

Zosano Pharma Corp  
Form 424B4  
January 27, 2015  
**Table of Contents**

**Index to Financial Statements**

**Filed pursuant to Rule 424(b)(4)  
Registration No. 333-196983**

## PROSPECTUS

**4,500,000 Shares**

**Common Stock**

This is the initial public offering of the common stock of Zosano Pharma Corporation. Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol ZSAN. The initial public offering price is \$11.00 per share.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See Prospectus Summary Implications of Being an Emerging Growth Company.

**Investing in our common stock involves risks. See Risk Factors beginning on page 12 of this prospectus.**

|   | <i>Per Share</i> | <i>Total</i>  |
|---|------------------|---------------|
| <b>Initial public offering price</b>                | \$ 11.00         | \$ 49,500,000 |
| <b>Underwriting discounts and commissions(1)(2)</b> | \$ 0.77          | \$ 3,465,000  |
| <b>Proceeds to us (before expenses)</b>             | \$ 10.23         | \$ 46,035,000 |

(1) We refer you to Underwriting beginning on page 154 of this prospectus for additional information regarding total underwriter compensation and a private placement fee payable to the representatives of the underwriters upon the completion of our concurrent private placement with Eli Lilly and Company as described in this prospectus.

(2) The underwriters will also be reimbursed for certain expenses incurred in this offering.

We have granted the underwriters a thirty-day option to purchase up to 675,000 additional shares of our common stock on the same terms and conditions described herein, solely to cover over-allotments, if any.

Eli Lilly and Company, one of our collaborators, has agreed to purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price. The sale of shares to Eli Lilly and Company will not be registered under the Securities Act of 1933, as amended.

Certain of our existing investors have agreed to purchase an aggregate amount of \$550,000 worth of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discounts and commissions on the shares purchased by these investors as they will on the other shares sold to the public in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares against payment therefor on or about January 30, 2015.

*Joint Book-Running Managers*

**Ladenburg Thalmann**

**Roth Capital Partners**

Prospectus dated January 26, 2015.

**Table of Contents**

**Index to Financial Statements**

Table of ContentsIndex to Financial Statements

## TABLE OF CONTENTS

|  |     |
|--|-----|
| <u>PROSPECTUS SUMMARY</u>  | 1   |
| <u>RISK FACTORS</u>  | 12  |
| <u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>                                  | 45  |
| <u>INDUSTRY AND MARKET DATA</u>  | 46  |
| <u>USE OF PROCEEDS</u>   | 47  |
| <u>DIVIDEND POLICY</u>   | 48  |
| <u>CAPITALIZATION</u>  | 49  |
| <u>DILUTION</u>  | 50  |
| <u>SELECTED CONSOLIDATED FINANCIAL DATA</u>  | 52  |
| <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u> | 54  |
| <u>BUSINESS</u>  | 85  |
| <u>MANAGEMENT</u>  | 121 |
| <u>EXECUTIVE COMPENSATION</u>  | 128 |
| <u>RELATED PERSON TRANSACTIONS</u>   | 137 |
| <u>PRINCIPAL STOCKHOLDERS</u>  | 142 |
| <u>DESCRIPTION OF CAPITAL STOCK</u>  | 145 |
| <u>SHARES ELIGIBLE FOR FUTURE SALE</u>   | 148 |
| <u>MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS</u>                  | 150 |
| <u>UNDERWRITING</u>  | 154 |
| <u>NOTICE TO INVESTORS</u>   | 158 |
| <u>LEGAL MATTERS</u>   | 160 |
| <u>EXPERTS</u>   | 160 |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u>   | 160 |
| <u>INDEX TO FINANCIAL STATEMENTS</u>   | F-1 |

**You should rely only on the information contained in this prospectus and any related free writing prospectus that we may provide you in connection with this offering. We and the underwriters have not authorized anyone to provide you with information that is different. We and the underwriters are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where such offers and sales are permitted. Regardless of the time of delivery of this prospectus or any related free writing prospectus that we may provide you in connection with this offering or any sale of our common stock, the information in this prospectus is accurate only as of the date of this prospectus, and the information in any related free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.**

For investors outside the United States: neither we nor any of the underwriters have taken any action to permit a public offering of the shares of our common stock or the possession or distribution of this prospectus or any related free writing prospectus that we may provide you in connection with this offering in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

---

Table of Contents

Index to Financial Statements

**PROSPECTUS SUMMARY**

*This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under Risk Factors beginning on page 12 and our financial statements and notes thereto that appear elsewhere in this prospectus. We use the terms Zosano, Company, we, us and our in this prospectus to refer to Zosano Pharma Corporation and its subsidiaries.*

**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 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.

**Daily ZP-PTH** is our proprietary formulation of teriparatide, a synthetic form of parathyroid hormone, PTH 1-34, or PTH, an anabolic product which regulates serum calcium, to be administered daily for the treatment of severe osteoporosis in women. Osteoporosis is a disease, primarily affecting post-menopausal women, that is characterized by low bone mineral density and structural deterioration of bone tissue, which can lead to an increase in bone fractures. We believe the only anabolic product currently available in the United States is Eli Lilly and Company's Forteo®, which generates approximately \$1.2 billion in annual revenues globally, with a relatively low patient

penetration of approximately 6% of all severe osteoporosis patients.

