

Zosano Pharma Corp  
Form 10-K  
March 26, 2015  
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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, 2014**

**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**  
(State or other jurisdiction of  
incorporation or organization)

**45-4488360**  
(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:**

| <b>Title of Each Class</b>                                  | <b>Name of Each Exchange on Which Registered</b> |
|---|--|
| Common stock, par value \$0.0001 per share                  | The NASDAQ Capital Market                        |
| Securities registered pursuant to Section 12(g) of the Act: |  |

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☒

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer 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 ☒

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

The aggregate market value of voting stock held by non-affiliates of the registrant on January 30, 2015, based on the closing price for shares of the registrant's common stock as reported by The NASDAQ Capital Market, was approximately \$54.4 million. The registrant has elected to use January 30, 2015, which was the closing date of the registrant's initial public offering of its common stock, as the calculation date because on June 30, 2014 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant was a privately-held company.

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As of March 10, 2015, the registrant had a total of 11,932,035 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, 2014**

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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 comparable terminology intended to reference future periods. Forward-looking statements include, but are not limited to, statements about:

the anticipated timing, costs and conduct of our planned clinical trials and preclinical studies, as applicable, for our Daily ZP-PTH, ZP-Glucagon and ZP-Triptan lead 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 an existing drug and attached to an adhesive patch. When the patch is applied with our hand-held applicator, the microneedles painlessly penetrate the skin to a depth of 200 microns or less, resulting in rapid dissolution and absorption of the drug coating 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, pain-free 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 lead product candidates, and the indications they are expected to treat, are as follows:

*Daily ZP-PTH, for severe osteoporosis;*

*ZP-Glucagon, for severe hypoglycemia; and*

*ZP-Triptan, for migraine.*

**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 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 limited competition and premium pricing.

***Maintain our focus on effective execution of our 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.

***Expand our manufacturing capabilities and reduce cost of goods.*** We intend to devote significant resources to expand the capacity and throughput of our manufacturing operations, and to reduce our manufacturing costs.

***Develop a targeted commercial infrastructure.*** We believe that the markets on which we have initially focused, and intend to focus in the future, are ones in which there are relatively concentrated prescriber bases that can be served by a small, targeted sales force dedicated to each product.



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*Partner selectively to expand the utilization of our microneedle patch drug delivery platform.* We have retained all commercial rights to our lead product candidates other than Daily ZP-PTH. We intend to continue to selectively collaborate with third parties with respect to delivery of their proprietary drugs, as we have done in our collaborations with Eli Lilly and Company and Novo Nordisk. We may also collaborate with third parties to pursue clinical and commercial development of our own products in geographies outside the United States where it may be more cost effective to do so.

**Our product candidates**

**Our osteoporosis opportunity    Daily ZP-PTH collaboration with Eli Lilly and Company**

Our product candidate Daily 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 daily 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 Daily ZP-PTH product candidate is intended to provide a convenient, easy-to-use, room-temperature-stable alternative for osteoporosis patients. We completed a Phase 2 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 November 2014, we entered into a strategic partnership 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. We plan to begin Phase 3 clinical development of Daily ZP-PTH by the end of the first quarter of 2016 with a trial designed as a non-inferiority study compared to Forteo<sup>®</sup>, the only anabolic agent approved in the United States for the treatment of severe osteoporosis, which is administered by daily injection. We intend to seek regulatory approval of Daily ZP-PTH pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, which is a regulatory approval pathway 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. In addition to the advantages we believe our microneedle patch system offers, the last of our issued patents covering key features of our microneedle patch system will not expire until 2027.

Under the terms of the license agreement with Lilly, we have granted to Lilly an exclusive, worldwide license to commercialize ZP-PTH administered through our microneedle patch system at any dosing frequency. The initial focus of our development efforts under the agreement will be on the development of Daily ZP-PTH. We are responsible, at our own expense, for developing Daily ZP-PTH, including clinical, regulatory and manufacturing scale-up activities. We will also manufacture and provide commercial supplies of Daily ZP-PTH to Lilly. Lilly will be responsible, pending successful clinical trial outcomes and regulatory approval, for commercialization of Daily ZP-PTH. Lilly will make non-refundable milestone payments to us totaling up to \$300 million upon achievement of certain regulatory approvals of Daily ZP-PTH and up to \$125 million upon achievement of certain sales milestones for Daily ZP-PTH.

We are also eligible to receive royalties at a percentage up to the low teens on sales of Daily ZP-PTH in major markets, and will receive reimbursement of manufacturing costs. In addition, in November 2014, we entered into a stock purchase agreement with Lilly

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pursuant to which Lilly purchased 1,363,636 shares of our common stock in a separate private placement concurrent with the closing of our initial public offering on January 30, 2015, for an aggregate cash purchase price of \$15.0 million.

The license agreement permits, but does not require, us to pursue development of Weekly ZP-PTH at our own expense. Weekly ZP-PTH is a proprietary formulation of PTH to be administered using our microneedle patch system on a weekly, rather than a daily, basis, for the treatment of severe osteoporosis, and was our lead product candidate prior to our entering into the license agreement with Lilly. Lilly has exclusive, worldwide rights under the agreement to commercialize Weekly ZP-PTH, but no royalty or other financial terms governing such commercialization are specified in the agreement. If Lilly chooses to commercialize Weekly ZP-PTH, then we will negotiate the financial terms with Lilly at that time. Lilly may terminate the agreement prior to regulatory approval of Daily ZP-PTH in the United States or Japan, if we fail to achieve certain critical success factors, or CSFs, relating to patient preference for Daily ZP-PTH, development activities culminating in regulatory approval of Daily ZP-PTH in the United States or Japan and commercial readiness activities, or if we fail to cure a material breach of the agreement. Lilly may also terminate the agreement at will at any time after regulatory approval of Daily ZP-PTH in the United States or Japan. We may terminate the agreement at any time prior to regulatory approval of Daily ZP-PTH in the United States or Japan if we determine that a CSF is commercially or scientifically unreasonable and we discontinue development of Daily ZP-PTH.

**Osteoporosis market is large, and existing treatments leave significant needs unmet**

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.

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.

**Forteo® is a market leader with \$1.2 billion in global revenue, making Lilly a valuable collaboration partner for us**

We believe that our collaboration with Lilly for ZP-PTH will provide an opportunity for accelerated market penetration given the strong presence of Lilly's Forte® in the osteoporosis market. There may be potential for synergies with the branding, patient support and physician education already in place for Forte®. In addition, we believe that the exclusive nature of our license agreement with Lilly, under which Lilly has agreed that it will not seek

to develop or commercialize a transdermal patch technology for the treatment of osteoporosis other than with us pursuant to our agreement, will provide us with significant competitive advantages.

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**Completed clinical development of Daily ZP-PTH to date**

In 2008, we completed a Phase 2 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 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.

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:

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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.<sup>®</sup>  $T_{MAX}$  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<sup>®</sup> as measured by both six-month spine BMD and six-month hip BMD, even with lower bioavailability versus Forteo<sup>®</sup>. Bioavailability is the degree and rate at which an administered dose of unchanged drug is absorbed into the body and reaches the blood.

**We have demonstrated 36-month stability of our Daily ZP-PTH formulation at room temperature**

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<sup>®</sup> 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). The following table illustrates the results of our internal stability studies of our Daily ZP-PTH product candidate and Forteo<sup>®</sup>.

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***Planned clinical development of Daily ZP-PTH***

We expect to conduct our Phase 3 Daily ZP-PTH clinical trial after having additional meetings with the FDA and regulatory authorities in Japan to discuss and seek renewed consensus on our development plan for Daily ZP-PTH, and expect to complete these discussions with regulatory authorities by the end of 2015.

The Phase 3 trial is currently designed as a 12-month, randomized, double-blind, double-dummy, multi-center global study comparing the safety and efficacy of Daily ZP-PTH to Forteo® for the treatment of postmenopausal osteoporosis, with a six-month safety extension. The trial will have three arms, with approximately 400 patients per arm: one Daily ZP-PTH 30 µg dose and one placebo injection, one Daily ZP-PTH 40 µg dose and one placebo injection, and daily administration of Forteo® (20 µg) subcutaneous injection and one placebo patch. The objectives of this trial will be to demonstrate non-inferior lumbar spine BMD changes over one year with Daily ZP-PTH 30 µg and Daily ZP-PTH 40 µg doses compared to Forteo®, to assess hip BMD changes over 12 months, to assess the effect of Daily ZP-PTH on biochemical markers of bone turnover, and to assess the safety of Daily ZP-PTH 30 µg and 40 µg doses, relative to that of Forteo®.

The primary efficacy endpoint will be the percent change in lumbar spine BMD (L1-L4) over 12 months, with the secondary efficacy endpoints being the percent change in total hip BMD over 12 months, percentage of responders in terms of lumbar spine BMD gains, percent change in femoral neck BMD, and percent change in one-third radius BMD, all measured after twelve months of treatment. The study will be powered to illustrate a non-inferiority margin of 1.5% of active comparator to Forteo®.

**Our hypoglycemia opportunity    ZP-Glucagon**

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 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. We are currently conducting a Phase 2 clinical trial in Australia to evaluate the performance of ZP-Glucagon 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. We commenced, or treated the first patient in, this Phase 2 clinical trial in January 2015 and expect to complete the clinical trial in the third quarter of 2015.

**Severe hypoglycemia market is attractive and underserved**

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



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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.

**Existing treatments require reconstitution and injection, limiting their usefulness in an emergency rescue situation**

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.

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 cm<sup>2</sup> patch and a single use applicator.

In our clinical trials, ZP-Glucagon has shown faster onset of action as compared to intramuscular injection. We believe that rapid injection, fast onset, high bioavailability and low variability will make ZP-Glucagon well suited for use in an emergency rescue situation to bring a patient out of severe hypoglycemia.

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.

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**Completed Phase 1 trial of ZP-Glucagon illustrated fast onset, high bioavailability and low variability across multiple application sites**

In January 2014, we completed a Phase 1 trial of ZP-Glucagon designed to assess relative bioavailability with our microneedle patch system on a 3cm<sup>2</sup> 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<br>(% > IM) | T max (min) | C max (pg/mL) |
|-------------|-----------|-----------|-----------------------|-------------|---------------|
| Glucagon IM | 1558±685  | 1106±553  |                       |             |               |
| Upper arm   | CV 44%    | CV 50%    |                       | 11.8±4.4    | 2333±1256     |
| Patch C     | 1921±551  | 1724±492  |                       |             |               |
|             |           |           | 56%                   | 6.9±2.4     | 5438±1754     |
| Upper arm   | CV 29%    | CV 29%    |                       |             |               |
| Patch C     | 1669± 473 | 1441±395  |                       |             |               |
|             |           |           | 30%                   | 8.1±3.9     | 4136±1393     |
| Forearm     | CV 28%    | CV 27%    |                       |             |               |
| Patch C     | 1988±769  | 1664±596  |                       |             |               |
|             |           |           | 50%                   | 8.4±3.4     | 4785±1791     |
| Abdomen     | CV 39%    | CV 36%    |                       |             |               |
| Patch D     | 1440±667  | 1270±580  |                       |             |               |
|             |           |           | 15%                   | 8.5±2.9     | 3918±2021     |
| Abdomen     | CV 46%    | CV 46%    |                       |             |               |

Note: AUC measured in ng\*hr/mL

***Current and planned clinical development of ZP-Glucagon*****Current Phase 2 trial**

We are currently conducting a Phase 2 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. We commenced this Phase 2 trial in January 2015 and expect to complete the clinical trial in the third quarter of 2015. Enrollment has been slower than expected due to the requirement of hypoglycemic induction in diabetics. To mitigate this slower than expected enrollment, we have added an additional site to the study.

This Phase 2 clinical trial is investigating 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 trial). Based on the higher bioavailability results from our Phase 1 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 are 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. We expect this

trial to inform our target dose for, and give us guidance to adequately power, the pivotal Phase 3 trial.

This Phase 2 clinical trial is a four-way crossover study with 16 diabetic patients, each of whom is being 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.

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The primary endpoints in this study are as follows:

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

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

Maximal change from baseline in blood glucose concentration; and

Incidence of adverse events.

**Planned pivotal Phase 3 trial**

We plan on conducting a single, open-label, crossover non-inferiority pivotal study for our Generation 1 ZP-Glucagon product with GlucaGen® as the active comparator, in approximately 100 diabetic patients in approximately 25 centers. This pivotal study will be a larger version of our Phase 2 trial. We expect to commence our planned Phase 3 clinical trial upon successful completion of our Phase 2 clinical trial and filing of an IND with the FDA.

The objectives of the study will be:

To demonstrate non-inferiority of ZP-Glucagon to normalize blood glucose in subjects with type 1 or type 2 diabetes mellitus after prior induction of hypoglycemia, compared to the intramuscular injection of glucagon at a dose of 1.0 mg; and

To characterize the safety profile of ZP-Glucagon for the emergency treatment of severe hypoglycemia in subjects with diabetes.

The endpoints in the pivotal study will be:

Time to increase in blood glucose concentration from baseline by 50 mg/dl, measured from treatment administration;

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

Maximal change from baseline in blood glucose concentrations;

Time to increase in blood glucose concentration from baseline by 50 mg/dl, as measured from begin of the treatment procedure; and

Incidence of vomiting.

After approval of our Generation 1 ZP-Glucagon product candidate, we intend to conduct a bridging study (which is a supplemental clinical trial designed to confirm that the pharmacokinetics of our Generation 2 product is not inferior to the pharmacokinetics of our Generation 1 product) in order to launch our Generation 2 ZP-Glucagon product with a 6 cm<sup>2</sup> patch and a single use applicator.

### **Our migraine opportunity    ZP-Triptan**

Our product candidate 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. 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. Because ZP-Triptan has demonstrated fast onset in preclinical studies, does not depend on gastrointestinal absorption, and provides easy, painless administration, we believe it could provide an attractive alternative to currently marketed triptan products for the treatment of migraine.

In the fourth quarter of 2013, we completed preclinical hairless guinea pig studies that compared the pharmacokinetic profile of ZP-Triptan to that of zolmitriptan administered intravenously. In these preclinical studies, ZP-Triptan achieved rapid onset and bioavailability that compared favorably with intravenous delivery. In 2014, we continued further confirmatory development of ZP-Triptan with additional preclinical studies. We

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intend to complete a Phase 1 clinical trial by the end of the fourth quarter of 2015 to compare the pharmacokinetic and safety/tolerability profiles of escalated patch doses of zolmitriptan to those of one subcutaneous injection of commercial sumatriptan, a synthetic triptan used for the treatment of migraine, in healthy volunteers. Our Phase 2 trial will be designed to assess the safety and efficacy of ZP-Triptan patches in the acute treatment of migraine in adults.

**Migraine is a large market, with existing treatments having significant disadvantages**

According to the Migraine Research Foundation, migraine affects 36 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 iontophoretic 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, painless administration, we believe it could provide an attractive alternative to currently marketed triptan products for the treatment of migraine.

**Our ZP-Triptan solution offers fast onset**

In migraine,  $T_{max}$  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 the time to maximum drug concentration in blood, or  $T_{\max}$ , 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)  $T_{\max}$  achieved in preclinical testing
- (5) Average  $T_{\max}$  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 trials, which include different doses of the same triptan.

Because ZP-Triptan has demonstrated a  $T_{\max}$  of nine minutes in preclinical studies, and because delivery of the drug does not depend on gastrointestinal absorption, we believe it has the potential for superior efficacy compared to currently marketed oral triptans.

#### Our ZP-Triptan solution offers ease-of-use

Our single-use disposable device is ready to apply after opening the packaging, intuitive, simple and painless to use, and poses no needle stick risk. Other potential competitive products in the migraine space are sumatriptan products using alternative delivery systems, notably Zecuity, marketed by Teva (which acquired Zecuity's developer, NuPath), and Sumavel DosePro, marketed by Endo International plc (which acquired Sumavel DosePro from Zogenix). We believe that our microneedle patch system offers significant advantages over these systems, including faster onset compared to Zecuity and ease of use compared to Sumavel DosePro.



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***Our preclinical studies demonstrated fast onset and high bioavailability***

In the fourth quarter of 2013, we conducted preclinical studies with a hairless guinea pig animal model. The objective of the study was to compare the pharmacokinetic profile of our ZP-Triptan to the pharmacokinetic profile of intravenous injection of zolmitriptan. In a representative study we utilized 3 cm<sup>2</sup> patches and 800 µg per patch. As represented in the graph below, ZP-Triptan achieved a time to maximum serum concentration of nine minutes and 100% bioavailability compared to intravenous injection of zolmitriptan, on a dose-normalized basis.

In addition, because it is delivered through the bloodstream, ZP-Triptan does not depend for its effectiveness on absorption through the gastrointestinal tract, and we believe will possess significant advantages over oral delivery of triptans. Moreover, we believe ZP-Triptan will also possess advantages over nasal spray delivery, which can be unpleasant in taste. In 2014, we continued further confirmatory development of ZP-Triptan with additional preclinical studies.

***Planned clinical development of ZP-Triptan***

Our ZP-Triptan clinical development strategy is predicated on leveraging our easy-to-use, integrated, single-use disposable system and the fast onset of action demonstrated in our preclinical studies. We intend to conduct our Phase 1 and Phase 2 clinical trials using an active injectable comparator to assess the relative speed of onset compared to an injectable. The margin of superiority, if significant, will determine whether our Phase 3 clinical trial involves an active comparator or placebo.

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#### **Planned Phase 1 clinical trial of ZP-Triptan**

Our planned Phase 1 clinical trial will be conducted in Australia and designed to compare the pharmacokinetic and safety / tolerability profiles of multiple patches of zolmitriptan and one subcutaneous injection of sumatriptan in healthy volunteers. Each subject will receive a sumatriptan injection, followed by the zolmitriptan patch treatments in ascending order. We intend to complete a Phase 1 clinical trial by the end of the fourth quarter of 2015 using an active injectable comparator to assess the relative speed of onset of ZP-Triptan compared to an injectable. The results of the ZP-Triptan Phase 1 clinical trial will guide the dose selection for the ZP Triptan Phase 2 clinical trial.

#### **Planned Phase 2 and Phase 3 clinical trials of ZP-Triptan**

Our Phase 2 clinical trial will be designed to assess the safety and efficacy of ZP-Triptan patches in the acute treatment of migraine in adults. This study is expected to be a randomized, controlled double-blind, parallel-group study with 200 migraine patients each of whom would be administered a ZP-Triptan patch coated with zolmitriptan, placebo patch and a subcutaneous injection of sumatriptan. We expect to discuss our planned Phase 2 and Phase 3 clinical trials of ZP-Triptan with the FDA after the completion of our planned Phase 1 clinical trial.

### **Type 2 diabetes    our collaboration with Novo Nordisk**

In January 2014, we entered into a strategic partnership and license agreement with Novo Nordisk A/S, or Novo Nordisk, to develop a microneedle patch product to administer semaglutide, Novo Nordisk's investigational proprietary human glucagon-like peptide-1 analogue, or GLP-1, to be applied once weekly for the treatment of type 2 diabetes. Under the terms of the agreement, we have granted Novo Nordisk a worldwide, exclusive license to develop and commercialize GLP-1 products, with the initial product candidate being Novo Nordisk's semaglutide using our microneedle patch system. We received an upfront payment of \$1 million upon entering into the agreement. We are eligible to receive payments upon achieving certain preclinical, clinical, regulatory and sales milestones, which could total \$60 million for the first product and \$55 million for each additional product. We are also eligible to receive royalties on sales of products in the low to mid-single digits and will receive development support, as well as reimbursement of all development and manufacturing costs relating to the Novo Nordisk program. Novo Nordisk will, pending successful outcomes of nonclinical and clinical testing, be responsible for commercialization of all products under the agreement. The term of the strategic partnership and license agreement will expire upon the expiration of all of Novo Nordisk's milestone and royalty payment obligations under the agreement with respect to licensed products. Additionally, Novo Nordisk may terminate the agreement at any time for convenience upon prior written notice to us or within a certain time period following completion of a feasibility study currently being conducted by the parties, and either party may terminate the agreement upon failure of the other party to cure a material breach of the agreement.

### **Transdermal drug delivery**

According to Research and Markets, the global value of the market for systemic transdermal drug delivery products in which we expect to participate was approximately \$25 billion in 2013 and is expected to grow to approximately \$40 billion by 2018. We believe this growth is driven by the increasing availability of transdermal systems for important therapeutic applications and changing disease demographics. We believe that our microneedle patch system has the potential to offer significant practical and therapeutic advantages, compared not only to conventional drug delivery methods such as oral formulations and injections but also to currently available transdermal delivery systems, that will enable us to compete effectively in this market.



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***Benefits of our microneedle patch drug delivery platform***

Our microneedle patch painlessly delivers therapeutic compounds into the skin and provides rapid systemic drug delivery in a convenient, easy-to-use system that offers the following therapeutic and practical benefits, among others:

rapid onset and high bioavailability;

room-temperature stability;

consistent delivery independent of the gastrointestinal tract;

convenience and ease of use;

short wear-time, typically thirty minutes or less, with near complete drug delivery (resulting in no drug overdose if the patient forgets to remove the patch); and

avoidance of the biohazard disposal and safety risks associated with needle injections.

Our microneedle patch system consists of a 3 to 6 cm<sup>2</sup> 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<sup>2</sup>, 3 cm<sup>2</sup> and 6 cm<sup>2</sup> 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<sup>2</sup> microneedle array is approximately 3.5 mg. The patch is applied with a hand-held applicator that painlessly 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. We believe our applicator has an intuitive, simple and patient-friendly design and is available in reusable form for chronic indications or in a disposable, single-use form for acute indications.

We believe our microneedle patch system has the potential to deliver a wide range of therapeutic compounds, including biologics and other large, complex molecules that have historically been difficult to deliver transdermally. Our microneedle technology and short-wear patch avoid the skin irritation and sensitization caused by skin-permeating ingredients that are necessary in some existing patch technologies, as well as the adhesion failures experienced when patches requiring extended wear times are worn by the patient, for example when swimming, bathing or during other normal daily activities. Our patch is small and unobtrusive compared to existing transdermal products, and our mechanical applicator is simple and easy to use, unlike some transdermal systems that involve cumbersome, complex and costly devices with external power sources.

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

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demonstrated a 36-month shelf life at room temperature for our Daily ZP-PTH product candidate and an initial six-month shelf life at up to 40 degrees Celsius for our ZP-Glucagon product candidate. 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). Our dry formulations and room temperature stability obviate the need for refrigeration, eliminate the need for time-consuming reconstitution prior to use, and provide enhanced convenience, portability and ease of use, potentially facilitating more effective treatment and patient compliance.

Our internal 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.

We believe we have sufficient manufacturing and test capabilities to produce the microneedle patch system for our contemplated preclinical and Phase 1 and Phase 2 clinical trials of all of our product candidates and pivotal Phase 3 trials for most 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.

**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, including the following:

Over 30,000 of our patches have been applied to over 400 patients in seven Phase 1 clinical trials and one Phase 2 trial. 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.

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The other compounds that we have assigned the highest priority for further investigation for use with our microneedle patch system include:

epinephrine, for treatment of anaphylactic shock; and

granisetron, for the treatment of chemo-induced nausea and vomiting.

