromodulation platform for the treatment of chronic pain. Under Dr. Alataris leadership, Nevro advanced from product concept to clinical testing to successful market launch and international commercialization. Dr. Alataris has also served as Executive Chairman of the Board of Directors at IRRAS AB, a CNS medical device and drug delivery company and Head of Digital Healthcare Strategy at mc10inc a wearable sensor company. Prior to NEVRO, he was Vice President at Bay City Capital, a healthcare focused venture capital firm based in San Francisco. He holds Master s degrees in Science and Business and a Ph.D. in Bioengineering with emphasis in Neuroscience from the University of Southern California.

Winnie W. Tso has served as our Chief Financial Officer since April 2014. From January 2014 to April 2014, Ms. Tso served as a consultant to us. Prior to joining us in January 2014, Ms. Tso served as Vice President, Finance and Corporate Controller of SciClone Pharmaceuticals, a publicly-traded specialty biopharmaceutical company, in 2013. Prior to that, Ms. Tso served in various Vice President and Principal Accounting Officer positions from 2009 to 2013, including at Velti plc where Ms. Tso helped lead Velti s U.S. public offering raising in excess of $150 million in equity financing. Prior to Velti, Ms. Tso held senior finance positions at several publicly-traded biopharmaceutical companies, including ARYx Therapeutics, Titan Pharmaceuticals and Genelabs Technologies, where she was responsible for building the finance and accounting infrastructures and implementing

systems of internal controls. Ms. Tso is a Certified Management Accountant, a Certified Financial Manager, a Certified Public Accountant licensed in the State of California and a member of the American Institute of Certified Public Accountants. Ms. Tso received her B.S. degree in Business Administration from the Haas School of Business at the University of California, Berkeley.

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

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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 2015 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.

Stockholder Recommendations for Director Candidates

Stockholders may recommend individuals to the nominating and corporate governance committee of our board of directors for consideration as potential director candidates by submitting their names, together with appropriate biographical information and background materials and a statement as to whether the stockholder or group of stockholders making the recommendation has beneficially owned more than five percent of our common stock for at least a year as of the date such recommendation is made, to our nominating and corporate governance committee, c/o Secretary, Zosano Pharma Corporation, 34790 Ardentech Court, Fremont, California 94555.

Assuming that appropriate biographical and background material is provided on a timely basis, the nominating and corporate governance committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates that it recommends. If the board of directors resolves to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included in our proxy card for the next annual meeting of stockholders. Any recommendation of a potential director nominee should also include a statement signed by the proposed nominee expressing a willingness to serve as a director if elected. As part of this responsibility, the committee will be responsible for conducting, subject to applicable law, any and all inquiries into the background and qualifications of any candidate for election as a director and such candidate s compliance with the independence and other qualification requirements established by the committee or imposed by applicable law or listing standards.

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

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regulations of the SEC and the NASDAQ Stock Market. The board of directors has also determined that Mr. Hagan qualifies as an audit committee financial expert, as defined by applicable rules of the NASDAQ Stock Market and the SEC.

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

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

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

Item 11. EXECUTIVE COMPENSATION

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, 2015. We refer to these individuals as our named executive officers.

	Year	Salary	Non-equity incentive plan compensation	Option Awards	Total
Vikram Lamba	2015	$ 424,360	$ 85,000[2]		$ 509,360
Chief Executive Officer [1]	2014	412,000	181,276[3]		593,276
Konstantinos Alataris, Ph.D.	2015	105,288	18,750[2]	1,297,504[5][6]	1,421,542
President and Chief Operating Officer [4]					
Laxmi Peri	2015	201,205	34,810[2]	251,459[5][6]	487,474
Senior Vice President Operations [7]					