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 clinical trial of Daily ZP-PTH in the United States (in connection with which we submitted an investigational new drug application, or IND, to the United States Food and Drug Administration, or FDA), Mexico and Argentina in 2008. In 2009, we held End-of-Phase 2 meetings with the FDA to consider the proposed Phase 3 clinical trial and identify any additional information necessary to support a marketing application for the use of Daily ZP-PTH to treat osteoporosis in postmenopausal

**Table of Contents**

**Index to Financial Statements**

women. We also held similar meetings with European regulatory authorities in 2009. These meetings provided us with guidance for Phase 3 development of Daily ZP-PTH which we believe will help speed the regulatory approval process for Daily ZP-PTH. We plan to conduct a Phase 3 trial designed as a non-inferiority study compared to Forteo®, and intend to seek regulatory approval of Daily ZP-PTH pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 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 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 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.

In November 2014, we entered into a stock purchase agreement with Lilly pursuant to which Lilly will purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price. In addition, under the terms of the license agreement, 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. Lilly has the right to terminate the license agreement prior to regulatory approval of Daily-ZP PTH in the event 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.

***ZP-Glucagon*** is our proprietary formulation of glucagon, a hormone that raises blood glucose levels, intended for the emergency treatment of 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. Time is of the essence in treatment of patients with severe hypoglycemia in an emergency situation. The currently available products on the market are injectables that require reconstitution at the time of need.

In January 2014 we completed a Phase 1 trial in Australia designed to assess relative bioavailability with our microneedle patch system at various application sites on the body compared to a currently available form of glucagon administered by intramuscular injection. With each of the ZP-Glucagon treatments, we achieved a 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) during the first 30 minutes following application compared to the glucagon injection. Additionally, application of our microneedle patch with our easy-to-use applicator avoids the delay in treatment associated with reconstitution of the currently available injectable products. We believe these attributes will provide significant advantages in the emergency rescue of a potentially comatose

patient.

We intend to conduct a Phase 2 trial in Australia to evaluate the performance of our ZP-Glucagon product candidate in type 1 diabetic patients at 0.5 milligram, or mg, and 1.0 mg doses, with induction of hypoglycemia, in



---

**Table of Contents**

**Index to Financial Statements**

comparison to comparable doses of glucagon administered by intramuscular injection. We expect to commence, or treat the first patient in, this Phase 2 trial in Australia in the first quarter of 2015 and also complete the trial in the first quarter of 2015.

**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, a debilitating neurological disease. Most triptans on the market have a long  $T_{MAX}$ , or time after administration before maximum serum concentration is reached, and published data indicates a correlation between  $T_{MAX}$  and onset and completeness of pain relief. ZP-Triptan has demonstrated a  $T_{MAX}$  of nine minutes in preclinical studies and does not depend on gastrointestinal absorption. As a result, 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 animal studies that compared the pharmacokinetic profile of ZP-Triptan to that of zolmitriptan administered intravenously. In these preclinical studies, ZP-Triptan demonstrated rapid onset and bioavailability comparable to intravenous delivery. In 2014, we continued further confirmatory development of ZP-Triptan with additional preclinical studies. We intend to commence a Phase 1 trial in the first half of 2015 to compare the pharmacokinetic and safety/tolerability profiles of escalated patch doses of zolmitriptan to those of one commercial subcutaneous injection of sumatriptan, a synthetic triptan used for the treatment of migraine, in healthy volunteers. Our Phase 2 trial, which we expect to commence in the second half of 2015, will be designed to assess the safety and efficacy of ZP-Triptan patches in the acute treatment of migraine in adults.

**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 using our system 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 a \$1 million upfront payment from Novo Nordisk, and 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 GLP-1 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.

**Microneedle Patch System for Drug Delivery**

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 30 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.

**Table of Contents**

**Index to Financial Statements**

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 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 30 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 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.

We have tested our microneedle patch system in preclinical studies and clinical trials that demonstrated its technical feasibility with approximately 30 compounds, ranging from small molecules to proteins, including the following:

## **Table of Contents**

### **Index to Financial Statements**

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 we are currently focused, where fast onset, room-temperature stability and ease of use will fill a significant unmet need.

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

### **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 with a competitive pricing model.

Maintain our focus on effective execution of our clinical trials.

Expand our manufacturing capabilities and reduce our cost of goods.

Develop a targeted commercial infrastructure.

Partner selectively to expand the utilization of our microneedle patch drug delivery platform.

### **Intellectual Property**

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 believe that the remaining life of our patent portfolio may make our technology particularly attractive for third parties seeking to extend the lifecycle of profitable drugs nearing the expiration of their patent protection.

### **Risks Associated with our Business**

Our ability to implement our business strategy is subject to numerous risks of which you should be aware before making an investment decision. These risks are described more fully in the section entitled "Risk Factors" beginning on page 12 of this prospectus. You are encouraged to read that section in its entirety before making an investment decision. These risks include, but are not limited to, the following:

We have a history of losses. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We have recognized only limited revenues and will need to raise additional capital to operate our business, which may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or lead product candidates.