We intend, independently or through strategic collaborations with others, to explore these and 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 lead 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 or developing products that treat severe osteoporosis that may compete with our Daily 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. Companies marketing products that treat migraine that may compete with our ZP-Triptan product candidate include Teva, Zogenix, GlaxoSmithKline, AstraZeneca and Allergan.

### *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, 2014, our research and development organization consisted of 10 people, located in our headquarters in Fremont, California. Our research and development staff is supervised by our founder and Chief Scientific Officer and has 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.

### **Manufacturing**

We operate a current good manufacturing practices, or cGMP, 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



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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 formulation, 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 manufacture 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 devote significant resources to expanding the capacity and throughput of our manufacturing operations, and to reducing our manufacturing costs. We believe this will be critical to support the late-stage development, launch and commercial production of our product candidates.

**Commercialization**

We do not have a sales, marketing or drug distribution infrastructure, as all of our product candidates are still in preclinical or clinical development. We generally expect to retain commercial rights in the United States for our current product candidates other than Daily ZP-PTH. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our drug candidates other than Daily ZP-PTH that obtain marketing approval. Lilly will be responsible, pending successful clinical trial outcomes and regulatory approval, for commercialization of Daily ZP-PTH, and Novo Nordisk will be responsible for commercialization of any product candidate that emerges from our collaboration with them. We intend to develop a small, cost-effective commercial infrastructure that will enable us to retain and maximize the commercial opportunity for our remaining product candidates.

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our drugs other than Daily ZP-PTH. We believe that such an organization will be able to target the community of physicians who are the key specialists in treating the patient populations for which our drug candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our drug candidates that obtain marketing approval other than Daily ZP-PTH.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any drugs that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to

approved drugs and establishing relationships with thought leaders in relevant fields of medicine.

### **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

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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, 2014, we held exclusive licenses to or owned 22 United States patents and nine 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 the four patent applications 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 lead 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 last of our issued 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 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 Daily ZP-PTH and ZP-Glucagon will each 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,

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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 held discussions with the FDA in 2008 with respect to our Daily ZP-PTH product candidate, but we have not initiated any discussions with the FDA with respect to our ZP-Glucagon or ZP-Triptan product candidates.

*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 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 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 or ZP-Triptan and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials 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 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

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

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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 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.

### *European Union EMA Process*

In the European Union, or the EU, medicinal products are authorized following a similar demanding process as that required in the United States. Applications are based on the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, Common Technical Document and must include a detailed plan for pediatric approval, if such approval is sought. Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures. We have not initiated any discussions with EMA with respect to seeking regulatory approval of either Daily ZP-PTH or ZP-Glucagon, but we held scientific advisory meetings in 2009 with regulatory authorities in the United Kingdom, Sweden, Denmark and Germany regarding our Daily ZP-PTH product candidate.

Like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Once we or our partners commercialize products, we will be required to comply with cGMP and product-specific regulations enforced by the European Commission, the EMA and the competent authorities of EU Member States following product approval. Also like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our or our partners equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations or the withdrawal of our product from the market.

### *Other International Markets Drug Approval Process*

In some international markets (e.g., China or Japan), although data generated in United States or EU trials may be submitted in support of a marketing authorization application, additional clinical trials conducted in the host territory, or studying people of the ethnicity of the host territory, may be required prior to the filing or approval of marketing applications within the country.

To be sold in Japan, most drugs, medical devices, and combination products must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval. The Japanese government, through the Ministry of Health, Labour and Welfare, or the MHLW, regulates drugs, devices, and combination products under the Pharmaceutical Affairs Law, or the PAL. Oversight for drugs, devices, and combination products is conducted with participation by the Pharmaceutical and Medical Devices Agency, or the PMDA, a quasi-government organization performing many of the review functions for the MHLW. A sponsor of a drug-device combination product submits an application for the product as corresponding to either drugs or medical devices, based on the primary mode of action, and the product is then reviewed according to the classification. No separate application for the drug in the combination product is necessary, unless the drug is marketed separately from the combination

product.

The premarket review of a new combination product generally requires the submission of clinical trial data, including clinical trial data gathered from Japanese subjects. These data requirements may be satisfied in some cases through bridging studies to demonstrate that the foreign clinical data apply to Japanese patients. Additionally, the manufacturer must obtain a license or accreditation if the combination product is reviewed as a drug, or a device manufacturer registration if the combination product is reviewed as a medical device. The

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manufacturer also must assess compliance with the standards for manufacture and quality management according to the Ministerial Ordinance on Good Manufacturing Practice GMP for Drugs and Quasi-drugs for combination products that are drugs, and the Ministerial Ordinance on Quality Management System QMS for Medical Devices and In Vitro Diagnostics for combination products that are medical devices.

Penalties for a company's noncompliance with the PAL could be severe, including revocation or suspension of a company's business license and criminal sanctions. The MHLW and PMDA also assess the quality management systems of the manufacturer and the product conformity to the requirements of the PAL.

*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.

*Sales and Marketing; Other Healthcare Laws*

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

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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 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.

### *Other Governmental Regulations and Environmental Matters*

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, 2014, we had 29 employees, of whom 26 were full-time employees. We make extensive use of third party contractors, consultants and advisors to perform many of our present activities. We expect to increase the number of our employees as we increase our operations.

## **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

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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](http://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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**Implications of Being an Emerging Growth Company**

As a company with less than \$1 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

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

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than \$1 billion in annual revenue, we have more than \$700 million in market value of our stock held by non-affiliates or we issue more than \$1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting burdens in this Annual Report on Form 10-K. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise 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.

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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, 2014 we incurred a net loss of \$ 14.2 million. As of December 31, 2014, we had an accumulated deficit of \$138.5 million. We expect to continue to incur additional significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue the development of our lead product candidates, Daily ZP-PTH, ZP-Glucagon and ZP-Triptan. These expenditures will be incurred for development, clinical trials, regulatory compliance, infrastructure, manufacturing and additional employees. Even if we succeed in developing, obtaining regulatory approval for and commercializing one or more of our lead 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, 2014, we had total revenue of \$2.9 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, and our secured note payable to our largest stockholder, an affiliate of BioMed Realty Trust, Inc., or BMR, each impose restrictions on our business, and if we default on our obligations, Hercules or BMR would have a right to foreclose on substantially all of our assets, including our intellectual property.***

In June 2014, we entered into a senior term loan facility with Hercules, under which Hercules made a \$4 million loan to us that matures in June 2017 and bears interest at a per annum rate equal to the greater of (i) 12.05% and (ii) 12.05% plus the prime rate as reported in The Wall Street Journal minus 5.25%. In connection with our reorganization in April 2012, we issued a secured promissory note to BMR in the original principal amount of approximately \$8.6 million. The BMR note is subordinated to the Hercules loan, due in April 2016 (but is not permitted to be repaid while the Hercules loan is outstanding) and bears interest at the same rate as the Hercules loan during the period that the Hercules loan remains outstanding, and otherwise at the annual rate of 8%. We also agreed to covenants in connection with the Hercules loan and the BMR note that may limit our ability to take some actions without the consent of Hercules or BMR, as applicable. In particular, without Hercules or BMR's 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, including the BMR note 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 and the BMR note;

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 and to BMR 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 and to BMR 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 or BMR 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 or BMR would significantly harm our business and our ability to operate.

***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

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production and sale of our products on a commercial scale. Our most advanced product candidate is our Daily ZP-PTH, which will be required to undergo at least one significant additional clinical trial before it can be commercialized, if at all. 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 lead product candidates;

obtaining required regulatory approvals;

formulating and manufacturing products; and

conducting sales and marketing activities.

Our operations continue to be focused on organizing and staffing 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 Kasei Pharma Corporation, or 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**

***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 are focusing our development efforts on three lead product candidates, Daily ZP-PTH, ZP-Glucagon, and ZP-Triptan. 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;

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;

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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.

***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 Daily ZP-PTH will take at least three years to complete and that completion of preclinical and clinical trials of 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.

***As an organization, we have only conducted one Phase 2 clinical trial and have never conducted a Phase 3 clinical trial or submitted a new drug application, or NDA, and may be unable to do so for any product candidates we are developing, including our three leading product candidates, Daily ZP-PTH, ZP-Glucagon or ZP-Triptan.***

We 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 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 and ZP-Triptan product candidates. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of Daily ZP-PTH or any other product candidate we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of products that we develop. Failure to commence or complete, or delays in, our planned clinical trials, would prevent us from or delay us in commercializing Daily ZP-PTH or any other product candidate we are developing.

***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.

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***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. For example, if the results of our Daily ZP-PTH trial do not achieve the primary efficacy endpoints or demonstrate expected safety, the prospects for approval of Daily ZP-PTH would be materially and adversely affected. If Daily ZP-PTH or our other product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

***We are conducting, and 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 2 clinical trial for Daily ZP-PTH was conducted in Mexico and Argentina in addition to the United States, and our Phase 1 clinical trial for ZP-Glucagon was 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 ZP-Glucagon or any future 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.

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

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including Daily ZP-PTH, ZP-Glucagon, ZP-Triptan 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 and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. 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.

We may never obtain regulatory clearance 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.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates for sale outside the United States.

***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

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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 Daily 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 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;

finest, 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.

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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.***

We currently do not have any products approved for sale. We have three product candidates in early stages of research and development, the most clinically advanced of which is Daily ZP-PTH. We recently entered into a strategic partnership and license agreement with Lilly to commercialize Daily ZP-PTH. We have also entered into a strategic partnership and license agreement with Novo Nordisk A/S, or Novo Nordisk, to commercialize Novo Nordisk's proprietary GLP-1, using our microneedle patch system.

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, from 2011 to 2013, we were a party to a strategic partnership and exclusive license agreement with Asahi to commercialize Asahi's Teribone<sup>TM</sup> product using our microneedle patch system. In January 2014, this relationship with Asahi 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.

***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.

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***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 product candidates that we identified for treatment of severe osteoporosis, severe hypoglycemia and 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.

***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 Daily ZP-PTH or any of our other 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.

***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.

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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.

***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.

## **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. Lilly will be responsible for commercialization of our Daily ZP-PTH product candidate, if approved, and we may decide to collaborate with third parties for the development and potential commercialization of one or more of our other 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

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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 may 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;

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;

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a collaboration partner may use our products or technology in such a way as to invite litigation from a third party; and

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

For example, under our strategic partnership and license agreement with Novo Nordisk, we and Novo Nordisk are currently conducting a feasibility study to evaluate the feasibility of using our microneedle patch system for the delivery of Novo Nordisk's proprietary GLP-1 product candidate. Following the completion of this feasibility study, Novo Nordisk will decide, in its sole discretion, whether to continue or terminate the license agreement. If Novo Nordisk elects to not continue the license agreement, then we will not be eligible to receive any milestone or royalty payments from Novo Nordisk under the agreement. Similarly, under our strategic partnership and license agreement with Lilly, Lilly may terminate the agreement prior to regulatory approval of Daily-ZP PTH in the United States or Japan if we fail to achieve certain critical success factors, or CSFs, relating to patient preference for Daily ZP-PTH, development activities culminating in regulatory approval of Daily ZP-PTH in the United States or Japan and commercial readiness activities. If we fail to achieve a CSF and Lilly exercises its right to terminate the license agreement, then we will not be eligible to receive any milestone or royalty payments from Lilly under the agreement. Lilly may also terminate the agreement at will at any time after regulatory approval of Daily ZP-PTH in the United States or Japan. If Lilly terminates the agreement after regulatory approval of Daily ZP-PTH in the United States or Japan, then we will no longer be eligible to receive any future milestone or royalty payments from Lilly under the 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 investigators, to

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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, such as our Daily ZP-PTH product candidate, 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.

***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

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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 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.

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***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 disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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**RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

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

We are a party to an Intellectual Property License Agreement dated October 5, 2006, as amended, with ALZA 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.

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

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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 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.

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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 may 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 may 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 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

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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 litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or

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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 not successfully manage our growth.***

Our success will depend upon the expansion of our operations and 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.

***Some of our current executive officers only work on a part-time basis, which may limit their ability to oversee the management of our business.***

Our current Chief Scientific Officer, Chief Operating Officer and Chief Medical Officer are, or are soon expected to be, engaged in our business activities on a part-time basis; each is expected to devote not more than 60% of his business time to us. As a result, these executive officers may be unable to provide the level of oversight required by their positions.



In addition, now that we have completed our initial public offering of our common stock, we are increasing the scope of our business activities, including conducting clinical trials of our product candidates , conducting research and development for our preclinical pipeline, and expanding and enhancing our manufacturing capabilities. This increase in business activities may require that our these executive officers engage in our business activities on a full-time basis or that we hire additional employees, otherwise our ability to carry out our business may be impaired.

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***Our business and operations would suffer in the event of computer system failures or security breaches.***

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development and manufacturing programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed.

***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 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, our chief scientific 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.

**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.***

Although our common stock has been listed on The NASDAQ Capital Market since our initial public offering in January 2015, an active trading market for our common stock may not develop or, 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;

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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 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, 2015, we had 11,932,035 shares of common stock outstanding. Approximately 6,000,000 of these shares are subject to lock-up agreements entered into by certain of our stockholders in connection with our initial public offering, which restrict the transfer of these shares prior to July 25, 2015, subject to certain exceptions. Upon the expiration of the restrictions contained in these lock-up agreements, these shares will become freely tradable, except for shares held by directors, executive officers and our other affiliates, which will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended.

We are planning to register on Form S-8 approximately 1,900,000 shares of our common stock that we may issue under our equity incentive plans. Once we issue these shares, they can be freely sold in the public market upon issuance, subject to any vesting restrictions, lock-up agreements, or Rule 144 transfer restrictions applicable to affiliates.

***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

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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.

***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 59% 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.

***We have identified a material weakness in our internal control over financial reporting, and if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

Our management has determined that as of December 31, 2013 and December 31, 2014, we had a material weakness in our internal control over financial reporting, due to the fact that we did not have the appropriate resources with the appropriate level of experience and technical expertise to provide oversight over the timely preparation and review of schedules necessary for the preparation of our financial statements and to make certain accounting judgments regarding accounting principles generally accepted in the United States, or U.S. GAAP.



We are taking steps to remediate the material weakness described above; however, we cannot assure you that we will be successful in such remediation, or that we or our independent registered public accounting firm will not identify additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. If we fail to remediate the material weakness described above, or fail to maintain

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effective internal controls in the future, it could result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis, which could cause investors to lose confidence in our financial information or cause our stock price to decline. Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company or until we are no longer a non-accelerated filer, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, whichever is later, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

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. Commencing with our fiscal year ending December 31, 2015, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs, which we estimate will be approximately \$300,000 to \$400,000 annually, to expand our accounting and finance functions and that we expend significant management efforts. Prior to our initial public offering in January 2015, we have never been required to assess our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

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.

***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.***

## Edgar Filing: Zosano Pharma Corp - Form 10-K

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;

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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;

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

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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 listed on The NASDAQ Capital Market since January 27, 2015 under the symbol ZSAN. Prior to such time, there was no public market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years.

**Holders of Common Stock**

As of March 10, 2015, there were 38 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, and our secured promissory note payable to BMV Direct SOTRS LP, or BioMed Ventures, one of our largest stockholders, contain covenants that restrict our ability to pay dividends.

**Recent Sale Of Unregistered Securities; Issuer Purchases Of Equity Securities**

On April 15, April 30 and July 10, 2014, we granted options to purchase an aggregate of 130,784 shares of common stock to employees and a director pursuant to our 2012 Stock Incentive Plan, at exercise prices ranging from \$1.28 to \$4.52 per share (or a weighted average exercise price of \$1.98 per share). During the year ended December 31, 2014, we issued an aggregate of 27,073 shares of common stock upon the exercise (at exercise prices of \$1.40 per share) of options granted pursuant to our 2012 Stock Incentive Plan, for aggregate consideration of \$37,902.20. The issuance of these options and shares was exempt from registration pursuant to Rule 701 of the Securities Act of 1933, as amended, or the Securities Act, as securities issued pursuant to a compensatory benefit plan.

In June 2014, in connection with our secured term loan facility with Hercules, we issued to Hercules a warrant to purchase either (i) shares of our common stock or (ii) shares of the series of preferred stock that we issue in any non-public equity financing resulting in gross proceeds to us of at least \$3.0 million that occurs prior to the consummation of an underwritten initial public offering of our common stock. The exercise price per share under the warrant is equal to the lesser of the lowest price per share of the stock issued in the non-public equity financing or \$8.84, and the warrant can be exercised for shares having an aggregate exercise price of up to \$280,000. The warrant is exercisable, in whole or in part, at any time until five years after our initial public offering of common stock. The warrant is currently exercisable for an aggregate of 31,674 shares of our common stock at an exercise price of \$8.84 per share. The issuance of this warrant to Hercules was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.

In June 2014, in consideration of BioMed Ventures agreeing to subordinate its secured promissory note and related security interest to our secured term loan facility with Hercules and its related security interest, we issued an aggregate of 31,250 shares of our common stock to BioMed Ventures. The issuance of these shares was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.



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In February 2014, we issued and sold convertible promissory notes in the aggregate original principal amount of \$2.5 million to certain of our existing stockholders. In December 2014, we issued and sold additional convertible promissory notes in the aggregate original principal amount of approximately \$1.3 million to certain of our existing stockholders. Pursuant to their terms, the principal and all unpaid and accrued interest on each note automatically converted upon the closing of our initial public offering of common stock into 431,595 shares of our common stock, at a conversion price equal to \$9.35 per share (or 85% of the initial public offering price of \$11.00 per share). The issuance of these convertible promissory notes was exempt from registration under Section 4(a)(2) of the Securities Act, as a sale not involving a public offering.

**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 firm shares of common stock plus an additional 110,000 shares of common 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 \$50.71 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 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 an affiliate of BioMed Ventures, which is a beneficial owner of in excess of ten percent of our outstanding capital stock. In addition, a portion, constituting less than 5%, of the net proceeds of the initial public offering may be used to make required payments of interest and principal as they become due under our secured promissory note payable to BioMed Ventures.

We did not receive any proceeds from the initial public offering until January 30, 2015, and therefore we did not utilize any of the proceeds during the year ended December 31, 2014. There has been no material change in the expected use of the net proceeds from our initial public offering from as described in the final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on January 27, 2015.

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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 2014 and 2013 and the balance sheet data as of December 31, 2014 and 2013 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

|  | Year Ended December 31,               |            |
|--|---------------------------------------|------------|
|  | 2014                                  | 2013       |
|  | (in thousands, except per share data) |            |
| <b>Consolidated Statements of Operations Data:</b>   |                                       |            |
| Revenue:   |                                       |            |
| License fees revenue   | \$ 1,955                              | \$ 4,250   |
| Collaborative development support services   | 906                                   | -          |
| Total revenue  | 2,861                                 | 4,250      |
| Operating expenses:  |                                       |            |
| Cost of license fees revenue   | 100                                   | -          |
| Research and development   | 10,953                                | 7,637      |
| General and administrative   | 4,420                                 | 4,582      |
| Total operating expenses   | 15,473                                | 12,219     |
| Loss from operations   | (12,612)                              | (7,969)    |
| Other expenses:  |                                       |            |
| Interest expense, net  | (1,848)                               | (760)      |
| Other expense  | (93)                                  | -          |
| Warrant revaluation expense  | (185)                                 | -          |
| Loss before equity in loss of joint venture, gain on termination of joint venture and gain on debt forgiveness | (14,738)                              | (8,729)    |
| Equity in loss of joint venture  | -                                     | (366)      |
| Gain on termination of joint venture   | -                                     | 3,487      |
| Gain on debt forgiveness   | 497                                   | -          |
| Net loss   | \$ (14,241)                           | \$ (5,608) |
| Net loss per common share basic and diluted  | \$ (2.78)                             | \$ (1.10)  |
| Weighted-average shares used in computing net loss per common share basic and diluted                          | 5,128                                 | 5,107      |

|   | December 31,   |          |
|---|----------------|----------|
|   | 2014           | 2013     |
|   | (in thousands) |          |
| <b><i>Selected Balance Sheets Data:</i></b> |                |          |
| Cash and cash equivalents                   | \$ 1,214       | \$ 5,913 |
| Working deficit                             | (11,719)       | (1,729)  |
| Total assets                                | 13,343         | 22,084   |
| Long-term debt                              | 13,291         | 9,711    |
| Accumulated deficit                         | (138,223)      | 124,223  |
| Total stockholders' equity (deficit)        | (13,401)       | 477      |

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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 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.

In October 2006, our business, originally named The Macroflux Corporation, was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson. Since inception, we have devoted substantially all of our resources to the development and commercialization of our microneedle patch system. Our lead product candidates are Daily 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 lead 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 are actively engaged in research and preclinical and clinical development for these lead product candidates. Of these product candidates, the most advanced is our Daily ZP-PTH, for which we have completed a Phase 2 clinical trial in the United States, Mexico and Argentina in 2008. For ZP-Glucagon, we have completed a Phase 1 clinical trial designed to assess relative bioavailability (which is the degree and rate at which an administered dose of unchanged drug is absorbed into the body and reaches the blood) with our microneedle patch system compared to a currently available form of glucagon administered by intramuscular injection. We commenced, or treated the first patient in, a Phase 2 clinical trial to evaluate the performance of ZP-Glucagon in January 2015 and expect to complete the trial in the third quarter of 2015. In the fourth quarter of 2013, we completed a preclinical animal study of 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 2014, we continued further confirmatory development of ZP-Triptan with additional preclinical studies. We intend to complete a Phase 1 clinical trial by the end of the fourth quarter of 2015 to evaluate the pharmacokinetic and safety/tolerability profiles of escalated patch doses of zolmitriptan in healthy volunteers.

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 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.

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In addition to developing our lead product candidates, we are actively seeking opportunities to collaborate with biopharmaceutical companies to explore other therapeutic uses for our microneedle patch system. During 2011, 2012 and 2013, we were a party to a strategic partnership and license agreement with Asahi Kasei Pharma Corporation, or Asahi, to develop and commercialize our microneedle patch system for delivery of Asahi's Teribone product for the treatment of severe osteoporosis in Japan, China, Taiwan and South Korea. This partnership and related license agreement was terminated in January 2014 and as a result, we recaptured global commercialization rights on our microneedle patch system for the delivery of parathyroid hormone. In November 2014, we entered into a strategic partnership 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. Under the terms of the license agreement, we have granted to Lilly an exclusive, worldwide license to commercialize ZP-PTH in all dosing frequencies. Lilly will be responsible, pending successful clinical trial outcomes and regulatory approval, for commercialization of Daily ZP-PTH. We are responsible, at our own expense, for developing Daily ZP-PTH, including clinical, regulatory and manufacturing scale-up activities. We will also manufacture and provide commercial supplies of Daily ZP-PTH to 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.

For the immediate future, our efforts and resources will be focused primarily on developing our lead product candidates and our preclinical pipeline, building manufacturing infrastructure, raising capital and recruiting key personnel.