(1) Mr. Lamba s employment with the Company terminated on January 6, 2016. He was succeeded as our President and Chief Executive Officer by Dr. Alataris.
(2) Represents cash bonus awarded in respect of 2015 and paid in March 2016. Bonus amounts were determined pursuant to a 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.
(3) Represents cash bonus awarded in respect of 2014 and paid in March 2015. 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.
(4) Dr. Alataris joined the Company on September 21, 2015.
(5) Represents the aggregate grant date fair value of option awards granted in fiscal year 2015 in accordance with ASC 718, *Compensation Stock Compensation*.
(6) The aggregate grant date fair value of option awards granted in fiscal year 2015 includes the impact of the options exchanged pursuant to the 2015 Stock Option Exchange Program. (See Note 12, Stock-Based Compensation for a description of the 2015 Stock Option Exchange Program).
(7) Laxmi Peri joined the Company on April 27, 2015. His employment was terminated on March 24, 2016.

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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 President and Chief Executive Officer for all executives other than our President and 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 had a formal employment agreement with Vikram Lamba, our former Chief Executive Officer and have such an agreement with Konstantinos Alataris, our current President, Chief Executive Officer and Chief Operating Officer. We also had an executed employment offer letter with Laxmi Peri, our Senior Vice President, Operations. Mr. Lamba s employment agreement provided for an initial base salary of $400,000, subject to increase from time to time, and in the fiscal year 2015, we paid Mr. Lamba an annual base salary of $424,360. Mr. Lamba s employment agreement provided for a target annual bonus of 40% of his annual base salary, to be determined by the board of directors in its discretion based on company performance against goals established annually by the compensation committee, as well as the company s then prevailing cash position. Dr. Alataris employment agreement provides for an initial base salary of $375,000, subject to increase from time to time. In January 2016, we amended Dr. Alataris employment agreement to reflect his capacity to serve as our Chief Executive Officer starting January 2016 at a base salary of $450,000. The amended employment agreement provides for a target annual bonus of 40% of his annual base salary for 2015, and a target annual bonus of 50% of his annual base salary for 2016, to be determined by the board of directors in its discretion based on company performance against goals established annually by the compensation committee, as well as the company s then prevailing cash position. Mr. Peri s employment offer letter provided for an initial annual base salary of $295,000, subject to increase from time to time. Mr. Peri s employment offer letter provided for a target annual bonus of 30% of his annual base salary. On January 6, 2016, Mr. Lamba s employment was terminated without cause by the board of directors. On January 6, 2016, Dr. Alataris was appointed by the board of directors to serve as our Chief Executive Officer. As a result of a company-wide workforce reduction plan, Mr. Peri s employment was terminated on March 24, 2016.

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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, 2015.

	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Option Exercise Price ($)	Option Expiration Date	Option Grant Date
Vikram Lamba	120,869	20,637[1]	$ 1.54	07/1/2017[2]	07/1/2012
Konstantinos Alataris		209,394	$ 2.26	12/15/2025	12/15/2015
Laxmi Peri		40,000[3]	$ 2.26	12/15/2025[4]	12/15/2015

(1) This option was exercisable for 25% of the underlying shares on the first anniversary of the grant date, and thereafter became 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; provided that if Mr. Lamba was terminated without cause or resigned for good reason (as these terms are defined in his employment agreement), then the option would become exercisable for an additional 18.75% of the total underlying shares. On January 6, 2016, Mr. Lamba was terminated without cause and this option was accelerated in full.

(2) Pursuant to its terms, this option expires 90 days following the termination of employment with the Company. Mr. Lamba was terminated on January 6, 2016 and due to such termination this option was accelerated in full. This option will expire on April 6, 2016.

(3) This option becomes 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. Pursuant to its terms, this option expires 90 days following the termination of employment with the Company. Mr. Peri was terminated on March 24, 2016 and due to such termination, this option will expire on June 24, 2016.

(4) In connection with Mr. Peri s termination, the Board of Directors of the Company approved the acceleration of Mr. Peri s unvested options such that the option became exercisable for 25% of the underlying shares on March 24, 2016.