During 2013 and 2014, we funded our operations predominantly through debt financing with certain related parties and with Hercules Technology Growth Capital, or Hercules. In September 2013, we raised approximately \$3 million through the sale of convertible promissory notes to certain current investors. In February 2014, we sold an additional \$2.5 million of the same series 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. The \$4 million loan, which we refer to as the Hercules loan, is a senior secured loan that bears interest at a per annum rate equal to the greater of (i) 12.05% and (ii) 12.05% plus the prime rate as reported in The Wall Street Journal minus 5.25%. We are required to pay interest on the outstanding principal balance of the Hercules loan on a monthly basis, beginning July 1, 2014. Repayment of the \$4 million principal amount of the Hercules loan is amortized over a 30-month period in equal monthly installments of principal and interest, beginning on January 1, 2015, with all outstanding amounts (including a \$100,000 end of term charge) due and payable on June 1, 2017. The Hercules loan is secured by a senior security interest in substantially all of our assets and prepayment is permitted after June 3, 2015, subject to prepayment penalty and end of term charge. As a result of the placement of the Hercules loan, our April 2012 secured promissory note payable to BMV Direct SOTRS LP, or BioMed Ventures, one of our largest stockholders and an affiliate of BioMed Realty Trust, Inc., or BMR, is subordinated in right of payment to the Hercules loan, and BioMed Ventures' security interest in substantially all of our assets under the secured promissory note is subordinate to Hercules' security interest under the Hercules loan. In exchange for BioMed Ventures' agreement to subordinate to the Hercules loan, we issued 31,250 shares of our common stock to BioMed Ventures.

## Edgar Filing: Zosano Pharma Corp - Form 10-K

In October 2013, we entered into a Stock Purchase Agreement with Eco Planet Corp. (currently named Zosano, Inc.), a Delaware corporation with common stock quoted for trading on OTC Markets, pursuant to which Zosano, Inc. issued and sold to us, for an aggregate cash purchase price of \$365,000, newly issued shares of common stock equal to 99.9% of the issued and outstanding common stock of Zosano, Inc. as of immediately following the transaction. In connection with our acquisition of Zosano, Inc., we planned to raise new capital

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through the sale of additional common stock or other securities to institutional investors in a private placement, or the PIPE financing. We had anticipated that in connection with the PIPE financing we would enter into a registration rights agreement pursuant to which the public company would agree to file a registration statement with the SEC to register for resale the securities it planned to issue in the PIPE financing. As of December 31, 2013, we decided not to undertake the PIPE financing as planned. We are actively pursuing the sale of Zosano, Inc.

**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 Note 2 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.

***Revenue recognition***

To date, we have generated revenue 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.

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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.

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.

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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.

We account for stock-based compensation to employees of ZP Group LLC, our prior joint venture with Asahi, in accordance with ASC 323-10-25 and ASC 323-10-35, Accounting by an Investor for Stock-Based Compensation Granted to Employees of an Equity Method Investee, using a fair value approach. Under the guidance, a reporting entity should recognize stock-based compensation expense at fair value under ASC 718 if it grants awards in the reporting entity's stock to employees of the investee, in this case ZP Group LLC, if other investors do not make proportionate awards and the reporting entity's ownership interest does not increase by a proportionate amount. 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. As a result of the termination of our joint venture with Asahi and the resultant termination of all ZP Group LLC employees, all outstanding unvested stock options granted to employees of ZP Group LLC as of December 20, 2013 were canceled. Vested stock options granted to employees of ZP Group LLC were subject to the post-termination exercise provisions under our 2012 Stock Incentive Plan. In February 2014, the board of directors extended the exercise period on the vested stock options by 60 days to allow for more time to exercise, if elected by the former employees of ZP Group LLC.

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 of common stock in January 2015, or IPO, 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.

**Financial Operations Overview**

***General***

Our revenue to date has been generated primarily from license and development revenue and termination fees under our collaboration and license agreement with Asahi, which was terminated in January 2014. We have not generated any commercial product revenue. As of December 31, 2014, we had an accumulated deficit of approximately \$138.5 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

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development and, if approved, commercialization. We cannot assure you that we will receive additional collaboration revenue in the future, whether pursuant to our agreement with Lilly, our agreement with Novo Nordisk or any other partnership that we might pursue.

We expect our research and development expenses and manufacturing expenses related to clinical trials to increase as we continue to advance our product candidates through clinical development. Because of the numerous risks and uncertainties associated with our technology and drug development, we are unable to predict 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 manufacturing development activities and to meet our operating requirements beyond mid-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 significantly reduce our operating expenses and delay or reduce the scope of or eliminate some of our development programs, enter into a collaboration or other similar arrangement with respect to commercialization rights to ZP-Glucagon or ZP-Triptan, 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.

***Revenue***

Our revenue to date has been generated primarily from non-refundable license fee payments and reimbursements for research and development expenses under our collaboration and license agreements with Asahi and Novo Nordisk. In addition to upfront license payments, we also received from Asahi other contingent payments upon the occurrence of certain contractually defined events. As of December 31, 2014, we had received a non-refundable upfront license fee payment of \$1.0 million from Novo Nordisk under the strategic partnership and license agreement, which was recorded as deferred revenue and will be recognized over the performance period as determined by us. In addition, reimbursements from Novo Nordisk for development support services and out-of-pocket expenses in connection with the strategic partnership will be recognized as service revenue when service is rendered and cost of material is incurred. During the year ended December 31, 2014, we recognized approximately \$0.8 million of license fees revenue and approximately \$0.9 million of collaborative development support services revenue from Novo Nordisk. Through December 31, 2013, we had received an aggregate of \$16.5 million under the license agreement with Asahi.

***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, where we licensed certain patents and patent applications from ALZA on an exclusive basis worldwide. Under the terms of the license agreement with ALZA, we are obligated to pay ALZA royalties 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 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. The license agreement will terminate upon the expiration of our obligations to make the royalty and other payments described above. We may terminate the agreement at any time

upon prior written notice to ALZA.

Pursuant to the intellectual property license agreement with ALZA, we are therefore obligated to make the respective payments to ALZA for each milestone received under our agreements with Lilly and Novo Nordisk beginning with the upfront payment we received upon execution of the Novo Nordisk agreement. The payment of \$0.1 million due to ALZA is charged to expense in our condensed consolidated statement of operations for the year ended December 31, 2014.

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***Research and development expenses***

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

Research and development expenses consist of:

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

fees paid to clinical consultants, clinical trial sites and vendors, including CROs, 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 CMOs;

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.

We expect our research and development expenses to substantially increase as we plan and initiate Phase 3 development of our Daily ZP-PTH product candidate, complete a Phase 2 clinical trial to investigate the safety and efficacy of our ZP-Glucagon product candidate, plan and initiate Phase 1 and Phase 2 trials of our ZP-Triptan product candidate, and as we begin to enhance our manufacturing facilities in preparation of commercial launch.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2014 and 2013, and from our inception to December 31, 2014:

| Year Ended December 31, |      | For the Period<br>from<br>inception<br>to December 31, |
|-------------------------|------|--|
| 2014                    | 2013 | 2014   |



*(In thousands)*

|  |                  |                 |                   |
|--|------------------|-----------------|-------------------|
| Product candidate:   |                  |                 |                   |
| ZP-PTH <sup>(1)</sup>  | \$ 598           | \$ 1,758        | \$ 38,733         |
| ZP-Glucagon <sup>(2)</sup>                                   | 1,228            | 2,886           | 4,254             |
| ZP-Triptan <sup>(3)</sup>                                    | 1,259            | 142             | 1,401             |
| Collaborative development support <sup>(4)</sup>             | 631              | -               | 2,513             |
| Other research projects <sup>(5)</sup>                       | 1,570            | 972             | 9,611             |
| Unallocated research and development expenses <sup>(6)</sup> | 5,667            | 1,879           | 64,513            |
| <b>Total research and development expenses</b>               | <b>\$ 10,953</b> | <b>\$ 7,637</b> | <b>\$ 121,025</b> |

- (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.
- (2) Spending to date on ZP-Glucagon reflects spending since project initiation in the third quarter of 2012.
- (3) We initiated our ZP-Triptan project in September 2013.
- (4) Collaborative development support includes services provided to Asahi in 2011 and 2012 and to Novo Nordisk in 2014 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 lead 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.

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The project-specific expenses summarized in the table above include costs directly attributable to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and indirect costs to our product candidates on a project-specific basis, and we include these costs in the project-specific expenses. We expect our research and development expenses to increase in the future. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors including but not limited to: the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Furthermore, we have entered into collaborations with major biopharmaceutical companies (Lilly and Novo Nordisk, and previously, Asahi) to participate in the development and commercialization of our microneedle patch system, and we may enter into additional collaborations in the future. 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 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. 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 expenses***

*Interest expense, net.* Interest expense, net of interest income, consists primarily of interest costs related to our short-term and long-term borrowings. Interest expense for 2013 reflects accrued interest on both the convertible bridge notes issued in September 2013 and the BioMed Ventures secured promissory note as well as interest on the line of credit which was forgiven in 2014. Interest expense for 2014 reflects accrued interest on the convertible bridge notes issued in September 2013 and in February and December 2014, accrued interest on the BioMed Ventures secured promissory note, and accrued and paid interest related to the Hercules loan.

*Other 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. For the year ended December 31, 2014, other expense consisted primarily of expense related to the fair value of 31,250 shares of common stock that were issued to BioMed Ventures in June 2014 as an inducement for the subordination of its secured promissory note in connection with the Hercules loan, partially offset by insurance payment on certain water damage claim.

*Warrant revaluation.* Warrant revaluation income or expense resulted from the re-measurement of our common stock warrant issued in connection with the Hercules 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, expire or converted into shares of our

common stock. In 2014, we recorded an expense of \$0.2 million reflecting the increase in fair value of the warrant liability.

**Table of Contents****Index to Financial Statements*****Joint venture gain (loss)***

In December 2013, we entered into a termination agreement with Asahi to terminate our joint venture, which effectively caused ZP Group LLC to cease all operations. In connection with the termination, Asahi agreed to pay us \$2.4 million as a termination payment, an additional \$3.5 million for the settlement of employee-related termination costs, including salaries and benefits, severance payments, and other termination-related fees and expenses, and reimbursement for certain out-of-pocket expenses and non-cancelable purchase commitments of ZP Group LLC. At December 31, 2013, we recorded accounts receivable from joint venture of \$3.4 million related to these agreements. In March 2014, the Company entered into a settlement agreement with Asahi, AKP USA Inc., or AKPUS, and ZP Group LLC for the settlement of all remaining liabilities, distribution, disposition and transfer of assets pursuant to the joint venture termination agreement entered into in December 2013. The agreement did not result in any changes to the balances recorded as of December 31, 2013 and its impact on the 2014 financial statements was limited to the collection of our receivables from Asahi of approximately \$3.4 million as final settlement.

*Equity in loss of joint venture.* Equity in loss of joint venture reflects our share of ZP Group LLC's net loss through the period ended December 20, 2013, as we owned a 50% equity interest in ZP Group LLC. Under the terms of ZP Group LLC's operating agreement, we recorded our share of ZP Group LLC's net loss after reimbursement of certain depreciation expense on our contributed capital equipment.

*Gain on termination of joint venture.* We recorded a one-time gain of approximately \$3.5 million in 2013 in connection with the termination of the joint venture in ZP Group LLC. The gain primarily consists of a notice period termination payment and excess personnel termination reimbursement from Asahi, partially offset by the net deficit of our investment in ZP Group LLC.

*Gain on debt forgiveness.* Our termination agreement with Asahi for the termination of joint venture provided for the cancellation of ZP Group LLC's revolving line of credit facility with Asahi, and the discharge, release and forgiveness of all outstanding principal and interest under such line of credit as of March 14, 2014. Accordingly, we recorded a gain on debt forgiveness of approximately \$0.5 million in the first quarter of 2014.

**Results of Operations*****Comparison of the year ended December 31, 2014 and 2013******Revenue***

|  | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|--|--------------------------------|-------------|---------------|----------|
|  | <b>2014</b>                    | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|  | <b>(In thousands)</b>          |             |               |          |
| <b>Revenue</b>                             |                                |             |               |          |
| License fee revenue                        | \$ 1,955                       | \$ 4,250    | \$ (2,295)    | (54)%    |
| Collaborative development support services | 906                            | -           | 906           | N/A      |
| Total revenue                              | \$ 2,861                       | \$ 4,250    | \$ (1,389)    | (33)%    |

Total revenue decreased \$1.4 million, or 33%, for the year ended December 31, 2014 as compared to the year ended December 31, 2013. The decrease was primarily due to the \$3.1 million of contract revenue we earned under our license and collaboration agreement with Asahi in 2013 that did not recur in 2014 as a result of the termination of our license and collaboration agreement with Asahi, partially offset by approximately \$0.8 million of license fee revenue earned under our collaboration and license agreement with Novo Nordisk in 2014 and approximately \$0.9 million of related development support service revenue.

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|                              | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|------------------------------|--------------------------------|-------------|---------------|----------|
|                              | <b>2014</b>                    | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|                              | <i>(In thousands)</i>          |             |               |          |
| Cost of license fees revenue | \$ 100                         | \$ -        | \$ 100        | N/A      |

Cost of license fees revenue represents our payment obligations under our intellectual property license agreement with ALZA. Cost of license fees revenue was \$0.1 million for the year ended December 31, 2014 as compared to the zero in 2013 due to the royalty attributable to our receipt of a \$1.0 million license fee from Novo Nordisk upon execution of our collaboration and license agreement with Novo Nordisk in 2014.

***Research and development expenses***

|                          | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|--------------------------|--------------------------------|-------------|---------------|----------|
|                          | <b>2014</b>                    | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|                          | <i>(In thousands)</i>          |             |               |          |
| Research and development | \$ 10,953                      | \$ 7,637    | \$ 3,316      | 43%      |

Research and development expenses increased \$3.3 million, or 43%, for the year ended December 31, 2014 as compared to the year ended December 31, 2013. Of this increase, approximately \$2.8 million was due to an increase in equipment depreciation expense following the return of equipment to us and approximately \$0.8 million was due to the rehiring of key personnel with critical manufacturing know-how upon the termination of our joint venture with Asahi in ZP Group LLC, \$1.1 million was due to the non-clinical study in preparation for our ZP-Triptan Phase 1 clinical trial expected to be completed by the fourth quarter of 2015, \$0.6 million related to servicing our collaboration and license agreement with Novo Nordisk, and \$0.6 million related to other research projects, partially offset by a \$1.2 million reduction in spending on our former Weekly ZP-PTH lead product candidate and a \$1.7 million reduction in spending on our ZP-Glucagon product candidate following the completion of our Phase 1 clinical trial of ZP-Glucagon in the January 2014.

***General and administrative expenses***

|                            | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|----------------------------|--------------------------------|-------------|---------------|----------|
|                            | <b>2014</b>                    | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|                            | <i>(In thousands)</i>          |             |               |          |
| General and administrative | \$ 4,420                       | \$ 4,582    | \$ (162)      | (4)%     |

General and administrative expenses decreased \$0.2 million, or 4%, for the year ended December 31, 2014 as compared to the year ended December 31, 2013. The decrease was primarily due to a \$0.6 million reduction in legal fees following the completion of our acquisition of a public shell in 2013 and a \$0.4 million reduction in market research and other spending, mostly offset by \$0.5 million of costs related to executive hiring and severance, and a \$0.3 million increase in facility related expenses as a result of the termination of our facility sharing arrangement in the joint venture with Asahi in ZP Group LLC.

*Other expenses*

|                             | Year Ended December 31, |        | Change   |      |
|-----------------------------|-------------------------|--------|----------|------|
|                             | 2014                    | 2013   | Amount   | %    |
|                             | <i>(In thousands)</i>   |        |          |      |
| Interest expense, net       | \$ 1,848                | \$ 760 | \$ 1,088 | 143% |
| Other expense               | 93                      | -      | 93       | N/A  |
| Warrant revaluation expense | 185                     | -      | 185      | N/A  |

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Interest expense, net, increased \$1.1 million, or 143%, for the year ended December 31, 2014 as compared to the year ended December 31, 2013. The increase was primarily due to the incremental interest expense incurred in connection with our bridge financings in September 2013 and in February and December 2014, as well as interest expense on the term loan we entered into with Hercules in June 2014.

Other expense for the year ended December 31, 2014 was primarily due to the one-time recognition of expense related to the fair value of the 31,250 shares of our common stock issued to BioMed Ventures in June 2014 as an inducement for its subordination of debt in connection with the Hercules loan, partially offset by insurance payment on certain water damage claim.

Warrant revaluation expense for the year ended December 31, 2014 resulted from the re-measurement of our common stock warrant issued in connection with the Hercules loan in June 2014.

***Joint venture gain (loss)***

|                                      | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|--------------------------------------|--------------------------------|-------------|---------------|----------|
|                                      | <b>2014</b>                    | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|                                      | <i>(In thousands)</i>          |             |               |          |
| Equity in loss of joint venture      | \$ -                           | \$ (366)    | \$ 366        | 100%     |
| Gain on termination of joint venture | -                              | 3,487       | (3,487)       | (100)%   |
| Gain on debt forgiveness             | 497                            | -           | 497           | N/A      |

Equity in loss of joint venture of \$0.4 million for the year ended December 31, 2013 reflects our share of ZP Group LLC's net loss in 2013.

Gain on termination of joint venture of \$3.5 million for the year ended December 31, 2013 was due to the termination of our strategic partnership with Asahi through the joint venture investment in ZP Group LLC. We received from Asahi a notice period termination fee of \$2.4 million and a non-refundable excess of approximately \$1.0 million in reimbursement for the cost of terminating personnel in connection with the wind down of ZP Group LLC.

The gain on debt forgiveness of \$0.5 million was a one-time transaction in March 2014 resulting from the cancellation of ZP Group LLC's revolving line of credit with Asahi, pursuant to the provisions of our joint venture termination agreement with Asahi.

**Income Taxes**

As of December 31, 2014, we had net deferred tax assets of \$58.6 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, 2014, we had federal net operating loss carryforwards of approximately \$146.9 million and state net operating loss carryforwards of approximately \$143.8 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, 2014 and 2013, 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.

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**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, 2014, had an accumulated deficit of \$138.5 million. We expect to incur additional losses in the future to conduct research and development on our product candidates and to conduct pre-commercialization manufacturing activities.

As of December 31, 2014, we had approximately \$1.2 million in cash and cash equivalents. On January 30, 2015, we closed our initial public offering by issuing 4,500,000 shares of our common stock at an offering price of \$11.00 per share, resulting in net proceeds of approximately \$44.4 million, after deducting underwriting discounts and commissions and estimated offering expenses. Concurrent with the closing of our initial public offering on January 30, 2015, we issued and sold an additional 1,363,636 shares of our common stock to Lilly in a separate private placement for net proceeds of \$14.5 million, after deducting a private placement fee payable by us. On February 27, 2015, we issued and sold an additional 110,000 shares of our common stock at a price of \$11.00 per share pursuant to the partial exercise of the overallotment option granted to the underwriters in our initial public offering, resulting in net proceeds to us of approximately \$1.1 million after underwriting discounts and commissions.

We believe our existing cash and cash equivalents, including the net proceeds from our initial public offering and concurrent private placement with Lilly, will be sufficient to sustain operations for at least the next 12 months 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 sources, 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;
- 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 some or all of our development programs 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.

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The following table shows a summary of our cash flows for the years ended December 31, 2014 and 2013:

|  | <b>Year Ended December 31,</b> |             |
|--|--------------------------------|-------------|
|  | <b>2014</b>                    | <b>2013</b> |
|  | <i>(in thousands)</i>          |             |
| Net cash (used in) provided by:                      |                                |             |
| Operating activities                                 | \$ (10,915)                    | \$ (3,724)  |
| Investing activities                                 | (1,133)                        | 1,139       |
| Financing activities                                 | 7,349                          | 3,525       |
| Net increase (decrease) in cash and cash equivalents | \$ (4,699)                     | \$ 940      |

*Operating Cash Flow:* Net cash used in operating activities was \$10.9 million and \$3.7 million for the years ended December 31, 2014 and 2013, respectively. Net cash used during 2014 was primarily the result of clinical and non-clinical costs, personnel costs related to the rehiring of key personnel with critical manufacturing know-how upon the termination of our joint venture with Asahi in ZP Group LLC and executive hiring, professional fees and administrative expenses incurred in the course of our continuing operations, partially offset by the collection of our receivables from Asahi of approximately \$3.4 million as final settlement of our joint venture in ZP Group LLC. Net cash used in 2013 was primarily the result of personnel-related costs, clinical trial costs, professional fees and administrative expenses, partially offset by the receipt of the \$2.4 million termination notice payment from Asahi in connection with the termination of our joint venture.

*Investing Cash Flow:* Net cash used in investing activities was \$1.1 million for the year ended December 31, 2014, as compared to net cash provided by investing activities of \$1.1 million for the year ended December 31, 2013. 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 for our former Weekly ZP-PTH lead product candidate and for our ZP-Glucagon and ZP-Triptan product candidates. During 2013, net cash provided by investing activities included a cash distribution of \$2.4 million from ZP Group LLC for the reimbursement of depreciation charges associated with the equipment we contributed to ZP Group LLC during the formation of our joint venture with Asahi, partially offset by the purchase of property and equipment of approximately \$0.9 million and the cost of acquiring equity invested in a public shell for approximately \$0.4 million.

*Financing Cash Flow:* Net cash provided by financing activities was \$7.3 million and \$3.5 million for the years ended December 31, 2014 and 2013, respectively. 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 convertible bridge notes to certain of our existing investors. Net cash generated from financing activities in 2013 included \$3.0 million from the issuance of our convertible bridge notes and \$0.5 million from reimbursements received from ZP Group LLC, funded through the revolving line of credit facility provided by AKPUS to ZP Group LLC.

**Table of Contents****Index to Financial Statements****Contractual Obligations**

The following table summarizes our contractual obligations as of December 31, 2014:

|  | Total     | Payment Due by Period |              |           |                      |
|--|-----------|-----------------------|--------------|-----------|----------------------|
|  |           | Less than<br>One Year | 1-3<br>Years | 3-5 Years | More than 5<br>Years |
|  |           | (in thousands)        |              |           |                      |
| <b><u>Contractual Obligations</u></b>      |           |                       |              |           |                      |
| Short and long-term debt obligations       |           |                       |              |           |                      |
| (including interest) <sup>(1)</sup>        | \$ 24,979 | \$ 7,991              | \$ 16,988    | \$ -      | \$ -                 |
| Operating lease obligations <sup>(2)</sup> | 2,768     | 688                   | 1,264        | 816       | -                    |
| Purchase commitments <sup>(3)</sup>        | 46        | 46                    | -            | -         | -                    |
| Total contractual obligations              | \$ 27,793 | \$ 8,725              | \$ 18,252    | \$ 816    | \$ -                 |

***(1) Short and long-term debt obligations******Bridge financing related parties convertible promissory notes***

In September 2013, we entered into a note purchase agreement with certain of our stockholders pursuant to which we issued convertible bridge notes, raising an aggregate amount of approximately \$3.0 million in debt financing. These convertible bridge notes accrued simple interest of 8% per annum, with all unpaid principal and accrued interest due and payable on the earlier of: (i) September 9, 2014; (ii) an event of default, as defined in the notes; or (iii) the date that is 30 days following the closing of a first firm commitment underwritten initial public offering pursuant to a registration statement filed under the Securities Act of 1933, unless earlier converted into equity securities pursuant to their terms. The notes permitted us to accelerate and prepay any portion of the outstanding principal and/or interest at any time upon written consent of the noteholders representing not less than 60% of the principal amount then outstanding.