Severance and Change in Control Arrangements

Pursuant to the terms of Mr. Lamba s employment agreement, if we terminated Mr. Lamba s employment without cause or Mr. Lamba resigned for good reason, as these terms are defined in the employment agreement, then Mr. Lamba was entitled to receive certain severance payments, including nine months salary, pro rata bonus payment in

respect of those nine months, and acceleration of vesting of a portion of his outstanding stock option. If within a year after a change of control, as defined in the employment agreement, Mr. Lamba s employment was terminated without cause or Mr. Lamba resigned for good reason, then Mr. Lamba s stock option would vest in full. As a result of the termination of Mr. Lamba s employment without cause, as defined in the employment agreement, effective January 6, 2016, Mr. Lamba received nine months of salary, pro rata bonus payment in respect of those nine months, and acceleration of vesting of all of his outstanding stock option in accordance with his employment agreement.

Pursuant to the terms of Mr. Alataris employment agreement, if we terminate Mr. Alataris employment without cause or Mr. Alataris resigns for good reason, as these terms are defined in the employment agreement, then Mr. Alataris is entitled to received certain severance payments, including twelve month s salary, an amount equal to the annual bonus awarded in the prior calendar year, and acceleration of vesting of a portion of his outstanding stock options. If within a year after a change of control, as defined in the employment agreement, Mr. Alataris employment is terminated without cause or Mr. Alataris resigns for good reason, then Mr. Alataris stock options will vest in full.

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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 0.033% 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 2015. For information concerning the compensation paid to Mr. Lamba and Dr. Alataris in their capacities as executive officers, see Summary Compensation Table above.

	Fees Earned or Paid in Cash	Option Awards [1]	Total
M. James Barrett [2]	$	$	$
Joseph P. Hagan	27,460	223,591	251,051
Bruce D. Steel			
Troy Wilson	42,497	30,180	72,677
Kleanthis G. Xanthopoulos	43,787	60,360	104,147

(1) Represents the aggregate grant date fair value of stock options and restricted stock awards granted in fiscal year 2015 in accordance with ASC Topic 505-50. The assumptions we use in calculating these amounts are discussed in note 12 to notes to financial statements appearing elsewhere in this report.

(2) Dr. Barrett resigned from our Board of Directors effective January 22, 2016.

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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, 2015 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	972,951	$ 2.35	858,606
Equity compensation plans not approved by security holders			
Total	972,951	$ 2.35	858,606

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 March 10, 2016, 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 March 10, 2016 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.

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Each stockholder s percentage ownership is determined in accordance with Rule 13d-3 under the Exchange Act and is based on 11,967,895 shares of our common stock outstanding as of March 10, 2016.

Name of Beneficial Owner [1]	Shares Beneficially Owned	Percentage
5%+ Stockholders		
BMV Direct SOTRS LP [2] 17190 Bernardo Center Drive San Diego, CA 92128	2,442,429	20.41%
New Enterprise Associates 12, Limited Partnership [3] Chevy Chase, MD 20815 5425 Wisconsin Avenue, Suite 800	2,158,539	18.04%
FRM LLC Company [4] 245 Summer Street Boston, MA 02210	1,795,043	15.00%
Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285	1,363,636	11.40%
Eventide Asset Management LLC [5] 1 International Place, 35th Floor Boston, MA 02110	888,300	7.42%
Vikram Lamba [6] 1750 Taylor St. San Francisco, CA 94133	772,756	6.38%
Directors and Named Executive Officers:		
Konstantinos Alataris		*
Joseph Hagan		*
Laxmi Peri		*
Bruce Steel		*
Winnie Tso [7]	18,679	*
Troy Wilson [8]	15,971	*
Kleanthis Xanthopoulos [9]	27,815	*
Current Directors and Executive Officers as a Group (7 persons) [10]	62,465	

* 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 such 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 respect to securities.

(2)

Shares owned as of March 10, 2016 include 1,896,982 shares of common stock owned by BMV Direct SOTRS LP and 545,447 shares of common stock owned by BMV Direct SO LP. The sole general partner of BMV Direct SOTRS LP is BioMed Realty Holdings, Inc. The sole shareholder 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 Steel is a limited partner with a variable economic interest in each of BMV Direct SOTRS LP and BMV Direct SO 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 therein.

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(3) Shares owned as of March 10, 2016 include 2,158,539 shares of common stock owned by New Enterprise Associates 12, Limited Partnership, or NEA 12. The shares directly held by NEA 12 are indirectly held by NEA Partners 12, Limited Partnership (NEA Partners 12), the sole general partner of NEA 12, NEA 12 GP, LLC, or NEA 12 LLC, the sole general partner of NEA Partners 12, and each of the individual Managers of NEA 12 LLC. The individual Managers of NEA 12 LLC are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Patrick J. Kerins, Krishna Kittu Kolluri and Scott D. Sandell. The shares directly held by Ven 2006 are indirectly held by Karen P. Welsh, the general partner of Ven 2006. NEA Partners 12, NEA 12 LLC and the Managers share voting and dispositive power with regard to the shares of the securities directly held by NEA 12. M. James Barrett has neither voting nor dispositive power with respect to the shares held by Ven 2006. M. James Barrett and all other indirect holders of these shares have disclaimed his beneficial ownership in these shares except to the extent of their pecuniary interest therein, if any.

(4) Shares owned as of March 10, 2016 include 1,196,540 of common stock owned by Select Biotechnology Portfolio and 598,503 of common stock owned by Fidelity Advisors Biotechnology Fund.

(5) Shares owned as of March 10, 2016 include 616,300 shares of common stock owned by Eventide Gilead Fund.

(6) Includes options to purchase 141,506 shares of our common stock that may be exercised within 60 days of March 10, 2016.

(7) Consists of options to purchase 18,679 shares of our common stock that may be exercised within 60 days of March 10, 2016.

(8) Includes options to purchase 12,971 shares of our common stock that may be exercised within 60 days of March 10, 2016.

(9) Includes options to purchase 21,815 shares of our common stock that may be exercised within 60 days of March 10, 2016.

(10) Includes options to purchase 53,465 shares of our common stock that may be exercised within 60 days of March 10, 2016.

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 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Person Transactions

The following is a description of transactions since January 1, 2014 and any currently proposed transactions to which we have been or will be a party, and in which the amounts involved exceeded or will exceed $120,000 (except as otherwise indicated) and any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or any of their respective affiliates or immediate family members, had or will have a direct or indirect material interest, which have not already been described in Item 11 of Part III (Executive Compensation) of this Annual Report on Form 10-K. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be

paid or received, as applicable, from unrelated third parties.

Real Property Lease with BMR

In April 2012, in connection with our April 2012 recapitalization, we issued 1,236,769 shares of our common stock and a four year non-callable secured promissory note in the original principal amount of

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$8,556,533 to BioMed Realty Holdings, Inc., or BMR Holdings, and 107,545 shares of our common stock to BioMed Realty, L.P., each of which is an affiliate of our landlord, BMR-34790 Ardentech Court LP. As a result, BMR Holdings and BioMed Realty, L.P. together held approximately 23.8% of our voting securities following the recapitalization. We issued these securities to BMR Holdings and BioMed Realty, L.P. in exchange for reduction of future rent payments pursuant to an amendment to our lease agreement with BMR-34790 Ardentech Court LP, cancellation of an unsecured convertible promissory note issued to BioMed Realty, L.P. in July 2011 and cancellation of a stock purchase warrant issued to BioMed Realty, L.P. in July 2011.

We also 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, 2014 and 2015, we recorded rent expense for BMR-34790 Ardentech Court LP in the amount of approximately $620,000. In April 2012, we amended the lease agreement to reduce future rent obligations to amounts ranging from approximately $600,000 to $891,000 per year over a new lease term of seven years in exchange for a potential reduction of premises from a recapturable premises clause. In June 2015, we entered into another amendment to the lease, pursuant to which BMR-34790 Ardentech Court LP s option to recapture a specified portion of the leased premises (comprising approximately 29,348 square feet of the approximate total 55,588 square feet of leased premises) has been suspended. We had the option until December 31, 2015 to extend the term of the lease. As of December 31, 2015, we did not exercise this option and as a result, the terms of the previous amendment entered in April 2012 remain in effect.