The notes provided that upon the closing of a qualified financing, which was defined under the terms of the notes as an equity financing on or before March 31, 2015 where we raise at least \$25.0 million, the principal and all unpaid and accrued interest on each note would automatically convert into shares of the equity security sold in the qualified financing at a price equal to 85% of the lowest per share price at which the equity security is sold in the qualified financing.

In February 2014, we sold \$2.5 million of additional notes of the same series to certain of the purchasers of the 2013 convertible bridge notes. In June 2014, we amended the 2013 and the 2014 convertible bridge notes to provide that any failure by us to pay any amount under the convertible bridge notes during the period from maturity of the convertible bridge notes through the date that the Hercules loan is repaid in full would not constitute a default under the convertible bridge notes.

In December 2014, we entered into a note purchase agreement with certain of the purchasers of the February 2014 convertible bridge notes pursuant to which we issued convertible bridge notes, raising an aggregate amount of approximately \$1.3 million in debt financing. These convertible bridge notes accrued simple interest of 8% per annum, with all unpaid principal and accrued interest due and payable on the earlier of: (i) June 1, 2017; (ii) an event of default, as defined in the notes; or (iii) the date that is 30 days following the closing of a first firm commitment underwritten initial public offering pursuant to a registration statement filed under the Securities Act of 1933, unless earlier converted into equity securities pursuant to their terms. The notes permitted us to accelerate and prepay any portion of the outstanding principal and/or interest at any time upon written consent of the noteholders representing not less than 60% of the principal amount then outstanding.

Upon the closing of our IPO in January 2015, the principal and all unpaid and accrued interest on these notes totaling \$7.4 million automatically converted into 792,182 shares of our common stock.

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*Secured financing with BMR*

In connection with our recapitalization in April 2012, we renegotiated a new lease agreement with our landlord, an affiliate of BMR, to include reduced rent obligations for our facility in Fremont, California. In connection with the rent reduction, we issued a new secured promissory note to another affiliate of BMR and all previously accrued interest, unpaid rent, future rent obligations and other fees due to BMR and its affiliates were either rolled into the note or eliminated. The note is a 4-year non-callable promissory note, bearing interest at the rate of 8% per annum, compound annually, and has an original principal amount of approximately \$8.6 million as of April 2012. This note is secured by a security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties. All principal and interest under the note are due and payable on the earliest of (i) April 26, 2016, (ii) the closing of a sale of our company or business, as defined in the note, or (iii) the date that any distribution is made to our stockholders, as defined in the note. We may prepay the note, in whole or in part, at any time without prepayment penalty or premium. Further, we are required to prepay the note immediately prior to, or in connection with, a sale or partial sale of our company, defined as a transaction in which we are acquired or in which we exclusively license or sell all or substantially all of our assets. In any similar transaction that does not qualify as a sale but results in our cash balance being at least \$5.0 million in excess of our cash requirements for the 12 months following the closing of such transaction, we are required to prepay an amount equal to half of the excess cash balance over \$5.0 million. In December 2012, BMR's affiliate assigned the note to BioMed Ventures. In June 2014, we amended the secured promissory note to increase the interest rate during the period that the Hercules loan remains outstanding to match the interest rate of the Hercules loan, and to provide that any failure by us to pay any amount under the secured promissory note during the period from the maturity date of the secured promissory note through the date that the Hercules loan is repaid in full will not constitute a default under the secured promissory note. In exchange for BioMed Ventures' agreement to subordinate the secured promissory note to the Hercules loan, we issued 31,250 shares of our common stock to BioMed Ventures.

The secured promissory note and the related security agreement contain customary conditions related to borrowing, events of default, and covenants, including covenants limiting our ability to dispose of collateralized assets, undergo a change of jurisdiction or relocation of our business, incur debt or incur liens, subject to certain exceptions. The agreements also require us to comply with certain basic affirmative covenants, such as maintenance of financial records, insurance and prompt payment of taxes.

*Secured financing with Hercules*

In June 2014, we entered into a loan and security agreement with Hercules Technology Growth Capital for a \$4 million term loan facility. The \$4 million loan is a senior secured loan that bears interest at a per annum rate equal to the greater of (i) 12.05% and (ii) 12.05% plus the prime rate as reported in The Wall Street Journal minus 5.25%. The interest rate floats, and will be determined in accordance with the preceding sentence based on changes to the prime rate as reported in The Wall Street Journal. We are required to pay interest on the outstanding principal balance of the Hercules loan on a monthly basis, beginning July 1, 2014. Repayment of the \$4 million principal amount of the Hercules loan is amortized over a 30-month period in equal monthly installments of principal and interest, beginning on January 1, 2015, with all outstanding amounts (including a \$100,000 end of term charge) due and payable on June 1, 2017. We are permitted to prepay the full outstanding principal balance of the Hercules loan and all unpaid accrued interest thereon, together with the \$100,000 end of term charge plus a prepayment charge equal to 1% of the principal balance repaid, after June 3, 2015, upon seven business days' prior notice to Hercules. The Hercules loan is secured by a senior security interest in substantially all of our assets. Under the terms of the loan facility, we agreed not to incur, be liable for or prepay any other indebtedness, with limited exceptions.

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The secured promissory note payable to BioMed Ventures is (and, while outstanding, the convertible bridge notes were) subordinated in right of payment to the Hercules loan, and BioMed Ventures' security interest in substantially all of our assets under the secured promissory note is subordinate to Hercules' security



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interest under the Hercules loan. Under the terms of the loan facility, we agreed to give Hercules prior written notice of any amount we propose to pay in respect of the secured promissory note, even if the subordination agreement between Hercules and BioMed Ventures allows for the payment. Any such payment will give Hercules the right to accelerate any or all of the Hercules loan.

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 an affiliate of BMR, which through its affiliates is our largest stockholder, 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. In April 2012, we amended the lease agreement to reduce future rent obligations with a new lease term of seven years and to provide for a potential reduction of premises from a recapturable premises clause. As a result of the lease renegotiation, we issued a secured promissory note in consideration for previously accrued interest, unpaid rent, future rent obligations and other fees due to the landlord resulting in prepaid rent which is being expensed on a straight-line basis over the term of the lease. As of December 31, 2014, the prepaid rent of \$5.0 million is offset against the deferred rent liability of \$5.1 million resulting in a net deferred rent liability of \$0.1 million.

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.

***(3) Purchase commitments***

Our material non-cancelable purchase commitment with an equipment manufacturer is related to the custom manufacturing of certain coating machinery for the production of our transdermal microneedle patches.

**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 \$1.2 million and \$5.9 million as of December 31, 2014 and 2013, 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.

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**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, 2014. The term “disclosure controls and procedures,” as defined in Rule 13a-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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weakness in internal control over financial reporting described below.

***Material Weakness in Internal Control Over Financial Reporting and Status of Remediation Efforts***

Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management’s authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements would be prevented or detected on a timely basis. This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of the company’s registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies.

However, our management has determined that as of December 31, 2013 and December 31, 2014, we had a material weakness in our internal control over financial reporting due to the fact that we did not have the appropriate resources with the appropriate level of experience and technical expertise to provide oversight over the timely preparation and review of schedules necessary for the preparation of our financial statements and to make certain U.S. GAAP accounting judgments. A material weakness is a control deficiency, or a combination of control deficiencies, such that there is a reasonable possibility that a material misstatement of interim or annual financial statements will not be prevented or detected on a timely basis.

Notwithstanding the existence of this material weakness described above, our management has concluded that the financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP. Our Chief Executive Officer and Chief Financial Officer have certified to their knowledge that this Annual Report on Form 10-K does not contain any untrue statements of material fact or omit to state any material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to

the period covered in this Annual Report. We have discussed this material weakness with our independent registered public accounting firm and our Audit Committee.

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In order to remediate this material weakness, we have taken, or are taking, the following actions:

during the second quarter of 2014, we recruited and hired additional accounting staff with technical expertise to ensure the proper application of U.S. GAAP, including a new chief financial officer, and expect to continue to expand our finance and accounting staff and to enhance our financial reporting systems;

we are implementing revised policies and procedures and enhancing our review of complex collaboration transactions to ensure consistent application of U.S. GAAP and enhanced internal control over financial reporting; and

we are increasing the level of preparation and review of our financial statements, and in connection therewith, we are implementing 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, share-based compensation expense, and indebtedness.

We are in the process of developing a plan for testing our internal controls and management's related assessment of internal control over financial reporting as provided under Section 404 of the Sarbanes-Oxley Act of 2002. If we are unable to correct the material weakness we have identified prior to the end of fiscal year 2015, or if we experience other problems that prevent the favorable assessment of the effectiveness of our internal control over financial reporting, we will be required to conclude and report that our internal control over financial reporting is not effective as of that date and investor confidence and our stock price could be adversely affected. Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company or until we are no longer a non-accelerated filer as defined in Rule 12b-2 under the Exchange Act, whichever is later, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

***Changes in Internal Control Over Financial Reporting***

Except for the remedial actions described above, there was no change in our internal control over financial reporting during the quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

***Inherent Limitations of Controls***

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. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a 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 management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**Item 9B. OTHER INFORMATION**

None.

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Our executive officers, directors and key employees, their positions and their ages as of March 10, 2015 are set forth below:

| <b>Name</b>                                      | <b>Age</b> | <b>Position(s)</b>                              |
|--|------------|---|
| Bruce D. Steel <sup>(1) (2)</sup>                | 48         | Chairman of Board of Directors                  |
| M. James Barrett <sup>(3)</sup>                  | 72         | Director  |
| Troy Wilson <sup>(1) (2) (3)</sup>               | 46         | Director  |
| Kleanthis G. Xanthopoulos <sup>(1) (2) (3)</sup> | 56         | Director  |
| Vikram Lamba                                     | 49         | President, Chief Executive Officer and Director |
| Peter E. Daddona                                 | 69         | Chief Scientific Officer, EVP R&D and Director  |
| Nandan Oza                                       | 53         | Chief Operations Officer                        |
| Winnie W. Tso                                    | 53         | 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.

**M. James Barrett** has served as a member of our board of directors since April 2012. Dr. Barrett served as a director of ZP Opco, Inc. (then named Zosano Pharma, Inc.) from October 2006 until April 2012, when ZP Opco was recapitalized and became a wholly owned subsidiary of Zosano Pharma Corporation. Dr. Barrett is a General Partner with New Enterprise Associates, or NEA, where he has served in that role since 2001. Dr. Barrett specializes in

biotechnology and works with members of NEA's healthcare investment group on medical devices, healthcare information systems and healthcare services companies. In addition to our board of directors, Dr. Barrett currently serves as a member of the board of directors of the following public companies: Amicus Therapeutics, Inc., Clovis Oncology, Inc., GlycoMimetics, Inc. and Supernus Pharmaceuticals, Inc. He also serves on the board of directors for Blend Biosciences, Inc., Cardioxyl Pharmaceuticals, Inc., Galera Therapeutics, Inc., Loxo Oncology, Inc., PhaseBio Pharmaceuticals, Inc., Psyadon Pharmaceuticals, Roka Bioscience, Inc. and Senseonics, Inc. Dr. Barrett formerly served on various other boards of directors, including at Targacept, Inc., CoGenesys, Inc. (acquired by Teva Pharmaceutical Industries, Inc.), Iomai Corporation (acquired by Intercell AG), MedImmune, LLC (acquired by AstraZeneca), Pharmion Corporation (acquired by Celgene Corporation), and Inhibitex, Inc. (acquired by Bristol-Myers Squibb). Prior to joining NEA, Dr. Barrett served as Founder, Chairman and Chief Executive Officer of Senseonics, Inc. from 1997 to 2001, where he remains Chairman. Before that, Dr. Barrett led three NEA-funded companies, serving as Chairman and Chief



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Executive Officer of Genetic Therapy, Inc., President and Chief Executive Officer of Life Technologies, and President and Chief Executive Officer of Bethesda Research Labs. Prior to that, Dr. Barrett worked in various divisions of SmithKline. Dr. Barrett received a Ph.D. in Biochemistry from the University of Tennessee, his M.B.A. from the University of Santa Clara, and a B.S. in Chemistry from Boston College. We believe that Dr. Barrett's extensive experience serving on boards of directors of both public and private companies in the healthcare sector and his deep industry experience qualify him to serve as a member of our board of directors.

**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 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 is the President and Chief Executive Officer and a member of the board of directors of Regulus Therapeutics Inc., 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 BIOCUM, 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. Xanthopoulos's senior executive experience managing and developing a major biotechnology company and his extensive industry knowledge and leadership experience in the biotechnology industry qualify him to serve as a member of our board of directors.

**Vikram Lamba** has served as our President and Chief Executive Officer, and as a member of our board of directors, since the inception of Zosano Pharma Corporation (then named ZP Holdings, Inc.) in January 2012. Before that, Mr. Lamba served as Chief Financial Officer and Chief Business Officer of Predictive Biosciences, Inc. from July 2008 until he joined Zosano Pharma in 2011. Prior to that, Mr. Lamba served as Vice President of Corporate Development at Advanced Medical Optics, Inc., where he was responsible for many significant merger and

acquisition transactions and strategic alliances. Mr. Lamba served as Vice President for Finance and Chief Financial Officer of GeneOhm Sciences, Inc. and has over 16 years of global experience in various positions with Burmah Castrol PLC and Bayer AG. During his eight years with Bayer in Canada, Germany and the U.S., Mr. Lamba held positions in areas of general management, mergers and acquisitions and finance. Mr. Lamba received an M.B.A. from the Asian Institute of Management and was an exchange student at The Wharton

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School of the University of Pennsylvania. We believe that Mr. Lamba's extensive industry knowledge and his experience in corporate management qualify him to serve as a member of our board of directors.

**Peter E. Daddona** has served as our Chief Scientific Officer, and as a member of our board of directors, since the inception of Zosano Pharma Corporation (then named ZP Holdings, Inc.) in January 2012. Dr. Daddona has also served as Chief Scientific Officer of Zosano Pharma since July 31, 2006. Dr. Daddona founded Zosano Pharma in 2006 as a spin-off of Johnson & Johnson, prior to which he served as Vice President, Scientific Leader and Board member of The Macroflux<sup>®</sup> Internal Venture at Johnson & Johnson. Previously, Dr. Daddona was Vice President of Macroflux<sup>®</sup> Technology Development and Biological Sciences and served on the Strategic Product Portfolio Review Committee at ALZA Corporation in Mountain View, California, and held an appointment as Consulting Associate Professor of Dermatology at Stanford University. Before joining ALZA, Dr. Daddona served as Vice President, Immunobiology Research at Centocor, where he focused on preclinical development of therapeutic monoclonal antibodies. Prior to joining Centocor, Dr. Daddona served as Associate Professor of Biological Chemistry and Internal Medicine at the University of Michigan. Dr. Daddona earned his Ph.D. from the University of Connecticut and completed post-doctoral training at Duke University. We believe that Dr. Daddona's long history with our company and his extensive experience in pharmaceutical drug development qualify him to serve as a member of our board of directors.

**Nandan Oza** has served as our Chief Operations Officer since May 2013. Prior to joining us, Mr. Oza was the Vice President of Chemistry, Manufacturing and Controls of Talon Therapeutics from August 2010 to May 2013. From February 2009 to August 2010, Mr. Oza served as the Founder and Principal of Ally CMC Consulting and grew the firm to have over twenty clients, including start-ups and mid-sized companies. Between February 2007 and February 2009, he was the Vice President of Manufacturing and Supply Chain Operations at Jazz Pharmaceuticals in Palo Alto, California, where he had complete management responsibility for Jazz's manufacturing operations.

**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.

***Section 16(a) Beneficial Ownership Reporting Compliance***

Effective as of January 26, 2015, Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, became applicable to our directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, requiring them to file reports of ownership of, and transactions in, our securities with the Securities and Exchange Commission, or the SEC. These directors, executive officers and

ten-percent stockholders are also required to furnish us with copies of all Section 16(a) forms they file. No such forms were due from any such reporting persons during the year ended December 31, 2014.

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***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](http://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. Steel, Dr. Wilson and Dr. Xanthopoulos. Our board of directors has determined that each of Dr. Wilson and Dr. Xanthopoulos satisfies the NASDAQ Stock Market independence standards and the independence standards of Rule 10A-3(b)(1) of the Exchange Act. We are availing ourselves of the exemption contained in Rule 10A-3(b)(1)(iv)(A) of the Exchange Act from the independence standards of Rule 10A-3(b)(1) with respect to Mr. Steel, and we believe that such reliance does not materially adversely affect the ability of the audit committee to act independently and to satisfy the other requirements of Rule 10A-3 of the Exchange Act in any proxy or information statement for a meeting of stockholders at which directors are elected that is filed with the SEC pursuant to the requirements of Section 14 of the Exchange Act. We are actively seeking to identify additional well-qualified individuals to serve as independent directors, and intend for our audit committee to be comprised entirely of independent directors no later than January 26, 2016. Each of the members of our audit committee meets the requirements for financial literacy under applicable rules and regulations of the SEC and the NASDAQ Stock Market. The board of directors has also determined that Mr. Steel qualifies as an audit committee financial expert, as defined by applicable rules of the NASDAQ Stock Market and the SEC.



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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 President and Chief Executive Officer and our two most highly compensated executive officers other than our President and Chief Executive Officer who served as executive officers as of December 31, 2014. We refer to these individuals as our named executive officers.

|                                 | <b>Year</b> | <b>Salary</b> | <b>Non-equity<br/>incentive<br/>plan<br/>compensation</b> | <b>Option<br/>awards <sup>(3)</sup></b> | <b>Total</b> |
|---------------------------------|-------------|---------------|---|---|--------------|
| Vikram Lamba                    | 2014        | \$ 412,000    | \$ 181,276 <sup>(1)</sup>                                 | \$                                      | \$ 593,276   |
| <i>Chief Executive Officer</i>  | 2013        | 412,000       | 185,400 <sup>(2)</sup>                                    |   | 597,400      |
| Peter Daddona                   | 2014        | 329,815       | 110,471 <sup>(1)</sup>                                    |   | 440,286      |
| <i>Chief Scientific Officer</i> | 2013        | 334,750       | 120,510 <sup>(2)</sup>                                    |   | 455,260      |
| Nandan Oza                      | 2014        | 203,333       | 61,325 <sup>(1)</sup>                                     | 4,766                                   | 269,424      |
| <i>Chief Operating Officer</i>  |             |               |   |   |              |

- (1) Represents cash bonus amounts 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.
- (2) Represents cash bonus amounts awarded in respect of 2013 and paid in February 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.
- (3) Represents the aggregate grant date fair value of option awards granted in fiscal year 2014 in accordance with ASC 718, *Compensation - Stock Compensation*.

***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.



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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 have formal employment agreements with Vikram Lamba, our President and Chief Executive Officer, Peter Daddona, our Chief Scientific Officer, and Nandan Oza, our Chief Operating Officer. Mr. Lamba's employment agreement provides for an initial annual base salary of \$400,000, subject to increase from time to time, and we currently pay Mr. Lamba an annual base salary of \$412,000. Mr. Lamba's employment agreement provides for a target annual bonus of 40% of his annual base salary, with a bonus opportunity between 0% and 80% of annual base salary, to be determined by the board of directors in its discretion based on individual and company performance against goals established annually by the compensation committee, as well as the company's then prevailing cash position. Dr. Daddona's employment agreement provides for an initial annual base salary of \$325,000, subject to increase from time to time, and we currently pay Dr. Daddona an annual base salary of \$334,745. Dr. Daddona's employment agreement provides for a target annual bonus of 30% of his annual base salary, with a bonus opportunity between 0% and 60% of annual base salary, to be determined by the board of directors in its discretion based on individual and company performance against goals established annually by the compensation committee, as well as the company's then prevailing cash position. Mr. Oza's employment agreement provides for an initial annual base salary of \$250,000, subject to increase from time to time, and was amended in January 2014 to provide for Mr. Oza's part-time employment and an annual base salary of \$180,000 effective February 1, 2014. Mr. Oza's employment agreement provides for a target annual bonus of 30% of his annual base salary, to be determined by the board of directors in its discretion based on individual and company performance against goals established annually by the compensation committee, as well as the company's then prevailing cash position. Each of Mr. Lamba, Dr. Daddona and Mr. Oza is an employee-at-will, and is entitled to certain severance benefits if he is terminated without cause or resigns for good reason, as defined in his agreement. Beginning with 2015, the annual bonuses payable to Mr. Lamba, Dr. Daddona and Mr. Oza will be determined by our compensation committee in accordance with an employee bonus program established by our compensation committee for all employees.

***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, 2014.

| Name | Number<br>of<br>Securities<br>Underlying<br>Unexercised<br>Options | Number of<br>Securities<br>Underlying<br>Unexercised<br>Options<br>(#) | Option Awards                    |                              | Option Grant<br>Date |
|------|--|--|----------------------------------|------------------------------|----------------------|
|      |  |  | Option<br>Exercise Price<br>(\$) | Option<br>Expiration<br>Date |                      |

|               | (#)<br><b>exercisable</b> | <b>unexercisable</b> |    |      |           |           |
|---------------|---------------------------|----------------------|----|------|-----------|-----------|
| Vikram Lamba  | 88,441 <sup>(1)</sup>     | 53,065               | \$ | 1.54 | 7/1/2017  | 7/1/2012  |
| Peter Daddona | 44,221 <sup>(1)</sup>     | 26,532               | \$ | 1.40 | 6/15/2022 | 6/15/2012 |
| Nandan Oza    | 16,804 <sup>(2)</sup>     | 25,648               | \$ | 1.40 | 5/24/2023 | 5/24/2013 |
|               |                           | 5,000 <sup>(2)</sup> | \$ | 1.28 | 4/15/2024 | 4/15/2014 |

- (1) 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; provided that if the holder is terminated without cause or

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resigns for good reason (as these terms are defined in the holder's employment agreement), then the option will become exercisable for an additional 18.75% of the total underlying shares; provided further that if the option holder is terminated without cause or resigns for good reason within one year after a change in control (as defined in the holder's employment agreement), then the option will become exercisable for 100% of the underlying shares.

- (2) 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; provided that if the holder is terminated without cause or resigns for good reason (as these terms are defined in the holder's employment agreement), then the option will become exercisable for an additional 12.5% of the total underlying shares; provided further that if the option holder is terminated without cause or resigns for good reason within one year after a change in control (as defined in the holder's employment agreement), then the option will become exercisable for 100% of the underlying shares.

***Severance and Change in Control Arrangements***

Pursuant to the terms of Mr. Lamba's employment agreement, if we terminate Mr. Lamba's employment without cause or Mr. Lamba resigns for good reason, as these terms are defined in the employment agreement, then Mr. Lamba is 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 is terminated without cause or Mr. Lamba resigns for good reason, then Mr. Lamba's stock option will vest in full.

Pursuant to the terms of Dr. Daddona's employment agreement, if we terminate Dr. Daddona's employment without cause or Dr. Daddona resigns for good reason, as these terms are defined in the employment agreement, then Dr. Daddona is 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, Dr. Daddona's employment is terminated without cause or Dr. Daddona resigns for good reason, then Dr. Daddona's stock option will vest in full.

Pursuant to the terms of Mr. Oza's employment agreement, if we terminate Mr. Oza's employment without cause or Mr. Oza resigns for good reason, as these terms are defined in the employment agreement, then Mr. Oza is entitled to receive certain severance payments, including six months' salary, pro rata bonus payment in respect of those six months, and acceleration of vesting of a portion of an outstanding stock option granted to him in May 2013. If within a year after a change in control, as defined in the employment agreement, Mr. Oza's employment is terminated without cause or Mr. Oza resigns for good reason, then the stock option granted to him in May 2013 will vest in full.

***Director Compensation***

Prior to our initial public offering of common stock in January 2015, we did not have a formal policy regarding compensation of our non-employee directors, and none of our non-employee directors other than Dr. Xanthopoulos and Dr. Wilson received any compensation for service on our board of directors in 2014. For 2014, we paid Dr. Xanthopoulos an annual cash fee of \$25,000, payable monthly in arrears. In June 2014, we agreed to pay Dr. Wilson an annual cash fee of \$25,000, payable monthly in arrears. The annual cash fee to Dr. Wilson was pro-rated for 2014 based on the portion of 2014 during which Dr. Wilson served as a director. In July 2014, we granted Dr. Wilson an option to purchase 28,301 shares of our common stock at an exercise price of \$4.52 per share. The option provides for vesting in equal monthly installments over a period of four years, and becomes fully vested

upon a change of control. We did not grant stock options to any of our other non-employee directors during 2014. We do not pay any compensation to our President and Chief Executive Officer or our Chief Scientific Officer in connection with their service on our board of directors.

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Beginning in 2015, 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 will be 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 2014. See **Executive Compensation** above for a discussion of the compensation of Mr. Lamba and Dr. Daddona.

|                           | <b>Fees Earned or</b> |   |              |
|---------------------------|-----------------------|---|--------------|
|                           | <b>Paid in Cash</b>   | <b>Option Awards <sup>(1) (2)</sup></b> | <b>Total</b> |
| M. James Barrett          | \$                    | \$                                      | \$           |
| Bruce D. Steel            |                       |   |              |
| Troy Wilson               | 12,500                | 95,164                                  | 107,664      |
| Kleanthis G. Xanthopoulos | 25,000                |   | 25,000       |

(1) Represents the aggregate grant date fair value of option awards granted in fiscal year 2014 in accordance with ASC Topic 505-50. The assumptions we use in calculating these amounts are discussed in note 10 to notes to financial statements appearing elsewhere in this report.

(2) Represents a non-statutory option to purchase 28,301 shares of common stock granted in July 2014.

## **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, 2014 under our equity compensation plans.

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| <b>Plan category</b>                                       | <b>Number of securities to be<br/>issued upon<br/>exercise of<br/>outstanding<br/>options,<br/>warrants and<br/>rights<br/>(a)</b> | <b>Weighted-average<br/>exercise<br/>price of outstanding options,<br/>warrants and<br/>rights<br/>(b)</b> | <b>Number of securities<br/>remaining available for<br/>future issuance under<br/>equity<br/>compensation plans (excluding<br/>securities reflected in column (a))<br/>(c)</b> |
|--|--|--|--|
| Equity compensation plans approved by security holders     | 497,753  | \$ 1.59  | 1,428,701 (1)  |
| Equity compensation plans not approved by security holders |  | \$   |  |
| <b>Total</b>   | <b>497,753</b>   | <b>\$ 1.59</b>   | <b>1,428,701</b>   |

(1) Includes 28,701 shares issuable under our 2012 Stock Incentive Plan, which may be issued pursuant to stock option awards and restricted stock awards, and 1,400,000 shares issuable under our Amended and Restated 2014 Equity and Incentive Plan, which may be issued pursuant to stock option awards, restricted stock awards, unrestricted stock awards, performance share awards and other equity-based awards.

***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, 2015, 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, 2015 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

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person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name. Except as otherwise indicated, the address of each of the persons in this table is c/o Zosano Pharma Corporation, 34790 Ardentech Court, Fremont, California 94555.

Each stockholder's percentage ownership is determined in accordance with Rule 13d-3 under the Exchange Act and is based on 11,932,035 shares of our common stock outstanding as of March 10, 2015.

| Name of Beneficial Owner <sup>(1)</sup>                             | Shares<br>Beneficially<br>Owned | Percentage |
|---|---------------------------------|------------|
| <i>5%+ Stockholders</i>   |                                 |            |
| BMV Direct SOTRS LP <sup>(2)</sup>                                  |                                 |            |
| 17190 Bernardo Center Drive   |                                 |            |
| San Diego, CA 92128   | 2,442,429                       | 20.47%     |
| New Enterprise Associates 12,<br>Limited Partnership <sup>(3)</sup> |                                 |            |
| Chevy Chase, MD 20815   |                                 |            |
| 5425 Wisconsin Avenue, Suite 800                                    | 2,158,543                       | 18.09%     |



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| <b>Name of Beneficial Owner <sup>(1)</sup></b>      | <b>Shares<br/>Beneficially<br/>Owned</b> | <b>Percentage</b> |
|---|--|-------------------|
| Eli Lilly and Company                               |  |                   |
| Lilly Corporate Center                              |  |                   |
| Indianapolis, IN 46285                              | 1,363,636                                | 11.43%            |
| <i>Directors and Named Executive Officers:</i>      |  |                   |
| Vikram Lamba <sup>(4)</sup>                         | 731,483                                  | 6.08%             |
| Peter Daddona <sup>(5)</sup>                        | 368,904                                  | 3.08%             |
| Nandan Oza <sup>(6)</sup>                           | 21,592                                   | *                 |
| M. James Barrett                                    | 5  | *                 |
| Bruce Steel   |  | *                 |
| Troy Wilson <sup>(7)</sup>                          | 5,896                                    | *                 |
| Kleanthis Xanthopoulos <sup>(8)</sup>               | 14,740                                   | *                 |
| Current Directors and Executive Officers as a Group |  |                   |
| (8 persons) <sup>(9)</sup>                          | 1,151,960                                | 9.49%             |

\* 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, 2015 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.
- (3) Shares owned as of March 10, 2015 include 2,158,539 shares of common stock owned by New Enterprise Associates 12, Limited Partnership, or NEA 12, and 4 shares of common stock owned by NEA Ventures 2006, Limited Partnership. 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) Includes options to purchase 100,233 shares of our common stock that may be exercised within 60 days of March 10, 2015.
- (5) Includes options to purchase 50,117 shares of our common stock that may be exercised within 60 days of March 10, 2015.
- (6) Consists of options to purchase 21,592 shares of our common stock that may be exercised within 60 days of March 10, 2015.
- (7) Consists of options to purchase 5,896 shares of our common stock that may be exercised within 60 days of March 10, 2015.

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- (8) Consists of options to purchase 14,740 shares of our common stock that may be exercised within 60 days of March 10, 2015.
- (9) Includes options to purchase 201,918 shares of our common stock that may be exercised within 60 days of March 10, 2015.

***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, 2013 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.

**Secured Loan and 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 \$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.

The secured promissory note bears interest at the annual rate of 8%, compounded annually, and all principal and interest are due and payable on the earliest of (i) April 26, 2016, (ii) the closing of a sale of our company or business, as defined in the secured promissory note, and (iii) the date that any distribution is made to our stockholders, as defined in the secured promissory note. We may prepay the secured promissory note, in whole or in part, at any time without prepayment penalty or premium. Further, we are required to prepay the secured promissory note immediately prior to, or in connection with, a sale or partial sale of our company or business, as defined as a transaction in which we are acquired or in which we exclusively license or sell all or substantially all of our assets. In any similar

transaction that does not qualify as a sale but results in our cash balance being at least \$5.0 million in excess of our cash requirements for the 12 months following the closing of such transaction, we are required to prepay an amount equal to half of the excess cash balance over \$5.0 million. The secured promissory note is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual property. As of the date of this report,

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the aggregate outstanding principal and accrued interest under the secured promissory note is approximately \$11.1 million. In June 2014, we amended the secured promissory note to increase the interest rate during the period our \$4.0 million term loan facility with Hercules Technology Growth Capital remains outstanding to match the interest rate of the Hercules loan and to provide that any failure by us to pay any amount under the secured promissory note during the period from the maturity date of the secured promissory note through the date that the Hercules loan is repaid in full will not constitute a default under the secured promissory note. As a result of this amendment, during the period our \$4.0 million term loan facility with Hercules Technology Growth Capital remains outstanding, the secured promissory note bears interest at an annual rate equal to the greater of (i) 12.05% and (ii) 12.05% plus the prime rate as reported in The Wall Street Journal minus 5.25%. The interest rate floats, and will be determined in accordance with the preceding sentence based on changes to the prime rate as reported in The Wall Street Journal. In connection with the Hercules loan, BMV Direct SOTRS LP, an affiliate of BMR Holdings and the current holder of the secured promissory note, agreed to subordinate the secured promissory note to the Hercules loan, and we issued 31,250 shares of our common stock to BMV Direct SOTRS LP in June 2014 as consideration for its agreement to subordinate.

In December 2012, BMR Holdings transferred the BMR secured promissory note and its 1,236,769 shares of our common stock to its affiliate, BMV Direct SOTRS LP. In December 2012, BioMed Realty, L.P. transferred its 107,545 shares of our common stock to its affiliate, BMV Direct SO LP. As a result of these transfers, each of BMV Direct SOTRS LP and BMV Direct SO LP owns more than 5% of our voting securities.

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. In 2011, 2012 and 2013, we recorded rent expense to BMR-34790 Ardentech Court LP in the amounts of approximately \$1,636,000, \$874,000 and \$620,000, respectively. 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.

**2013 Bridge Loan**

In September 2013, we issued and sold convertible promissory notes, which we refer to as the 2013 bridge notes, in the aggregate original principal amount of approximately \$3.0 million to our stockholders BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P. and ProQuest Management LLC. Each of BMV Direct SOTRS LP, BMV Direct SO LP (together with its affiliate BMV Direct SOTRS LP), New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P., and ProQuest Management LLC (together with its affiliate ProQuest Investments IV, L.P.) then owned more than 5% of our voting securities, and as of the date of this report each of BMV Direct SOTRS LP, BMV Direct SO LP (together with its affiliate BMV Direct SOTRS LP) and New Enterprise Associates 12, Limited Partnership owns more than 5% of our voting securities. The following is the original principal amount of 2013 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 \$1.0 million;

BMV Direct SO LP, in the original principal amount of approximately \$300,000;

New Enterprise Associates 12, Limited Partnership, in the original principal amount of approximately \$1.2 million; and

ProQuest Investments IV, L.P. and its affiliate ProQuest Management LLC, in the aggregate original principal amount of approximately \$600,000.

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As consideration for our issuance of the 2013 bridge notes, each investor paid us an amount equal to the original principal amount of the note issued to the investor. The 2013 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 2013 bridge notes was approximately \$3.4 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 117,796 shares of common stock to BMV Direct SOTRS LP, 36,058 shares of common stock to BMV Direct SO LP, 137,822 shares of common stock to New Enterprise Associates 12, Limited Partnership, and 68,911 shares of common stock to ProQuest Investments IV, L.P. In June 2014, we amended the 2013 bridge notes to provide that any failure by us to pay any amount under the 2013 bridge notes during the period from maturity of the 2013 bridge notes through the date that the Hercules loan is repaid in full will not constitute a default under the 2013 bridge notes. In September 2014, we amended the 2013 bridge notes to extend the date by which a qualified financing must occur in order for the 2013 bridge notes to convert into equity securities to December 31, 2014, and in December 2014, we amended the 2013 bridge notes to further extend the date by which a qualified financing must occur in order for the 2013 bridge notes to convert into equity securities to March 31, 2015.

**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 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.

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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 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.

### **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 are 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***

Our common stock is listed on The NASDAQ Capital Market. Under the rules of The NASDAQ Stock Market, independent directors must comprise a majority of a listed company's board of directors within 12 months from the date of listing in connection with the company's initial public offering. In addition, the rules of the NASDAQ Stock Market require that (i) on the date of listing in connection with a company's initial public offering, at least one member of each of the listed company's audit, compensation and nominating and corporate governance committees be

independent, (ii) within 90 days of the date of listing in connection with the company's initial public offering, a majority of the members of such committees be independent and (iii) within one year of the date of listing in connection with the company's initial public offering, all the

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members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the NASDAQ Stock Market, a director will only qualify as an independent director if, in the opinion of the company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

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 Troy Wilson and Kleanthis Xanthopoulos is an independent director as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules, and that each of M. James Barrett, Peter Daddona, Vikram Lamba and 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 with the goal of adding one of such additional independent director no later than April 26, 2015, and a second independent director no later than January 26, 2015. We intend to comply with the other independence requirements for committees within the time periods specified above.

***Board Committees***

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

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

*Compensation Committee.* The current members of our compensation committee are Dr. Barrett, Dr. Wilson and Dr. Xanthopoulos, of whom each of Dr. Wilson and Dr. Xanthopoulos is an independent director and Dr. Barrett is not an independent director by reason of his affiliation with New Enterprise Associates 12, Limited Partnership. We intend for our compensation committee to be comprised entirely of independent directors no later than January 26, 2016. 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.* The current members of our nominating and corporate governance committee are Mr. Steel, Dr. Wilson and Dr. Xanthopoulos, of whom each of Dr. Wilson and Dr. Xanthopoulos is an independent director and Mr. Steel is not an independent director by reason of his affiliation with BMV Direct SOTRS LP and BMV Direct SO LP. We intend for our nominating and corporate governance committee to be comprised entirely of independent directors no later than January 26, 2016. The nominating and corporate governance committee:

identifies individuals qualified to become board members;

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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 the Company for the years ended December 31, 2014, and 2013, by Marcum LLP, the Company's independent registered public accounting firm:

|                                  | <b>Year ended December 31,</b> |                  |
|----------------------------------|--------------------------------|------------------|
|                                  | <b>2014</b>                    | <b>2013</b>      |
| Annual audit fees <sup>(1)</sup> | \$ 279,782                     | \$ 69,981        |
| Audit-related fees               |                                |                  |
| Tax fees                         |                                |                  |
| All other fees                   |                                |                  |
| <b>Total fees</b>                | <b>\$ 279,782</b>              | <b>\$ 69,981</b> |

- (1) Audit fees in 2014 include fees billed or incurred by Marcum LLP for professional services rendered in connection with the annual audit of our consolidated financial statements and the review of our quarterly financial results for the year ending December 31, 2014, the review of our registration statement on Form S-1 as well as other procedures related to our initial public offering. Audit fees in 2013 include fees billed or incurred by Marcum LLP for professional services rendered in connection with the annual audit of our consolidated financial statements for the year ending December 31, 2013.

**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.



**Table of Contents****Index to Financial Statements****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/ Vikram Lamba  
 Vikram Lamba  
 President and Chief Executive Officer  
 Date: March 26, 2015

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.

| <b>Signature</b>                 | <b>Title</b>   | <b>Date</b>    |
|----------------------------------|--|----------------|
| /s/ Vikram Lamba                 |  | March 26, 2015 |
| <b>Vikram Lamba</b>              | Chief Executive Officer, President and Director (Principal Executive Officer)          |                |
| /s/ Winnie W. Tso                |  | March 26, 2015 |
| <b>Winnie W. Tso</b>             | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) |                |
| /s/ Peter Daddona                |  |                |
| <b>Peter Daddona</b>             | Director   | March 26, 2015 |
| /s/ Bruce Steel                  |  |                |
| <b>Bruce Steel</b>               | Director   | March 26, 2015 |
| /s/ M. James Barrett             |  |                |
| <b>M. James Barrett</b>          | Director   | March 26, 2015 |
| /s/ Kleanthis G. Xanthopoulos    |  |                |
| <b>Kleanthis G. Xanthopoulos</b> | Director   | March 26, 2015 |
| /s/ Troy Wilson                  |  |                |
| <b>Troy Wilson</b>               | Director   | March 26, 2015 |



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**Zosano Pharma Corporation and Subsidiaries**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of the  
  
Board of Directors and Shareholders of  
  
Zosano Pharma Corporation

We have audited the accompanying consolidated balance sheets of Zosano Pharma Corporation and subsidiaries (the Company ) as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders equity (deficit) and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Zosano Pharma Corporation and subsidiaries, as of December 31, 2014 and 2013, and the consolidated results of their operations and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP

Marcum LLP

San Francisco, CA

March 26, 2015

**Table of Contents****Index to Financial Statements****ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(in thousands, except par value)**

|  | <b>December 31,<br/>2014</b> | <b>December 31,<br/>2013</b> |
|--|------------------------------|------------------------------|
| <b><u>ASSETS</u></b>                           |                              |                              |
| Current assets:                                |                              |                              |
| Cash and cash equivalents                      | \$ 1,214                     | \$ 5,913                     |
| Accounts receivable                            | 111                          | -                            |
| Accounts receivable from joint venture partner | -                            | 3,426                        |
| Prepaid expenses and other current assets      | 311                          | 465                          |
| Total current assets                           | 1,636                        | 9,804                        |
| Restricted cash                                | 35                           | 65                           |
| Property and equipment, net                    | 9,681                        | 11,714                       |
| Other long-term assets                         | 1,991                        | 501                          |
| Total assets                                   | \$ 13,343                    | \$ 22,084                    |

**LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)**

|  |          |          |
|--|----------|----------|
| Current liabilities:   |          |          |
| Accounts payable   | \$ 1,447 | \$ 3,412 |
| Accrued compensation   | 1,676    | 2,676    |
| Revolving line of credit   | -        | 496      |
| Deferred revenue   | 170      | 1,125    |
| Secured promissory note, current (net of debt discount and include accrued interest) | 1,408    | -        |
| Related parties convertible notes (include accrued interest)                         | 7,362    | 3,108    |
| Freestanding warrant liability   | 300      | -        |
| Other accrued liabilities  | 992      | 716      |
| Total current liabilities  | 13,355   | 11,533   |
| Deferred rent  | 98       | 363      |
| Secured promissory note (net of debt discount and including accrued interest)        | 2,530    | -        |
| Related party note payable (include accrued interest)                                | 10,761   | 9,711    |
| Total liabilities  | 26,744   | 21,607   |
| Commitments and contingencies  |          |          |

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Stockholders' equity (deficit):

Common stock, \$0.0001 par value; 30,000 shares authorized; 5,165 shares and 5,107 shares issued and outstanding as of December 31, 2014 and 2013, respectively

|                            |           |           |
|----------------------------|-----------|-----------|
|                            | 1         | 1         |
| Additional paid-in capital | 125,062   | 124,699   |
| Accumulated deficit        | (138,464) | (124,223) |

|                                |          |     |
|--------------------------------|----------|-----|
| Stockholders' equity (deficit) | (13,401) | 477 |
|--------------------------------|----------|-----|

|  |           |           |
|--|-----------|-----------|
| Total liabilities and stockholders' equity (deficit) | \$ 13,343 | \$ 22,084 |
|--|-----------|-----------|

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

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[Table of Contents](#)[Index to Financial Statements](#)**ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except per share amounts)**

|  | <b>Year Ended December 31,</b> |             |
|--|--------------------------------|-------------|
|  | <b>2014</b>                    | <b>2013</b> |
| Revenue:   |                                |             |
| License fees revenue   | \$ 1,955                       | \$ 4,250    |
| Collaborative development support services   | 906                            | -           |
| Total revenue  | 2,861                          | 4,250       |
| Operating expenses:  |                                |             |
| Cost of license fees revenue   | 100                            | -           |
| Research and development   | 10,953                         | 7,637       |
| General and administrative   | 4,420                          | 4,582       |
| Total operating expenses   | 15,473                         | 12,219      |
| Loss from operations   | (12,612)                       | (7,969)     |
| Other expenses:  |                                |             |
| Interest expense, net  | (1,848)                        | (760)       |
| Other expense  | (93)                           | -           |
| Warrant revaluation expense  | (185)                          | -           |
| Loss before equity in loss of joint venture, gain on termination of joint venture and gain on debt forgiveness | (14,738)                       | (8,729)     |
| Equity in loss of joint venture  | -                              | (366)       |
| Gain on termination of joint venture   | -                              | 3,487       |
| Gain on debt forgiveness   | 497                            | -           |
| Net loss   | \$ (14,241)                    | \$ (5,608)  |
| Net loss per common share basic and diluted  | \$ (2.78)                      | \$ (1.10)   |
| Weighted-average shares used in computing net loss per common share basic and diluted                          | 5,128                          | 5,107       |

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

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Table of ContentsIndex to Financial Statements**ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

(in thousands)

|   | <b>Common Stock</b> |               | <b>Additional</b>      | <b>Accumulated</b> | <b>Total</b>                         |
|---|---------------------|---------------|------------------------|--------------------|--------------------------------------|
|   | <b>Shares</b>       | <b>Amount</b> | <b>Paid-In Capital</b> | <b>Deficit</b>     | <b>Stockholders Equity (Deficit)</b> |
| <b>Balance at January 1, 2013</b>   | 5,107               | \$ 1          | \$ 124,634             | \$ (118,615)       | \$ 6,020                             |
| Stock-based compensation expense  | -                   | -             | 65                     | -                  | 65                                   |
| Net loss  | -                   | -             | -                      | (5,608)            | (5,608)                              |
| <b>Balance at December 31, 2013</b>   | 5,107               | 1             | 124,699                | (124,223)          | 477                                  |
| Issuance of common stock in connection with debt financing in June 2014                           | 31                  | -             | 141                    | -                  | 141                                  |
| Issuance of common stock to employees upon exercise of stock options for cash at \$1.40 per share | 27                  | -             | 38                     | -                  | 38                                   |
| Stock-based compensation expense  | -                   | -             | 184                    | -                  | 184                                  |
| Net loss  | -                   | -             | -                      | (14,241)           | (14,241)                             |
| <b>Balance at December 31, 2014</b>   | 5,165               | \$ 1          | \$ 125,062             | \$ (138,464)       | \$ (13,401)                          |

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

**Table of Contents****Index to Financial Statements****ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONSOLIDATED CASH FLOW STATEMENTS****(in thousands)**

|   | <b>Year Ended December 31,</b> |             |
|---|--------------------------------|-------------|
|   | <b>2014</b>                    | <b>2013</b> |
| <b>Cash flows from operating activities:</b>  |                                |             |
| Net loss  | \$ (14,241)                    | \$ (5,608)  |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: |                                |             |
| Depreciation  | 3,042                          | 428         |
| Stock-based compensation  | 184                            | 65          |
| Equity in loss of joint venture   | -                              | 366         |
| Gain on termination of joint venture  | -                              | (3,487)     |
| Gain on debt forgiveness  | (497)                          | -           |
| Amortization of debt issuance cost  | 61                             | -           |
| Accretion of interest payment   | 1,544                          | 765         |
| Cost of debt subordination  | 141                            | -           |
| Revaluation of warrants to fair value   | 185                            | -           |
| Impairment of long-lived assets   | 166                            | -           |
| Deferred rent   | (265)                          | (239)       |
| Change in operating assets and liabilities:   |                                |             |
| Accounts receivable   | (111)                          | 130         |
| Accounts receivable from joint venture partner  | 3,426                          | 3,204       |
| Prepaid expenses and other assets   | 154                            | (532)       |
| Accounts payable  | (2,631)                        | 265         |
| Accrued compensation and other liabilities  | (1,118)                        | 3,169       |
| Deferred revenue  | (955)                          | (2,250)     |
| Net cash flow used in operating activities  | (10,915)                       | (3,724)     |
| <b>Cash flow from investing activities:</b>   |                                |             |
| Distribution from joint venture   | -                              | 2,431       |
| Purchase of property and equipment  | (1,176)                        | (897)       |
| Decrease (increase) in restricted cash  | 30                             | (30)        |
| Decrease in (purchase of) long-term investment  | 13                             | (365)       |
| Net cash flow (used in) provided by investing activities                                  | (1,133)                        | 1,139       |
| <b>Cash flow from financing activities:</b>   |                                |             |
| Proceeds from exercise of stock options and issuance of common stock                      | 38                             | -           |