February 2014 Bridge Loan

In February 2014, we issued and sold convertible promissory notes, which we refer to as the February 2014 bridge notes, in the aggregate original principal amount of $2.5 million to our stockholders BMV Direct SOTRS LP, BMV Direct SO LP and New Enterprise Associates 12, Limited Partnership. Each of BMV Direct SOTRS LP, BMV Direct SO LP and New Enterprise Associates 12, Limited Partnership then owned, and as of the date of this report owns, more than 5% of our voting securities. The following is the original principal amount of February 2014 bridge notes that were issued to our directors, executive officers and holders of more than 5% of our voting securities, and their affiliates or immediate family members:

- BMV Direct SOTRS LP, in the original principal amount of approximately $1.1 million;
- BMV Direct SO LP, in the original principal amount of approximately $250,000; and
- New Enterprise Associates 12, Limited Partnership, in the original principal amount of approximately $1.2 million.

As consideration for our issuance of the February 2014 bridge notes, each investor paid us an amount equal to the original principal amount of the note issued to the investor. The February 2014 bridge notes matured on September 9, 2014 and accrued simple interest at the annual rate of 8%. As of January 30, 2015, the aggregate outstanding principal and accrued interest under the February 2014 bridge notes was approximately $2.7 million. Upon the closing of our initial public offering of common stock on January 30, 2015, which constituted a qualified financing as defined under

the terms of the notes, the principal and all unpaid and accrued interest on each note automatically converted into shares of our common stock at a conversion price equal to $9.35 per share (or 85% of the initial public offering price), resulting in the issuance of 122,882 shares of common stock BMV Direct SOTRS LP, 28,603 shares of common stock to BMV Direct SO LP, and 135,700 shares of common stock to New Enterprise Associates 12, Limited Partnership. In June 2014, we amended the February 2014 bridge notes to provide that any failure by us to pay any amount under the February 2014 bridge notes during the period from maturity of the February 2014 bridge notes through the date that the Hercules loan is repaid in full will not constitute a default under the February 2014 bridge notes. In September 2014, we amended the February 2014 bridge notes to extend the date by which a qualified financing must occur in order for the February 2014 bridge notes to convert into equity securities to December 31, 2014, and in December 2014, we amended the February 2014 bridge notes to further extend the date by which a qualified financing must occur in order for the February 2014 bridge notes to convert into equity securities to March 31, 2015.

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December 2014 Bridge Loan

In December 2014, we issued and sold convertible promissory notes, which we refer to as the December 2014 bridge notes, in the aggregate original principal amount of $1.3 million to our stockholders BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership. Each of BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership then owned, and as of the date of this report owns, more than 5% of our voting securities. The following is the original principal amount of December 2014 bridge notes that were issued to our directors, executive officers and holders of more than 5% of our voting securities, and their affiliates or immediate family members:

- BMV Direct SOTRS LP, in the original principal amount of approximately $710,000; and
- New Enterprise Associates 12, Limited Partnership, in the original principal amount of approximately $620,000.

As consideration for our issuance of the December 2014 bridge notes, each investor paid us an amount equal to the original principal amount of the note issued to the investor. The December 2014 bridge notes matured on June 1, 2017 and accrued simple interest at the annual rate of 8%. As of January 30, 2015, the aggregate outstanding principal and accrued interest under the December 2014 bridge notes was approximately $1.4 million. Upon the closing of our initial public offering of common stock on January 30, 2015, which constituted a qualified financing as defined under the terms of the notes, the principal and all unpaid and accrued interest on each note automatically converted into shares of our common stock at a conversion price equal to $9.35 per share (or 85% of the initial public offering price), resulting in the issuance of 76,731 shares of common stock BMV Direct SOTRS LP and 67,679 shares of common stock to New Enterprise Associates 12, Limited Partnership.

Private Placement with Eli Lilly and Company

In November 2014, we entered into a stock purchase agreement with Eli Lilly and Company, or Lilly, pursuant to which Lilly agreed to purchase up to $15.0 million worth of our common stock in a private placement concurrent with the closing of our initial public offering, at a price per share equal to the initial public offering price. On January 30, 2015, pursuant to the stock purchase agreement and concurrent with the closing of our initial public offering, we issued and sold 1,363,636 shares of our common stock to Lilly at a price per share of $11.00 in a private placement, for an aggregate cash purchase price of $15.0 million. We received net proceeds of approximately $14.5 million from the sale of shares to Lilly in the private placement, after payment by us of a private placement fee to the representatives of the underwriters of our initial public offering. The shares of common stock issuable to Lilly under the stock purchase agreement were deemed beneficially owned by Lilly in accordance with Rule 13d-3 under the Exchange Act upon the parties entry into the stock purchase agreement in November 2014, making Lilly a beneficial owner of more than 5% of our voting securities at that time. As of the date of this Annual Report on Form 10-K, Lilly continues to own more than 5% of our voting securities.

Interests of Directors in Our Financial Relationships

Two of our current and former directors, Bruce Steel and M. James Barrett, may be deemed to have indirect material interests in our financial relationships with certain of our stockholders based on their association with such stockholders:

Bruce 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.

M. James Barrett is one of seven Managers of NEA 12 GP, LLC, or NEA 12 LLC, the sole general partner of NEA Partners 12, Limited Partnership, or NEA Partners 12, which is the sole general partner of our

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stockholder, New Enterprise Associates 12, Limited Partnership. NEA Partners 12, NEA 12 LLC and each of the Managers of NEA 12 LLC share voting and dispositive power with regard to our securities directly held by New Enterprise Associates 12, Limited Partnership. Dr. Barrett disclaims beneficial ownership in these shares except to the extent of his pecuniary interest therein, if any. Dr. Barrett resigned from our Board of Directors effective January 22, 2016.

Participation in our Initial Public Offering

BMV Direct SO purchased 26,543 shares, or an aggregate amount of $291,973 worth, of our common stock in our initial public offering in January 2015, and New Enterprise Associates 12, Limited Partnership purchased 23,457 shares, or an aggregate amount of $258,027 worth, of our common stock in our initial public offering in January 2015, in each case at the initial public offering price of $11.00 per share. The shares purchased by BMV Direct SO and New Enterprise Associates 12, Limited Partnership in our initial public offering were subject to lock-up agreements pursuant to which these investors agreed, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the 180-day period following January 26, 2015, except with the prior written consent of the representatives of the underwriters for the initial public offering.

Indemnification of Directors and Officers

Our amended and restated certificate of incorporation and 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 any of our subsidiaries 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

As of the date of this report and 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 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 Bruce Steel is 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. We are actively seeking to identify additional well-qualified individuals to serve as independent directors.

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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 Dr. Xanthopoulos, Dr. Wilson, and Mr. Hagan 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 Dr. Wilson, Mr. Hagan and Dr. Xanthopoulos, and each of whom is an independent director. 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, 2015, and 2014, by Marcum LLP, our independent registered public accounting firm:

	Year ended December 31,	
	2015	2014
Annual audit fees [1]	$ 133,000	$ 279,782
Audit-related fees		
Tax fees		
All other fees		
Total fees	$ 133,000	$ 279,782

(1) Audit fees include fees for audit services primarily related to the audit of our annual consolidated financial statements; the review of our quarterly consolidated financial statement; 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).

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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.

(b) Exhibits. The exhibits listed in the accompanying Exhibit Index are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

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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/ Konstantinos Alataris
Konstantinos Alataris
President and Chief Executive Officer
Date: March 29, 2016

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/ Konstantinos Alataris	Chief Executive Officer and President	