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|  |          |          |
|--|----------|----------|
| Payment of deferred offering costs                         | (442)    | -        |
| Proceeds from borrowing under related parties bridge notes | 3,833    | 3,525    |
| Proceeds from debt financing, net of issuance cost         | 3,920    | -        |
| Net cash flow provided by financing activities             | 7,349    | 3,525    |
| Net increase (decrease) in cash and cash equivalents       | (4,699)  | 940      |
| Cash and cash equivalents at beginning of year             | 5,913    | 4,973    |
| Cash and cash equivalents at end of year                   | \$ 1,214 | \$ 5,913 |

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|  | <b>Year Ended December 31,</b> |             |
|--|--------------------------------|-------------|
|  | <b>2014</b>                    | <b>2013</b> |
| <b>Supplemental cash flow information:</b>   |                                |             |
| Interest paid  | \$ 243                         | \$ -        |
| Income taxes paid  | \$ -                           | \$ 20       |
| Transfer of receivables as a result of termination of joint venture                                | \$ -                           | \$ 5,900    |
| Assumption of accounts payable and accrued liabilities as a result of termination of joint venture | \$ -                           | \$ 2,764    |
| <b>Non-cash investing and financing activities:</b>  |                                |             |
| Issuance of common stock in connection with debt financing   | \$ 141                         | \$ -        |
| Issuance of warrant in connection with debt financing  | \$ 115                         | \$ -        |
| Accrued deferred offering cost   | \$ 1,062                       | \$ -        |
| Transfer of property and equipment upon termination of joint venture                               | \$ -                           | \$ 9,856    |

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

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**Zosano Pharma Corporation and Subsidiaries**

**Notes to Consolidated Financial Statements**

**For the Years Ended December 31, 2014 and 2013**

**1. Organization**

***The Company***

Zosano Pharma Corporation and subsidiaries (the Company) is a clinical stage specialty pharmaceutical company that has developed a drug delivery platform, based on its proprietary transdermal microneedle patch system, which is used to deliver the Company's proprietary formulations of established drugs through the skin to treat a variety of indications. The Company's microneedle patch system offers rapid onset, consistent drug delivery, improved ease of use and room-temperature stability, which often are unavailable using oral formulations or injections. The Company believes its microneedle patch system can be used to deliver numerous medications for a wide variety of indications, in commercially attractive markets. The Company was incorporated as a Delaware Corporation as ZP Holdings, Inc. in January 2012, and changed its name to Zosano Pharma Corporation in June 2014. The Company was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006 originally incorporated under the name The Macroflux Corporation, and changed its 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 Zosano Pharma Corporation was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of Zosano Pharma Corporation. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc.

The Company has two wholly owned subsidiaries as of December 31, 2014 and 2013: ZP Opco, Inc. (Opco), through which the Company conducts its primary research and development activities, and ZP Group LLC, originally a joint venture with Asahi Kasei Pharmaceuticals USA. The joint venture ceased operations in December 2013.

The Company has incurred significant losses and had an accumulated deficit of \$138.5 million as of December 31, 2014. The Company has financed its operations primarily through sale of equity securities, debt financing and payments received under its licensing and collaboration agreements pharmaceutical partners and has completed its initial public offering (IPO) in January 2015 raising approximately \$60 million (See Note 15 Subsequent Events). To date, none of the Company's product candidates have been approved for sale. Management expects operating losses to continue for the foreseeable future. Although management has been successful in raising capital in the past, most recently in January 2015, there can be no assurance that the Company will be successful, or that any needed financing will be available in the future at terms acceptable to the Company.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Use of Estimates***

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of the accompanying consolidated financial

statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

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***Consolidation***

The consolidated financial statements include the accounts of Zosano Pharma Corporation, ZP Opco, Inc., and ZP Group LLC post-termination of the joint venture (see Note 6 – Settlement of Joint Venture Affairs). Intercompany balances and transactions have been eliminated in consolidation.

***Reverse Stock Split***

On July 11, 2014, the Company effected a 1-for-4 reverse stock split of its common stock, whereby each share of common stock outstanding immediately prior to that date was changed into one-fourth (1/4th) of a fully paid and non-assessable share of common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse split. All common shares, common share equivalents and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

***Segment Reporting***

The Company operates in one business segment to develop human pharmaceutical products. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States.

***Cash and Cash Equivalents***

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

***Restricted Cash***

The Company entered into a pledge and security agreement with a bank whereby \$35,000 and \$65,000 was restricted for use as security for its corporate purchasing cards and is classified as restricted cash as of December 31, 2014 and 2013, respectively.

***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents, and restricted cash. Bank deposits are held by a single financial institution having a strong credit rating. These deposits may at times be in excess of insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents, and restricted cash.

***Accounts Receivable from Joint Venture Partner***

The Company recorded a receivable from Asahi Kasei Pharma Corporation (Asahi) and its affiliate AKP USA, Inc. (AKPUS) as of December 31, 2013 for payment due to the Company pursuant to the terms of the joint venture operating agreement. The receivable included reimbursement for the depreciation of the Company's contributed equipment capital in the formation of ZP Group LLC and other payments stipulated under the joint venture termination agreement, which was collected in 2014.

***Loss in Equity of Joint Venture***

Prior to the termination of its joint venture with Asahi in December 2013, the Company recorded a loss in its 2013 consolidated statement of operations to reflect its share of the losses of ZP Group LLC for the period from January 1, 2013 to December 20, 2013. The Company accounted for its equity investment with ZP Group LLC under the equity method of accounting as it had significant influence but not control. The Company's equity investment was initially recognized at cost, with the Company's subsequent share of the investments' profits or losses recognized in the consolidated statements of operations. ZP Group LLC became a wholly-owned subsidiary of the Company on December 21, 2013.

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***Property and Equipment***

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

***Impairment of Long-Lived Assets***

The Company identifies and records impairment losses on long-lived assets used in operations when events and changes in circumstances indicate that the carrying amount of an asset likely is not recoverable. Recoverability is measured by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. The Company recorded an impairment charge as part of research and development expenses of approximately \$0.2 million in the consolidated statement of operations for the year ended December 31, 2014 related primarily to certain construction in progress equipment that will no longer be placed into service.

***Long-Term Investment***

On October 31, 2013, the Company entered into a stock purchase agreement with Zosano, Inc. (the Shell Corporation), a Delaware corporation, pursuant to which the Company acquired 10,016,973 shares of the Shell Corporation's common stock, \$0.0001 par value, for an aggregate cash purchase price of \$0.4 million. Immediately following the closing of the acquisition, 10,027,000 shares of the Shell Corporation's common stock were issued and outstanding, approximately 99.9% of which were held by the Company.

The Company accounts for its investment in the Shell Corporation using the cost method of accounting and classifies it as other long-term assets in its consolidated balance sheet. As of December 31, 2014, the Company is pursuing the sale of the Shell Corporation.

***Deferred Offering Costs***

Deferred offering costs, consisting of legal, accounting, printing and filing fees related to the Company's initial public offering (IPO) in January 2015 were capitalized, for offset against proceeds from equity offering upon the closing of the Company's IPO on January 30, 2015 (see Note 15 – Subsequent Events). As of December 31, 2014, approximately \$1.5 million of expenses related to the initial public offering had been deferred and included in other long-term assets in the Company's consolidated balance sheet. No offering costs were deferred as of December 31, 2013.

***Deferred Rent***

Rent expense is recognized on a straight-line basis over the non-cancelable term of the Company's operating lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The Company also records lessor-funded lease incentives, such as reimbursable leasehold improvements, as a deferred rent liability, which is amortized as a reduction of rent expense over the non-cancelable term of its operating lease.

***Promissory Notes***

The Company accounts for its unsecured and secured promissory notes issued to certain related and non-related parties as liabilities. They are recorded on the Company's consolidated balance sheets at cost plus accrued interest, and classified as short-term and long-term liabilities based on their maturities.

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***Revenue Recognition***

The Company generates revenue from collaboration arrangements for the development and commercialization of its technology. Collaboration and license agreements may include non-refundable upfront license fees, partial or complete reimbursement of research and development costs, contingent consideration payments based on the achievement of defined collaboration objectives and royalties on sales of commercialized products. The Company's performance obligations under the collaborations may include the license or transfer of intellectual property rights, obligations to provide research and development services and related materials and obligations to participate on certain development and/or commercialization committees with the collaborators.

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. Revenue under collaboration and license arrangements is recognized based on the performance requirements of the contract. The Company's credit policy does not provide for rights of refund or return. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees. Should changes in conditions cause management to determine that these criteria are not met for any new or modified transactions, revenue recognized could be adversely affected.

The Company's license and collaboration agreements may contain multiple elements as evaluated under the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 605-25, *Revenue Recognition Multiple-Element Arrangements*, including grants of licenses to know-how and technologies relating to the Company's product candidates as well as agreements to provide research and development services, and manufacturing and commercialization services. Each deliverable under the agreement is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has standalone value to the customer. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. This evaluation requires subjective determinations and requires the Company to make judgments about the selling price of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

Upfront payments for licenses are evaluated to determine if the licensee can obtain standalone value from the license separate from the value of the research and development services and other deliverables in the arrangement to be provided by the Company. The assessment of multiple element arrangements also requires judgment in order to determine the allocation of revenue to each deliverable and the appropriate point in time, or period of time, over which revenue should be recognized. If the Company determines that the license does not have standalone value separate from the research and development services, the license and the services are combined as one unit of accounting and upfront payments are recorded as deferred revenue in the consolidated balance sheet and are recognized as revenue over an estimated performance period that is consistent with the term of performance obligations as determined by the Company. When standalone value is identified, the related consideration is recorded as revenue in the period in which the license or other intellectual property is delivered.

The Company's license and collaboration agreements may also contain milestone payments that become due to the Company upon achievements of certain milestones. Under the milestone method, the Company recognizes revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) for which there is

substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. A milestone

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payment is considered substantive when the consideration payable to the Company for each milestone (a) is consistent with the Company's performance necessary to achieve the milestone or the increase in value to the collaboration resulting from the Company's performance, (b) relates solely to the Company's past performance, and (c) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, the Company considers all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

Amounts related to research and development funding are recognized as the related services or activities are performed, in accordance with the contract terms. Payments are generally made to the Company based on the number of full-time equivalent employees assigned to the collaboration project and the related research and development expenses incurred.

Royalty revenue from sales of the Company's licensed products, if any, will be recognized when earned and collectible.

***Research and Development Expenses***

Research and development costs are charged to expense as incurred and consist of costs related to (i) servicing the Company's collaborative development efforts with other pharmaceutical companies, (ii) furthering the Company's research and development efforts, and (iii) designing and manufacturing the Company's transdermal microneedle patch and applicator for the Company's clinical and nonclinical studies. Research and development costs include salaries and related employee benefits, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, costs of active pharmaceutical ingredients and raw materials, research and development related overhead expenses, fees paid to contract research organizations that conduct clinical trials on behalf of the Company, and fees paid to contract manufacturing organizations that conduct manufacturing activities on behalf of the Company.

For the year ended December 31, 2014, the Company incurred research and development costs of \$0.6 million in support of the Company's collaborative development services to Novo Nordisk A/S (Novo Nordisk), \$4.4 million in connection with the Company's research and development efforts, and \$5.9 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates. For the year ended December 31, 2013, the Company incurred research and development costs of \$6.5 million in connection with the Company's research and development efforts and \$1.1 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates.

***Clinical Trial Costs***

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

***Stock-Based Compensation***

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

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

The Company accounts for stock options granted to employees of its joint venture, ZP Group LLC, in accordance with the recognition provisions of ASC 323-10-25 and ASC 323-10-35, *Accounting by an Investor for Stock-Based Compensation Granted to Employees of an Equity Method Investee*, 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 Company's valuation at that time.

***Income Taxes***

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

***Comprehensive Income (Loss)***

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive income (loss) and, therefore, for all periods presented, the Company's comprehensive income (loss) was the same as its reported net income (loss).

***Net Loss Per Common Share***

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

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

**Year Ended December 31,**

|                                   | <b>2014</b>        | <b>2013</b> |
|-----------------------------------|--------------------|-------------|
|                                   | <b>(in shares)</b> |             |
| Warrants to purchase common stock | 31,674             |             |
| Options to purchase common stock  | 497,753            | 469,776     |
|                                   | 529,427            | 469,776     |

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**Table of Contents****Index to Financial Statements*****Recently Issued Accounting Standards***

In May 2014, the FASB issued a new financial accounting standard which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of this accounting standard.

In August 2014, the FASB issued a new accounting standard which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern for each annual and interim reporting period and to provide related footnote disclosures in certain circumstances. 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.

**3. Fair Value of Financial Instruments**

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

Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying values of certain assets and liabilities of the Company, such as cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The carrying value of the Company's short-term notes payable approximates their fair value as the terms of the borrowing are consistent with current market rates and the duration to maturity is short. The carrying value of the Company's long-term notes payable approximates fair value because the interest rates approximate market rates that the Company could obtain for debt with similar terms and maturities.

The following tables set forth the fair value of the Company's financial instruments as of December 31, 2014 and 2013:

|                   | Level I | December 31, 2014 |           | Total |
|-------------------|---------|-------------------|-----------|-------|
|                   |         | Level II          | Level III |       |
|                   |         | (in thousands)    |           |       |
| Financial Assets: |         |                   |           |       |

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|   |       |      |        |        |
|---|-------|------|--------|--------|
| Certificates of deposit (restricted cash) | \$ 35 | \$ - | \$ -   | \$ 35  |
| <b>Financial Liabilities:</b>             |       |      |        |        |
| Freestanding warrant liability            | \$ -  | \$ - | \$ 300 | \$ 300 |

|   | December 31, 2013 |          |           |       |
|---|-------------------|----------|-----------|-------|
|   | Level I           | Level II | Level III | Total |
|   | (in thousands)    |          |           |       |
| Financial Assets:                         |                   |          |           |       |
| Certificates of deposit (restricted cash) | \$ 65             | \$ -     | \$ -      | \$ 65 |

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The Company's freestanding warrant liability, which is measured and disclosed at fair value on a recurring basis, is classified within the Level 3 designation (see Note 9 – Warrants to Purchase Common Stock). There were no transfers between levels within the fair value hierarchy during the periods presented.

The following table presents changes in financial instruments measured at fair value using Level 3 significant unobservable inputs:

|                                 | <b>Common Stock<br/>Warrant<br/>Liability<br/>(in thousands)</b> |
|---------------------------------|--|
| Balance at January 1, 2014      | \$ -   |
| Issuance of warrant             | 115  |
| Change in fair value of warrant | 185  |
| Balance at December 31, 2014    | \$ 300   |

**4. Property and Equipment**

|                                 | <b>December 31,<br/>2014</b> | <b>2013</b> |
|---------------------------------|------------------------------|-------------|
|                                 | <b>(in thousands)</b>        |             |
| Laboratory and office equipment | \$ 1,043                     | \$ 1,108    |
| Manufacturing equipment         | 10,712                       | 10,769      |
| Computer equipment and software | 210                          | 230         |
| Leasehold improvements          | 15,838                       | 15,534      |
| Construction in progress        | 1,437                        | 738         |
|                                 | 29,240                       | 28,379      |
| Less: accumulated depreciation  | (19,559)                     | (16,665)    |
|                                 | \$ 9,681                     | \$ 11,714   |

Depreciation and amortization expense was approximately \$3.0 million and \$0.4 million for the years ended December 31, 2014 and 2013, respectively.

**5. Research and Development Collaboration and License Agreements*****Strategic Alliance with Eli Lilly and Company***

In November 2014, the Company entered into an agreement with Eli Lilly and Company (Lilly) to develop a formulation of PTH to be administered daily using the Company's microneedle patch system for the treatment of osteoporosis. Under the terms of the agreement, the Company granted to Lilly an exclusive, worldwide license to commercialize any PTH product using the Company's microneedle patch system. Lilly will be responsible, pending successful clinical study outcomes and regulatory approval, for commercialization of the daily PTH product, and the Company is responsible, at its own expense, for developing the daily PTH product. Potential payments to the Company under the agreement include non-refundable milestone payments of up to \$300 million upon achievement of certain regulatory approvals of the daily PTH product and up to \$125 million upon achievement of certain sales milestones for the daily PTH product. The Company is also eligible to receive royalties at a percentage up to the low teens on sales of the daily PTH product in major markets, and will receive reimbursement of manufacturing costs. As of December 31, 2014, the Company has received no payment in connection with the Lilly agreement.

The Company also entered into a common stock purchase agreement with Lilly pursuant to which Lilly agreed to purchase up to \$15 million worth of the Company's common stock in a private placement concurrent

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with the closing of the Company's planned initial public offering of shares of its common stock, at a price per share equal to the initial public offering price. On January 30, 2015, concurrent with the closing of the Company's initial public offering, the Company issued and sold 1,363,636 shares of its common stock to Eli Lilly and Company and received net proceeds of \$14.5 million pursuant to the common stock purchase agreement (see Note 15 - Subsequent Events).

***Collaboration Agreement with Novo Nordisk***

In January 2014, the Company entered into an agreement with Novo Nordisk to develop a new transdermal presentation of semaglutide, an investigational proprietary human GLP-1 (Glucagon-Like Peptide-1) analogue, to be administered once weekly using the Company's microneedle patch system for the treatment of type 2 diabetes. Under the terms of the agreement, the Company granted Novo Nordisk a worldwide, exclusive license to develop and commercialize Novo Nordisk's proprietary GLP-1 analogues using the Company's microneedle patch system. Novo Nordisk will, pending successful outcomes of preclinical and clinical testing, be responsible for commercialization of all products under the agreement.

Potential payments to the Company under the agreement include an upfront payment and additional payments upon achieving certain preclinical, clinical, regulatory and sales milestones, with aggregate payments totaling more than \$60 million for the first product. The Company is also eligible to receive royalties on sales of products and will receive development support, as well as reimbursement of all development and manufacturing costs.

Initially, the Company and Novo Nordisk had agreed to engage in collaborative efforts to carry out preclinical experiments to verify delivery of semaglutide using the microneedle patch system, known as a feasibility study plan.

As of December 31, 2014, the Company has received an upfront payment of \$1.0 million. The Company evaluated the upfront payment for the license of its technology and determined that the license does not have standalone value apart from the development support services. Accordingly, the license and the development support services are combined as one unit of accounting and the upfront payment is recorded as deferred revenue in the consolidated balance sheet and recognized as revenue over an estimated fourteen months performance period that is consistent with the term of performance obligations under the specified feasibility study plan. The Company will continue to reevaluate the estimated performance period as the study progresses and adjust the period over which the upfront payment is recognized prospectively as needed.

Revenue from the reimbursement of research and development and out-of-pocket expenses is recognized as the related services were performed under the collaboration agreement on a time and material basis. The corresponding cost of service revenue is recorded as research and development expense in the consolidated statements of operations. During the year ended December 31, 2014, the Company recorded \$0.6 million as cost of collaboration service revenue in connection with the Novo Nordisk collaboration agreement.

***Termination of Collaboration with Asahi Kasei Pharma Corporation***

In February 2011, the Company entered into a strategic collaboration and license agreement with Asahi Kasei Pharma Corporation (Asahi), a pharmaceutical company headquartered in Japan, to develop and commercialize Teribone<sup>®</sup>, Asahi's formulation of parathyroid hormone 1-34, administered once per week using the Company's microneedle patch system for the treatment of severe osteoporosis in Japan, China, Taiwan and South Korea.

In 2011, pursuant to the collaboration and license agreement, the Company received a non-refundable, up-front payment for the delivery of its proprietary licenses totaling \$7.5 million, reimbursement for the full cost (at no margin) associated with research and development services and out-of-pocket expenses (billed on time and material basis), for which the associated costs were recorded in operating expenses in the consolidated statements of operations. The Company applied the guidance under ASC 605-25, *Multiple Element*

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*Arrangements*, to account for the collaboration agreement with Asahi. The Company evaluated the underlying goods and services delivered and concluded that the licenses delivered under the collaboration agreement do not have standalone value and, accordingly, the consideration received under the upfront license fee of \$7.5 million was initially deferred and recorded as deferred revenue in the consolidated balance sheet. The Company recognized the deferred revenue over the term of the research and development services. Revenue recognized from the upfront license fee was approximately \$1.1 million and \$2.3 million for the years ended December 31, 2014 and 2013, respectively, and was recorded as license fees revenue in the consolidated statements of operations. Also under the collaboration and license agreement, the Company received payments based upon the achievement of certain contractually specified events. Revenue recognized for the fulfillment of these contractually specified events was none and \$2.0 million for the years ended December 31, 2014 and 2013, respectively, and was recorded as license fees revenue in the consolidated statements of operations.

The Company's collaboration and license agreement with Asahi was terminated on January 27, 2014, at which time the performance and service period effectively ended. Pursuant to the terms of the collaboration and license agreement, the Company is under no obligation to return any portion of the upfront license fee to Asahi. As a result, the Company recognized as revenue the remaining \$1.1 million of the nonrefundable upfront license fee in the first quarter of 2014. Effective upon Asahi's notice of termination on January 27, 2014, the Company no longer provides development support services to Asahi and therefore those services will no longer be a source of revenue to the Company.

Pursuant to the terms of the collaboration and license agreement and upon its termination, commercialization rights to the Company's transdermal drug delivery technology in Japan, China, Taiwan and South Korea were returned to the Company.

**6. Settlement of Joint Venture Affairs**

In April 2012, the Company acquired a 50% interest in ZP Group LLC. ZP Group LLC was formed to provide product development services and manufacturing of clinical trial material to Asahi that the Company was obligated to supply under the collaboration and license agreement with Asahi. The Company contributed \$14.6 million (net book value) of equipment to ZP Group LLC in exchange for its 50% membership interest. The Company accounts for the joint venture in ZP Group LLC as an equity investment using the equity method of accounting. The Company's share of loss on investment in ZP Group LLC is presented as equity in loss of equity investment in the consolidated statements of operations.

On December 20, 2013, the Company and Asahi entered into a termination agreement to terminate the joint venture in ZP Group LLC, which effectively caused ZP Group LLC to cease all operations as of the effective date of the termination. In connection with the termination, the Company received:

- (i) \$2.4 million termination payment in connection with the notice period provision of the joint venture agreement;
- (ii) \$3.5 million for the settlement of employee-related termination costs, including salaries and benefits, severance payment, and other termination-related fees and expenses, where the excess payment over actual

settlement cost is non-refundable to Asahi; and

- (iii) reimbursement for certain out-of-pocket expenses and non-cancelable purchase commitments of ZP Group LLC.

The Company accounted for the notice period termination payment and the excess employee termination settlement payment as a gain on investment, and the reimbursement for out-of-pocket expenses and non-cancelable purchase commitments as a reduction in operating expenses in the consolidated statements of operations. Pursuant to the joint venture termination agreement, the Company recorded a receivable of \$3.4 million from its joint venture partner for the net amount due the Company on its consolidated balance sheet as of December 31, 2013.

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The joint venture termination agreement also provided for a period of reconciliation and finalization of costs and expenses in connection with the wind-down of ZP Group LLC's operations and settlement for outstanding liabilities and commitments. In March 2014, the Company entered into a settlement agreement with Asahi, AKP USA Inc. (AKPUS), and ZP Group LLC for the settlement of all remaining liabilities, distribution, disposition and transfer of assets pursuant to the joint venture termination agreement entered into in December 2013. The agreement did not result in any changes to the balances recorded as of December 31, 2013 pursuant to the terms of the December 2013 joint venture termination agreement with Asahi and its impact on the December 31, 2014 financial statements was limited to the collection of the Company's receivables from Asahi of \$3.4 million as final settlement.

The following summarizes the Company's investment in the joint venture as of December 31, 2013:

|   | <b>Carrying Value<br/>(in thousands)</b> |
|---|--|
| Balance as of December 31, 2012         | \$ 12,298                                |
| Share of loss from equity investment    | (366)                                    |
| Distribution                            | (2,324)                                  |
| Disposition of interest in ZP Group LLC | (9,608)                                  |
| Balance as of December 31, 2013         | \$ -                                     |

In the year of termination and as of December 20, 2013, ZP Group LLC had current assets of approximately \$5.3 million and non-current assets of approximately \$9.9 million, current liabilities of approximately \$5.7 million and no non-current liabilities. For the period ended December 20, 2013, ZP Group LLC recorded revenue of approximately \$17.1 million and had operating expenses totaling \$17.5 million, resulting in a net loss of approximately \$0.4 million.

The following table provides a reconciliation of ZP Group LLC's net loss to the Company's equity in loss in the joint venture in the year of termination:

|   | <b>For the Period Ended<br/>December 20, 2013<br/>(in thousands)</b> | <b>Company's<br/>Equity in Loss of<br/>Joint Venture<br/>Computation</b> |
|---|--|--|
|   | <b>ZP Group<br/>LLC</b>  |  |
| Reported net loss of joint venture  | \$ (423)   |  |
| Contractual adjustment for special items solely allocated to the Company* | 308  | (308)  |
| Adjusted net loss of joint venture to be allocated to members             | (115)  |  |

The Company's share of allocated net loss (58)

|                                 |    |       |
|---------------------------------|----|-------|
| Equity in loss of joint venture | \$ | (366) |
|---------------------------------|----|-------|

\* Pursuant to ZP Group LLC's operating agreement, items related to the loss in connection with depreciation of the property and equipment contributed to ZP Group LLC by the Company, net of reimbursement received by ZP Group LLC from Asahi for a portion of the amount of the depreciation, are to be allocated exclusively to the Company and excluded from the joint venture entity's calculation of income or loss to be allocated to its members.

## **7. Payment Obligations to ALZA**

The Company is a party to an intellectual property license agreement dated October 5, 2006, as amended, with ALZA Corporation, or ALZA, where the Company licensed certain patents and patent applications from ALZA on an exclusive basis worldwide. Under the terms of the license agreement with ALZA, the Company is

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obligated to pay ALZA royalties on sales by the Company of products that would otherwise infringe one of the licensed patents or that is developed by the Company based on certain ALZA know-how or inventions, and to pay ALZA royalties on sales by its sublicensees of such products. The Company is 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 the Company receives from its sublicensees on third party products where no generic equivalent is available to the public. The license agreement will terminate upon the expiration of the Company's obligations to make the royalty and other payments described above. The Company may terminate the agreement at any time upon prior written notice to ALZA.

Pursuant to the intellectual property license agreement with ALZA, the Company is therefore obligated to make the respective royalty payments to ALZA for each milestone payment received under its agreement with Novo Nordisk beginning with the upfront payment it received upon the execution of the agreement. The payment of \$100,000 was charged to expense and recorded as cost of license fees revenue in the Company's consolidated statement of operations for the year ended December 31, 2014.

## **8. Debt Financing**

### ***Bridge Financing    Related Parties Convertible Promissory Notes***

#### ***September 2013 Convertible Promissory Notes***

In September 2013, the Company and certain of its major stockholders entered into a debt financing pursuant to a note purchase agreement under which the Company issued to these stockholders unsecured, subordinated convertible promissory notes for an aggregate of approximately \$3.0 million. Each note accrued simple interest of 8% per annum, with all unpaid principal and accrued interest due and payable on the earlier of: (i) September 9, 2014; (ii) an event of default, as defined; or (iii) the date that is 30 days following the closing of the Company's first firm commitment underwritten initial public offering pursuant to a registration statement filed under the 1933 Securities Act. The notes permitted the Company to accelerate and repay any portion of the outstanding principal and/or interest at any time upon written consent of the noteholders representing not less than 60% of the principal amount then outstanding.

The notes provided that upon the closing of a qualified financing, which was defined as an equity financing where the Company raises at least \$25.0 million, the principal and all unpaid and accrued interest on each note shall automatically convert into shares of the Company's common stock based on a pre-determined formula. The notes also provided that upon the sale of the Company, as defined in the note purchase agreement, each noteholder shall be entitled to receive an amount equal to any unpaid and accrued interest plus twice (2 times) the outstanding principal balance of each note.

The note purchase agreement contained customary conditions related to events of default and certain general covenants. The note purchase agreement did not require that the Company to comply with any affirmative covenants.

#### ***February 2014 Convertible Promissory Notes***

In February 2014, the Company issued certain unsecured, subordinated convertible promissory notes to certain existing noteholders for an additional \$2.5 million in debt financing. All terms of the promissory notes, including interest rate and maturity date, automatic conversation features and change of control or sale of company provisions,

were the same as the promissory notes issued to the same parties in September 2013.

*Amendments to the September 2013 and February 2014 Convertible Promissory Notes*

In June 2014, the Company amended the September 2013 and February 2014 convertible promissory notes to provide that any failure by the Company to pay any amount under the convertible promissory notes during

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the period from maturity of the convertible promissory notes through the date that the loan with Hercules Technology Growth Capital, Inc. (Hercules) is repaid in full would not constitute a default under the convertible promissory notes.

In September 2014, the Company amended the September 2013 and February 2014 convertible promissory notes to extend the date by which a qualified financing must occur in order for the convertible promissory notes to convert into equity securities from September 9, 2014 to December 31, 2014, and in December 2014, the Company amended the convertible promissory notes to further extend the date by which a qualified financing must occur in order for the convertible promissory notes to convert into equity securities to March 31, 2015.

*December 2014 Convertible Promissory Notes*

In December 2014, the Company entered into a note purchase agreement with certain of the purchasers of the February 2014 convertible promissory notes pursuant to which the Company issued convertible promissory notes, raising an aggregate amount of approximately \$1.3 million in debt financing. These convertible promissory notes accrued simple interest of 8% per annum, with all unpaid principal and accrued interest due and payable on the earlier of: (i) June 1, 2017; (ii) an event of default, as defined in the notes; or (iii) the date that is 30 days following the closing of a first firm commitment underwritten initial public offering pursuant to a registration statement filed under the 1933 Securities Act.

The notes provided that upon the closing of a qualified financing, which was defined in the convertible promissory notes as an equity financing on or before March 31, 2015 in which the Company raises at least \$25 million, the principal and all unpaid and accrued interest shall automatically convert into the equity security sold in the qualified financing, at a price equal to 85% of the lowest per share price at which the equity security is sold in the qualified financing.

Upon the closing of the Company's initial public offering on January 30, 2015, the principal and all unpaid and accrued interest on the September 2013, February 2014 and December 2014 convertible promissory notes outstanding as of January 30, 2015 automatically converted into shares of the Company's common stock (see Note 15 – Subsequent Events).

***Secured Financing with BMR Holdings***

In connection with the recapitalization of the Company in April 2012, the Company renegotiated its lease agreement with its landlord, BioMed Realty Holdings, Inc. and affiliates (BMR Holdings), to include reduced rent obligations. In connection with the rent reduction, the Company issued a secured promissory note (the BMR Note) to BMR Holdings and all previously accrued interest, unpaid rent, future rent obligations and other fees due to BMR Holdings were either rolled into the BMR Note or eliminated. BMR Holdings assigned the BMR Note to its affiliate BMV Direct SOTRS LP in December 2012. The BMR Note is a 4- year non-callable promissory note that bears interest at the rate of 8% per annum, compounded annually and has an original principal amount of approximately \$8.6 million. The BMR Note is secured by a first priority security interest and lien in and to all of the Company's tangible and intangible properties and assets, including intellectual properties. All principal and interest are due and payable to BMV Direct SOTRS LP on the earliest of (i) April 26, 2016, (ii) the closing of a sale of the Company, as defined, or (iii) the date that any distribution is made, as defined under the terms of the BMR Note. The Company may prepay the BMR Note, in whole or in part, at any time without prepayment penalty or premium. Further, the Company is required to prepay the BMR Note immediately prior to, or in connection with, a sale or partial sale of the Company, as defined as a transaction in which the Company is acquired or in which the Company exclusively licenses or sells all or

substantially all of its assets. In any similar transaction that does not qualify as a sale but results in the Company's cash balance being at least \$5.0 million in excess of its cash requirements for the 12 months following the closing of such transaction, the Company is required to prepay an amount equal to half of the excess cash balance over \$5.0 million.

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The BMR Note and the security agreement in connection with the note contain customary conditions related to borrowing, events of default, and covenants, including covenants limiting the Company's ability to dispose of collateralized assets, undergo a change of jurisdiction or relocation of its business, incur debt or incur liens, subject to certain exceptions. The BMR Note and security agreement also require the Company to comply with certain basic affirmative covenants, such as maintenance of financial records, insurance and prompt payment of taxes.

In June 2014, the Company amended the BMR Note to increase the interest rate during the period that the Company's loan with Hercules Technology Growth Capital, Inc. (Hercules) remains outstanding to match the interest rate of the Company's loan with Hercules. The change to the terms of the BMR Note did not result in debt modification accounting in accordance with ASC 470-50. Also in June 2014, the Company amended the BMR Note to provide that any failure by the Company to pay any amount under the BMR Note during the period when the Company's loan with Hercules is outstanding will not constitute a default.

***Line of Credit with AKP USA, Inc.***

In April 2012, ZP Group LLC obtained a \$25 million facility under a revolving line of credit arrangement with AKP USA, Inc. (AKPUS), an affiliate of Asahi. The facility bore an interest rate of 1.15% per year, and ZP Group LLC was obliged to pay interest on the principal outstanding on the last day of each month until any outstanding principal is paid in full. All outstanding and unpaid principal and interest were due and payable upon the earlier of (i) the date on which AKPUS no longer holds any membership interest in ZP Group LLC, or (ii) March 31, 2021.

Pursuant to the termination of the Company's joint venture with AKPUS, the termination agreement resulted in the cancellation of the remaining unused line of credit under the revolving line of credit facility. The termination agreement also provided that the entire outstanding principal and any unpaid and accrued interest shall be discharged, released and forgiven on March 14, 2014, the effective date of the termination of this line of credit facility. Accordingly, the Company recorded a gain on debt forgiveness of \$0.5 million on its consolidated statement of operations for the year ended December 31, 2014.

***Senior Secured Term Loan with Hercules***

On June 3, 2014, the Company entered into a loan and security agreement with Hercules which provided the Company \$4.0 million in debt financing (the Hercules Term Loan). In accordance with the terms of the loan and security agreement, the Company paid \$25,000 as a non-refundable upfront loan origination fee to Hercules and issued Hercules a warrant to purchase shares of the Company's stock having a purchase price of up to \$280,000 at an exercise price equal to the lesser of the lowest price per share of the stock sold in the Company's next round of equity financing that results in gross proceeds of at least \$3.0 million prior to the closing of an initial public offering, or \$8.84 per share. The agreement provides that amounts borrowed will be subject to an interest-only period beginning July 1, 2014 and expiring on December 31, 2014, followed by 30 equal monthly installment payments of principal and interest beginning January 1, 2015 at a variable rate of the greater of (i) 12.05%, or (ii) 12.05% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. In addition, the Company will be obligated to make an end-of-term payment of \$100,000 at loan maturity or at the date the Company prepays the outstanding obligation. Further, should the Company elect to prepay the loan after the twelve month lock-in period, a 1% prepayment penalty on the outstanding principal will become due and payable.

Under the loan and security agreement, Hercules was given the right to invest up to \$1.0 million in the Company's stock on the same terms, conditions and pricing as others participating in the Company's first subsequent equity

financing after the closing of the Hercules Term Loan. Hercules was further given an additional right to convert up to \$0.5 million of the principal amount of the Hercules Term Loan in the first subsequent equity financing on the same terms, conditions and pricing as others on such equity financing. However, in July 2014, Hercules waived its participation and conversion rights in respect of the Company's initial public offering.

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The Hercules Term Loan is secured by a first priority security interest and lien in and to all of the Company's tangible and intangible properties and assets, including intellectual properties. Accordingly, BMV Direct SOTRS LP agreed to subordinate the 2012 BMR secured promissory note to the Hercules Term Loan. In exchange for its agreement to subordinate the BMR secured promissory note to the Hercules Term Loan, the Company issued, in June 2014, 31,250 shares of common stock to BMV Direct SOTRS LP. The Company recorded the fair value of the common stock issued to BMV Direct SOTRS LP of approximately \$141,000 as a cost of debt subordination and included this amount as other expense in its consolidated statement of operations for the year ended December 31, 2014. In addition, the Company amended the BMR secured promissory note to increase the interest rate during the period that the Hercules Term Loan remains outstanding to match the interest rate of the Hercules Term Loan. The change to the terms of the BMR secured promissory note did not result in debt modification accounting in accordance with ASC 470-50.

The Company incurred legal and closing costs of approximately \$80,000 (including the \$25,000 upfront loan origination fee) in connection with the Hercules Term Loan that have been capitalized as debt issuance costs and are being amortized to interest expense over the term of the loan using the effective interest method. In addition, the Company issued warrants to Hercules in connection with the Hercules Term Loan. The warrants were recorded as a liability on the Company's balance sheet at their fair value of approximately \$0.1 million on the date of issuance, with a corresponding debt discount that is being amortized to interest expense over the debt repayment period using the effective interest method. For the year ended December 31, 2014, the Company recorded interest expense related to the Hercules Term Loan of approximately \$0.3 million.

The following tables summarize the Company's outstanding short-term financing and long-term debt as of December 31, 2014:

*Short-term related parties convertible promissory notes and current portion of secured promissory notes:*

| Lender                                      | Description     | Maturity Date       | Outstanding |          |          |           | Interest Rate/<br>Weighted-<br>Average | Security/Covenant |
|---|-----------------|---------------------|-------------|----------|----------|-----------|--|-------------------|
|   |                 |                     | Principal   | Debt     | Accrued  | Interest  | Interest Rate                          |                   |
|   |                 |                     | Amount      | Discount | Interest | Per Annum |  |                   |
| (in thousands)                              |                 |                     |             |          |          |           |  |                   |
| BMV Direct<br>SO LP                         | Working capital | September 9, 2014 * | \$ 552      | \$ -     | \$ 48    | 8.00%     | Unsecured, convertible<br>to common    |                   |
| BMV Direct<br>SOTRS LP                      | Working capital | September 9, 2014 * | 2,061       | -        | 175      | 8.00%     | Unsecured, convertible<br>to common    |                   |
| New<br>Enterprise<br>Associates<br>12, L.P. | Working capital | September 9, 2014 * | 2,341       | -        | 201      | 8.00%     | Unsecured, convertible<br>to common    |                   |
| ProQuest<br>Investments<br>IV, L.P.         | Working capital | September 9, 2014 * | 580         | -        | 61       | 8.00%     | Unsecured, convertible<br>to common    |                   |
| BMV Direct<br>SOTRS LP                      | Working capital | June 1, 2017        | 708         | -        | 5        | 8.00%     | Unsecured, convertible<br>to common    |                   |

|  |                              |          |         |        |        |  |
|--|------------------------------|----------|---------|--------|--------|--|
| New<br>Enterprise<br>Associates<br>12, L.P.  | Working capital June 1, 2017 | 625      | -       | 4      | 8.00%  | Unsecured, convertible<br>to common  |
| <i>Related Parties Convertible Notes</i>   |                              | 6,867    | -       | 494    | 8.00%  |  |
| Hercules<br>Technology<br>Growth<br>Capital, Inc.                                  | Working capital June 1, 2017 | 1,452    | (85)    | 42     | 12.05% | First security interest<br>in all properties and<br>assets, including<br>intellectual properties |
| <i>Related Parties Convertible Notes and Current<br/>Portion of Long-Term Debt</i> |                              | \$ 8,319 | \$ (85) | \$ 536 | 8.71%  |  |

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*Long-term debt secured promissory notes:*

| Lender                                   | Description      | Maturity Date  | Outstanding      |               | Accrued Interest | Interest Rate Per Annum | Security/Covenant  |
|--|------------------|----------------|------------------|---------------|------------------|-------------------------|--|
|  |                  |                | Principal Amount | Debt Discount |                  |                         |  |
|  |                  |                | (in thousands)   |               |                  |                         |  |
| BMV Direct SOTRS LP                      | Recapitalization | April 26, 2016 | \$ 8,557         | \$ -          | \$ 2,204         | 8% - 12.05%**           | Second security interest in all properties and assets, including intellectual properties |
|  |                  |                |                  |               |                  | 8% -                    |  |
| Related Party Promissory Note            |                  |                | 8,557            | -             | 2,204            | 12.05%**                |  |
| Hercules Technology Growth Capital, Inc. | Working capital  | June 1, 2017   | 2,548            | (49)          | 31               | 12.05%                  | First security interest in all properties and assets, including intellectual properties  |
| Long-Term Debt                           |                  |                | \$ 11,105        | \$ (49)       | \$ 2,235         |                         |  |

\* In June 2014, the Company amended the convertible promissory notes to provide that any failure to pay any amount under the convertible promissory notes during the period from maturity of the convertible promissory notes through the date that the Hercules Term Loan is repaid in full will not constitute a default under the convertible promissory notes.

\*\* In June 2014, the Company amended the BMR Note to increase the interest rate during the period that the Hercules Term Loan remains outstanding to match the interest rate of the Hercules Term Loan. The change to the terms of the BMR Note did not result in debt modification accounting in accordance with ASC 470-50.

The following tables summarize the Company's outstanding short-term financing and long-term debt as of December 31, 2013:

*Short-term financing and related parties convertible promissory notes:*

| Lender | Description | Maturity Date | Outstanding Principal Amount | Accrued Interest | Interest Rate/ Weighted-Average | Security/Covenant |
|--------|-------------|---------------|------------------------------|------------------|---------------------------------|-------------------|
|--------|-------------|---------------|------------------------------|------------------|---------------------------------|-------------------|

|  |                 |                   |          |       | Interest Rate<br>Per Annum |                                  |  |
|--|-----------------|-------------------|----------|-------|----------------------------|----------------------------------|--|
| (in thousands)                           |                 |                   |          |       |                            |                                  |  |
| BMV Direct SO LP                         | Working capital | September 9, 2014 | \$ 303   | \$ 7  | 8.00%                      | Unsecured, convertible to common |  |
| BMV Direct SOTRS LP                      | Working capital | September 9, 2014 | 990      | 24    | 8.00%                      | Unsecured, convertible to common |  |
| New Enterprise Associates 12, L.P.       | Working capital | September 9, 2014 | 1,160    | 30    | 8.00%                      | Unsecured, convertible to common |  |
| ProQuest Investments IV, L.P.            | Working capital | September 9, 2014 | 580      | 14    | 8.00%                      | Unsecured, convertible to common |  |
| <i>Related Parties Convertible Notes</i> |                 |                   | 3,033    | 75    | 8.00%                      |                                  |  |
| AKP USA, Inc.                            | Line of credit  | March 14, 2014    | 491      | 5     | 1.15%                      | Unsecured                        |  |
| <i>Short-Term Financing</i>              |                 |                   | \$ 3,524 | \$ 80 | 7.05%                      |                                  |  |

*Long-term debt:*

| Lender              | Description      | Maturity Date  | Outstanding Principal Amount | Accrued Interest | Interest Rate Per Annum | Security/Covenant   |
|---------------------|------------------|----------------|------------------------------|------------------|-------------------------|---|
|                     |                  |                | (in thousands)               |                  |                         |   |
| BMV Direct SOTRS LP | Recapitalization | April 26, 2016 | \$ 8,557                     | \$ 1,154         | 8.00%                   | First security interest in all properties and assets, including certain intellectual properties |

|                                      |          |          |
|--------------------------------------|----------|----------|
| <i>Related Party Promissory Note</i> | \$ 8,557 | \$ 1,154 |
|--------------------------------------|----------|----------|

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For the years ended December 31, 2014 and 2013, total interest expense on the Company's short-term debt was \$0.7 million and \$80,000, respectively, and interest expense on the Company's long-term debt was \$1.1 million and \$0.7 million, respectively.

As of December 31, 2014, future minimum payments on the Company's long-term debt, including payment of principal and interest, for each year ending December 31 are as follows (in thousands):

|      |           |
|------|-----------|
| 2015 | \$ 1,861  |
| 2016 | 14,347 *  |
| 2017 | 1,042     |
|      | \$ 17,250 |

\* Under the terms of the BMR Note, payment of principal and interest is due April 2016. In June 2014, the Company amended the BMR Note to provide that any failure by the Company to pay any amount under the BMR Note during the period when the Hercules Term Loan is outstanding will not constitute a default.

**9. Warrants to Purchase Common Stock**

In connection with the Hercules Term Loan (see Note 8 Debt Financing), the Company issued a warrant to purchase shares of the Company's stock at an exercise price which is the lesser of the lowest price per share of stock in any non-public equity financing resulting in more than \$3.0 million of gross proceeds that occurs prior to the Company's initial public offering or \$8.84 per share. The warrant is exercisable at any time, in whole or in part, until the earlier of (1) ten years from date of issuance, or (2) five years from the date of the Company's IPO. The Company determined the initial fair value of the warrant to be approximately \$0.1 million using the Black-Scholes option valuation model with the following input assumptions: expected term of 10 years; volatility of 89%; risk free interest rate of 2.75%; and no dividend yield.

In accordance with ASC 480, *Distinguishing Debt from Equity*, the Company accounts for the warrant as a liability in the accompanying consolidated balance sheet. The fair value of the warrant on the date of issuance was recorded on the Company's balance sheet as a liability with a corresponding debt discount, which is being amortized to interest expense over the debt repayment period using the effective interest method. The warrant liability is revalued at each subsequent balance sheet date until the earlier of (1) the exercise of warrant, or (2) the expiration of warrant, with fair value changes recognized as increases or decreases to warrant revaluation income or expense in the accompanying consolidated statements of operations.

For the year ended December 31, 2014, the Company recorded other expense of approximately \$0.2 million related to the change in fair value of the warrant. The Company determined the fair value of the warrant as of December 31, 2014 using the Black-Scholes option valuation model with the following assumptions: expected term of 9.42 years; volatility of 89%; risk free interest rate of 2.28%; and no dividend yield.

## **10. Commitments and Contingencies**

### ***Operating Leases***

The Company has an operating lease with an affiliate of BMR for its office, research and development, and manufacturing facilities in Fremont, California. The original lease was scheduled to expire in 2017. The lease agreement provides for an escalation of rent payments. The initial lease agreement provided for tenant improvement allowances of up to \$8.3 million for application against construction costs incurred by the Company. In October 2008, the lease agreement was amended to provide for additional tenant improvement advances of up to \$2.1 million. Through December 31, 2010, the Company had received the entire amount of \$10.4 million of tenant improvement allowances. The allowances are being amortized over the term of the lease as a reduction of rent expense. The Company executed 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.

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The Company records rent expense under the lease on a straight-line basis over the term of the lease. The difference between the actual lease payments and the expense recognized under the lease, along with the unamortized tenant improvement allowances, resulted in a deferred rent liability of \$5.1 million and \$6.3 million as of December 31, 2014 and 2013, respectively. As a result of the lease renegotiation in April 2012, the Company issued the 2012 Note in consideration for previously accrued interest, unpaid rent, future rent obligations and other fees due to the landlord resulting in prepaid rent which is being expensed on a straight-line basis over the term of the lease. As of December 31, 2014, the prepaid rent of \$5.0 million is offset against the deferred rent liability of \$5.1 million, resulting in a net deferred rent liability of \$0.1 million. As of December 31, 2013, the prepaid rent of \$5.9 million is offset against the deferred rent liability of \$6.3 million, resulting in a net deferred rent liability of \$0.4 million.

Also in April 2012, the Company entered into a sub-lease agreement with ZP Group LLC. The sub-lease terminated on December 20, 2013 as a result of the termination of the Company's joint venture with Asahi. Rental income of \$0.6 million was recorded as reduction of rental expense for the year ended December 31, 2013.

For the years ended December 31, 2014 and 2013, rental expense under operating leases before rental income was \$0.8 million and \$0.6 million, respectively.

As of December 31, 2014, future minimum payments under non-cancelable operating leases for each year ending December 31 are as follows (in thousands):

|                 |    |       |
|-----------------|----|-------|
| 2015            | \$ | 688   |
| 2016            |    | 626   |
| 2017            |    | 639   |
| 2018            |    | 651   |
| 2019 and beyond |    | 164   |
|                 | \$ | 2,768 |

***Indemnification and Guarantees***

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2014.

## **11. Stockholders Equity**

### ***Common Stock***

The Company's certificate of incorporation authorizes the Company to issue 30,000,000 shares of common stock. Common stockholders are entitled to dividends if and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. Each share of common stock is entitled to one vote.

On July 11, 2014, the Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation pursuant to which the Company will be authorized to issue up to

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100,000,000 shares of common stock and up to 5,000,000 shares of preferred stock. The amendment became effective upon the closing of the Company's IPO in January 2015 (see Note 15 Subsequent Events).

**12. Stock-Based Compensation*****The 2012 Stock Incentive Plan***

The 2012 Stock Incentive Plan (the 2012 Plan) provides for the granting of stock options and restricted stock awards to employees, directors and consultants of the Company. Options granted under the 2012 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of December 31, 2014, the Company had reserved 566,027 shares of common stock for issuance under the 2012 Plan. Options and awards under the 2012 Plan may be granted for periods of up to ten years and can be exercisable immediately subject to rights of repurchase by the Company dependent upon the continued employment of the optionee and/or other conditions as determined. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions as determined by the Board of Directors.

***The 2014 Equity and Incentive Plan***

The 2014 Equity and Incentive Plan (the 2014 Plan) provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company's common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of December 31, 2014, the Company had reserved 1,400,000 shares of our common stock for issuance under our 2014 Plan, subject to automatic annual increases as set forth in the plan. Options and awards under the 2014 Plan may be granted for periods of up to ten years and can be exercisable immediately subject to rights of repurchase by the Company dependent upon the continued employment of the optionee and/or other conditions as determined. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions as determined by the Board of Directors.

As of December 31, 2014, the Company had not issued any options or awards under the 2014 Plan. In connection with the Company's initial public offering of its common stock (see Note 15 Subsequent Events), the Company's board of directors terminated the 2012 Plan effective as of January 27, 2015 and no further awards may be issued under the 2012 Plan, provided however that the awards outstanding under the 2012 Plan at January 27, 2015 continue to be governed by the terms of the 2012 Plan.

The following table summarizes option and award activity under the 2012 Plan:

| Shares<br>Available for | Outstanding<br>Number | Weighted-<br>Average | Weighted-<br>Average | Aggregate<br>Intrinsic |
|-------------------------|-----------------------|----------------------|----------------------|------------------------|
|-------------------------|-----------------------|----------------------|----------------------|------------------------|

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|  | <b>Grant</b> | <b>of Shares</b> | <b>Exercise<br/>Price per Share</b> | <b>Remaining<br/>Contractual<br/>Term<br/>(In Years)</b> | <b>Value</b> |
|--|--------------|------------------|-------------------------------------|--|--------------|
| Balance at December 31, 2013                     | 83,751       | 469,776          | \$ 1.44                             | 7.39   |              |
| Granted  | (130,784)    | 130,784          | \$ 1.98                             |  |              |
| Exercised/vested and released                    | -            | (27,073)         | \$ 1.40                             |  |              |
| Cancelled/forfeited                              | 75,734       | (75,734)         | \$ 1.39                             |  |              |
| Balance at December 31, 2014                     | 28,701       | 497,753          | \$ 1.59                             | 6.77   |              |
| Exercisable at December 31, 2014                 |              | 212,512          | \$ 1.51                             | 5.68   | \$ 2,017     |
| Vested and expected to vest at December 31, 2014 |              | 474,898          | \$ 1.61                             | 6.67   | \$ 4,461     |

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The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company's common stock for in-the-money options at December 31, 2014. The Company completed its initial public offering on January 30, 2015 at a price of \$11.00 per common share. As such, management believes the fair value of its common shares at December 31, 2014 closely approximated its value at its initial public offering due to the short time lapse between its fiscal year-end 2014 and the offering date.

The following summarizes the composition of stock options outstanding and exercisable as of December 31, 2014:

| Exercise Price  | Options Outstanding and Exercisable |   |
|-----------------|-------------------------------------|---|
|                 | Number of<br>Shares                 | Weighted-Average<br>Remaining<br>Contractual<br>Life (in years) |
| \$1.28          | 2,781                               | 9.30  |
| \$1.40          | 117,752                             | 7.88  |
| \$1.54          | 88,441                              | 2.50  |
| \$4.52          | 3,538                               | 9.53  |
| \$1.28 - \$4.52 | 212,512                             | 5.68  |

The weighted-average grant-date fair value of options and awards granted during the years ended December 31, 2014 and 2013 were \$1.47 and \$0.97, respectively. The total fair value of options and awards that vested during the years ended December 31, 2014 and 2013 were \$137,085 and \$98,118, respectively.

***Options Granted to Non-employees***

During the years ended December 31, 2014 and 2013 the Company granted options to purchase zero and 2,500 shares of common stock, respectively, to non-employees at an exercise price of \$1.40 per share.

Stock-based compensation expense will fluctuate as the estimated fair value of the common stock fluctuates over the vesting period. In connection with the grant of stock options to non-employees, the Company recognized stock-based compensation expense of \$35,000 and an immaterial amount, for the years ended December 31, 2014 and 2013, respectively.

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered. The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black-Scholes option pricing model.

***Stock-Based Compensation Expense***

Total stock-based compensation expense recognized was as follows:

|                            | <b>Year Ended December 31,</b> |             |
|----------------------------|--------------------------------|-------------|
|                            | <b>2014</b>                    | <b>2013</b> |
|                            | <b>(in thousands)</b>          |             |
| Research and development   | \$ 76                          | \$ 11       |
| Manufacturing              | 16                             | 5           |
| General and administrative | 92                             | 49          |
|                            | \$ 184                         | \$ 65       |

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At December 31, 2014, the Company had \$0.3 million of total unrecognized stock-based compensation, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 2.6 years.

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 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.

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

|                         | <b>Year Ended December 31,</b> |             |
|-------------------------|--------------------------------|-------------|
|                         | <b>2014</b>                    | <b>2013</b> |
| Dividend yield          | 0%                             | 0%          |
| Risk-free interest rate | 2.0%                           | 2.1%        |
| Expected volatility     | 89%                            | 89%         |
| Expected term (years)   | 6.1                            | 6.1         |

**13. Income Taxes**

The Company has incurred cumulative net operating losses since inception and, consequently, has not recorded any income tax expense for the years ended December 31, 2014 and 2013 due to its net operating loss position.

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

|  | <b>Year Ended December 31,</b> |   |             |   |
|--|--------------------------------|---|-------------|---|
|  | <b>2014</b>                    |   | <b>2013</b> |   |
| Federal statutory tax rate                       | (34.00)                        | % | (34.00)     | % |
| State statutory tax rate, net of federal benefit | (5.85)                         | % | (5.85)      | % |
| Warrant revaluation                              | 1.30                           | % | -           | % |
| Stock-based compensation                         | 1.29                           | % | 1.16        | % |
| Other  | 0.05                           | % | 0.37        | % |

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|                     |       |   |       |   |
|---------------------|-------|---|-------|---|
| Valuation allowance | 37.21 | % | 38.32 | % |
|                     | -     | % | -     | % |

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2014 and 2013, the Company had net deferred tax assets of \$62.2 million and \$56.5 million, respectively. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately \$5.7 million during the year ended December 31, 2014, and increased by approximately \$2.6 million during the year ended December 31, 2013.

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Significant components of the Company's net deferred tax assets and liabilities at December 31, 2014 and 2013 are as follows:

|                                  | <b>Year Ended December 31,</b> |             |
|----------------------------------|--------------------------------|-------------|
|                                  | <b>2014</b>                    | <b>2013</b> |
|                                  | <b>(in thousands)</b>          |             |
| Net operating loss carryforwards | \$ 58,360                      | \$ 52,823   |
| Deferred revenue                 |                                | 448         |
| Accruals                         | 115                            | 300         |
| Deferred rent                    | 127                            | 601         |
| Research and development credits | 4,665                          | 4,491       |
| AMT credit                       | 20                             | 20          |
| Other                            | 294                            | 294         |
| Depreciation and amortization    | (1,404)                        | (2,498)     |
| Net deferred tax assets          | 62,177                         | 56,479      |
| Valuation allowance              | (62,177)                       | (56,479)    |
|                                  | \$                             | \$          |

As of December 31, 2014, the Company had federal net operating loss carryforwards of approximately \$146.9 million and state net operating loss carryforwards of approximately \$143.8 million. As of December 31, 2013, the Company had federal net operating loss carryforwards of approximately \$133.1 million and state net operating loss carryforwards of approximately \$129.6 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 the Company's net operating loss and tax credit carryforwards may be subject to substantial annual limitation in the event that there is a change in ownership as provided by section 382 of the Internal Revenue Code and similar state provisions. Such a limitation could result in the expiration of the net operating loss carryforwards and tax credits before utilization. The Company has not performed an analysis under Section 382 and, accordingly, some or all of its net operating loss carryforwards may not be available to offset future taxable income.

As of December 31, 2014, the Company had federal and state research and development credit carryforwards of approximately \$3.5 million and \$3.6 million, respectively. As of December 31, 2013, the Company had federal and state research and development credit carryforwards of approximately \$3.4 million and \$3.4 million, respectively. If not utilized, the federal tax credits will begin to expire in 2026 and state tax credits currently do not expire. Utilization of the research and development credit carryforwards are also subject to the limitations as discussed above. The Company has not performed an analysis under Internal Revenue Code Section 383 and, accordingly, some or all of its research and development credit carryforwards may not be available to offset future taxable income.

The American Taxpayer Relief Act of 2012, signed into law on January 2, 2013, extended Section 41 research credits for two years retroactively from January 1, 2013 through December 31, 2014. The new law also resolves an issue regarding the treatment of qualified research expenditures in the event of an acquisition or disposition of a trade or business. The credit rates for both the regular credit, 20%, and the alternative simplified credit, 14%, remain

unchanged by this credit extension. The Act retroactively extended the federal research credit through 2014 and extended 50% bonus depreciation. The Act does not have any impact on the Company's federal tax credits carryforward as of December 31, 2014.

The Company files income tax returns in the U.S. federal and California state jurisdictions. The Company is subject to U.S. federal and state income tax examinations by authorities for all tax years due to the accumulated net operating losses that are being carried forward for tax purposes.

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**Table of Contents****Index to Financial Statements*****Uncertain Income Tax Positions***

The Company only recognizes tax benefits if it is more likely than not that they will be sustained upon audit by the relevant tax authority based upon their technical merits. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company had approximately \$1.4 million of unrecognized tax benefits as of both December 31, 2014 and 2013. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits will reduce the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months. A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows:

|  | <b>Year Ended December 31,</b> |             |
|--|--------------------------------|-------------|
|  | <b>2014</b>                    | <b>2013</b> |
|  | <b>(in thousands)</b>          |             |
| Balance at the beginning of year               | \$ 1,359                       | \$ 1,249    |
| Increase related to prior year tax positions   |                                |             |
| Increase related to current year tax positions | 56                             | 110         |
| Balance at the end of year                     | \$ 1,415                       | \$ 1,359    |

In July 2013, the FASB issued guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss or tax carryforward exists. FASB concluded that an unrecognized tax benefit should be presented as a reduction of a deferred tax asset except in certain circumstances the unrecognized tax benefit should be presented as a liability and should not be combined with deferred tax assets. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. The Company adopted this guidance during the year ended December 31, 2014 and presented its unrecognized tax benefit as a reduction of deferred tax assets as of December 31, 2014 and 2013.

Interest and penalty related to unrecognized tax benefits would be included as income tax expense in the Company's consolidated statements of operations. As of December 31, 2014 and 2013, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

**14. Employee Benefit Plan**

The Company has established a 401(k) tax-deferred savings plan (the 401(k) Plan), which permits participants to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. The Company is responsible for administrative costs of the 401(k) Plan. The Company may, at its discretion, make matching contributions to the 401(k) Plan. No employer contributions have been made to date.

**15. Subsequent Events**

***Amendments to Articles of Incorporation or Bylaws***

On January 29, 2015, the Company's amended and restated certificate of incorporation (the "Restated Charter"), was filed with the Secretary of State of the State of Delaware and became effective. The Restated Charter amends and restates the Company's certificate of incorporation in its entirety to, among other things: (i) increase the authorized number of shares of Common Stock to 100,000,000 shares; and (ii) authorize 5,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors in one or more series.

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***Initial Public Offering***

On January 30, 2015, the Company completed its initial public offering on the NASDAQ Capital Market. The Company sold 4,500,000 shares of its common stock at \$11.00 per share, resulting in net proceeds of approximately \$44.4 million after deducting underwriting commissions and expenses. On February 27, 2015, the underwriters exercised the overallotment option resulting in the Company's issuing an additional 110,000 shares of its common stock at \$11.00 per share, resulting in additional net proceeds of approximately \$1.1 million after underwriting discounts.

***Concurrent Private Placement***

On January 30, 2015, the Company issued and sold 1,363,636 shares of its common stock to Lilly pursuant to a common stock purchase agreement dated November 21, 2014 between the Company and Lilly and received net proceeds of \$14.5 million, after underwriting discounts. The closing of this private placement took place concurrently with the Company's initial public offering.

***Conversion of Related Parties Convertible Promissory Notes***

On January 30, 2015, upon the closing of the Company's initial public offering, the principal and all unpaid and accrued interest on each convertible promissory note outstanding as of January 30, 2015 of \$ 7.4 million were automatically converted into an aggregate of 792,182 shares of common stock at a price equal to 85% of the initial public offering price, resulting in the liability for such notes being reclassified to permanent equity.

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**EXHIBIT INDEX**

| <b>Exhibit number</b> | <b>Description</b>  |
|-----------------------|---|
| 3.1                   | Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Commission on February 3, 2015)  |
| 3.2                   | Amended and Restated Bylaws of Zosano Pharma Corporation (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed with the Commission on February 3, 2015)  |
| 4.1                   | Specimen certificate evidencing shares of common stock of Zosano Pharma Corporation (incorporated by reference to Exhibit 4.1 to the registrant's Amendment No. 3 to Registration Statement on Form S-1 filed with the Commission on July 25, 2014)   |
| 10.1*                 | Collaboration, Development and License Agreement, dated January 31, 2014, between Zosano Pharma, Inc. and Novo Nordisk A/S (incorporated by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.2                  | Notice of Termination, dated January 27, 2014, of the Amended and Restated License Agreement dated as of April 1, 2012 among Zosano Pharma, Inc. and Asahi Kasei Pharma Corporation (incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014) |
| 10.3                  | Letter Amendment to Intellectual Property License Agreement, dated February 22, 2011 between ALZA Corporation and Zosano Pharma, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.4*                 | Intellectual Property License Agreement, dated as of October 5, 2006, between ALZA Corporation and The Macroflux Corporation (incorporated by reference to Exhibit 10.4 to the registrant's Amendment No. 2 to Registration Statement on Form S-1 filed with the Commission on July 17, 2014)                                     |
| 10.5                  | Secured Promissory Note, dated April 26, 2012, between ZP Holdings, Inc. and BioMed Realty Holdings, Inc. (incorporated by reference to Exhibit 10.5 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.6                  | Security Agreement, dated as of April 26, 2012, between ZP Holdings, Inc. and BioMed Realty Holdings, Inc. (incorporated by reference to Exhibit 10.6 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.7                  | Intellectual Property Security Agreement, dated as of April 26, 2012, between ZP Holdings, Inc. and BioMed Realty Holdings, Inc. (incorporated by reference to Exhibit 10.7 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.8                  | Guaranty, made as of April 1, 2012, by ZP Holdings, Inc. in favor of BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.8 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.9                  |   |

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Lease Agreement, dated May 1, 2007, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

- 10.10 First Amendment to Lease, dated June 20, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
- 10.11 Second Amendment to Lease, dated October 16, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

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| <b>Exhibit number</b> | <b>Description</b>  |
|-----------------------|---|
| 10.12                 | Third Amendment to Lease, dated April 29, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.12 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)                                       |
| 10.13                 | Fourth Amendment to Lease, dated July 31, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.13 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)                                       |
| 10.14                 | Fifth Amendment to Lease, dated April 1, 2012, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.15                 | Form of Indemnification Agreement for Directors associated with an Investment Fund (incorporated by reference to Exhibit 10.15 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.16                 | Form of Indemnification Agreement for Directors not associated with an Investment Fund (incorporated by reference to Exhibit 10.16 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.17 <sup>±</sup>    | Employment Letter Agreement, dated April 30, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and W. Tso (incorporated by reference to Exhibit 10.17 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.18 <sup>±</sup>    | Amendment to Amended and Restated Employment Letter Agreement, dated January 31, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Nandan Oza (incorporated by reference to Exhibit 10.18 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014) |
| 10.19 <sup>±</sup>    | Amended and Restated Employment Letter Agreement, dated July 22, 2013, among Zosano Pharma, Inc., ZP Holdings, Inc. and Nandan Oza (incorporated by reference to Exhibit 10.19 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)                 |
| 10.20                 | Loan and Security Agreement, dated as of June 3, 2014, between Zosano Pharma, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.20 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)                    |
| 10.21                 | Joinder Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.21 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)                                |
| 10.22                 | ZP Holdings, Inc. Pledge Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.22 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)               |
| 10.23 <sup>±</sup>    | Amendment No. 2 to Employment Letter Agreement, dated January 16, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona (incorporated by reference to Exhibit 10.23 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)             |
| 10.24 <sup>±</sup>    | Amendment to Employment Letter Agreement, dated January 6, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona (incorporated by reference to Exhibit 10.24 to the registrant's   |

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Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

- 10.25<sup>±</sup> Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona (incorporated by reference to Exhibit 10.25 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
- 10.26<sup>±</sup> Amendment to Employment Letter Agreement, dated December 17, 2013, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba (incorporated by reference to Exhibit 10.26 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

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| <b>Exhibit number</b> | <b>Description</b>  |
|-----------------------|---|
| 10.27±                | Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba (incorporated by reference to Exhibit 10.27 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.28                 | Letter Amendment to Independent Director Agreement, dated July 15, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos (incorporated by reference to Exhibit 10.28 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.29                 | Independent Director Agreement, dated as of March 28, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos (incorporated by reference to Exhibit 10.29 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.30±                | ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.30 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.31±                | Form of Incentive Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.31 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.32±                | Form of Non-Statutory Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.32 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.33±                | Zosano Pharma Corporation Amended and Restated 2014 Equity and Incentive Plan   |
| 10.34                 | Warrant Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.34 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.35                 | Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BioMed Realty Holdings, Inc., Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.35 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)  |
| 10.36                 | Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P., ProQuest Management LLC, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.36 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014) |
| 10.37                 | Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.37 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.38                 | First Amendment to Secured Promissory Note, dated as of June 3, 2014, among BMV Direct SOTRS LP, ZP Holdings, Inc. and Zosano Pharma, Inc. (incorporated by reference to Exhibit 10.38 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)   |
| 10.39                 |   |



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Independent Director Agreement, dated as June 23, 2014, between Zosano Pharma Corporation and Troy Wilson (incorporated by reference to Exhibit 10.39 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

- 10.40 Subordination Agreement, dated as of December 2, 2014, among BMV Direct SOTRS LP, New Enterprise Associates 12, Limited Partnership, ZP Opco, Inc., Zosano Pharma Corporation and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.40 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)

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| <b>Exhibit number</b> | <b>Description</b>  |
|-----------------------|---|
| 10.41*                | Collaboration, Development and License Agreement, dated as of November 21, 2014, between ZP Opco, Inc. and Eli Lilly and Company (incorporated by reference to Exhibit 10.41 to the registrant's Amendment No. 7 to Registration Statement on Form S-1 filed with the Commission on January 20, 2015) |
| 10.42                 | Common Stock Purchase Agreement, dated as of November 21, 2014, between Zosano Pharma Corporation and Eli Lilly and Company (incorporated by reference to Exhibit 10.42 to the registrant's Amendment No. 5 to Registration Statement on Form S-1 filed with the Commission on December 10, 2014)     |
| 10.43                 | Form of Side Letter regarding private placement fee (incorporated by reference to Exhibit 10.43 to the registrant's Amendment No. 6 to Registration Statement on Form S-1 filed with the Commission on January 9, 2015)   |
| 21.1                  | Subsidiaries of Registrant (incorporated by reference to Exhibit 21.1 to the registrant's Amendment No. 3 to Registration Statement on Form S-1 filed with the Commission on July 25, 2014)   |
| 31.1                  | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |
| 31.2                  | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |
| 32.1                  | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |

Filed herewith

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

± Management contract or compensatory plan or arrangement