Our loan facility with Hercules Technology Growth Capital and our secured note payable to our largest stockholder, an affiliate of BioMed Realty Trust, or BMR, each impose restrictions on our business, and if we default on our obligations, Hercules or BMR's affiliate would have a right to foreclose on substantially all of our assets, including our intellectual property and proceeds of this offering and of the concurrent private placement with Lilly. We intend to use a portion of the proceeds of this offering

**Table of Contents**

**Index to Financial Statements**

to make required payments of interest and principal as they become due under the loan facility with Hercules and the secured note payable to BMR's affiliate.

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

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.

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

We use our own 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 have no experience selling, marketing or distributing products and have limited internal capability to do so, and we have limited experience manufacturing our proposed products.

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.

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.

We may not successfully manage our growth.

**Concurrent Private Placement**

Lilly has agreed to purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price. The sale of shares to Lilly in the concurrent private placement will not be registered under the Securities Act of 1933, as amended. We have agreed to pay the representatives of the underwriters a private placement fee in an amount equal to 3.5% of the gross proceeds of the concurrent private placement.

**Corporate Information**

## Edgar Filing: Zosano Pharma Corp - Form 424B4

We were incorporated under the laws of the State of Delaware as ZP Holdings, Inc. in January 2012, and changed our name to Zosano Pharma Corporation in June 2014. Our business was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006. We were originally incorporated under the name The Macroflux Corporation, and changed our name to Zosano Pharma, Inc. in 2007 following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of ZP Holdings was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of ZP Holdings. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc. Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. Our telephone number is (510) 745-1200. Our website address is [www.zosanopharma.com](http://www.zosanopharma.com). The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

**Table of Contents**

**Index to Financial Statements**

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate that we or their respective owners will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any such companies.

**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 prospectus. 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.

**Table of Contents**

**Index to Financial Statements**

**The Offering**

|   |  |
|---|--|
| Common stock offered by us  | 4,500,000 shares   |
| Common stock to be sold in the concurrent private placement to Eli Lilly and Company    | 1,363,636 shares   |
| Common stock to be outstanding after this offering and the concurrent private placement | 11,816,112 shares (12,491,112 shares in the event the underwriters elect to exercise in full their over-allotment option to purchase additional shares from us).   |
| Use of proceeds   | We estimate that the net proceeds from this offering will be approximately \$44.4 million, or approximately \$51.3 million if the underwriters exercise in full their over-allotment option, based on the initial public offering price of \$11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will also receive net proceeds of approximately \$14.5 million from the sale of common stock to Lilly in the concurrent private placement, after payment by us of the private placement fee due to the representatives of the underwriters. We plan to use the net proceeds from this offering and the concurrent private placement to prepare for a Phase 3 clinical trial of our Daily ZP-PTH product candidate, conduct Phase 2 and Phase 3 clinical trials of our ZP-Glucagon product candidate and conduct preclinical studies and Phase 1 and Phase 2 clinical trials of our ZP-Triptan product candidate. We intend to use remaining amounts to fund research and development for our preclinical pipeline, to make required payments of interest and principal as they become due under our loan facility with Hercules Technology Growth Capital and our secured note payable to our largest stockholder, an affiliate of BioMed Realty Trust, expand and enhance our manufacturing capabilities, and for working capital and other general corporate purposes. See Use of Proceeds on page 47 for additional information. |
| Risk factors  | You should read the Risk Factors section beginning on page 12 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.   |

NASDAQ Capital Market symbol                      ZSAN

Certain of our existing investors have agreed to purchase an aggregate amount of \$550,000 worth of our common stock in this offering at the initial public offering price. The shares purchased by these investors will be subject to lock-up restrictions described in Shares Eligible for Future Sale.

The number of shares of our common stock to be outstanding after this offering and the concurrent private placement set forth above is based on 5,165,123 shares of our common stock outstanding as of December 31, 2014, and includes an additional 787,353 shares of our common stock that will be issued upon the automatic conversion of our convertible promissory notes outstanding at December 31, 2014.

**Table of Contents**

**Index to Financial Statements**

The number of shares of common stock to be outstanding after this offering and the concurrent private placement set forth above excludes:

31,674 shares of common stock issuable upon the exercise of a warrant outstanding as of December 31, 2014 at an exercise price of \$8.84 per share;

497,753 shares of common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan as of December 31, 2014, at a weighted average exercise price of \$1.59 per share;

28,701 shares of common stock available for future issuance under our 2012 Stock Incentive Plan as of December 31, 2014; and

an additional 1,400,000 shares of our common stock that will be made available for future issuance under our 2014 Equity and Incentive Plan adopted in connection with the closing of this offering.

Except as otherwise noted, all information in this prospectus:

gives effect to a 1-for-4 reverse split of our common stock effected on July 11, 2014;

assumes no exercise of outstanding options or the warrant described above;

assumes the issuance and sale of 1,363,636 shares of common stock to Lilly in the concurrent private placement;

assumes no exercise by the underwriters of their over-allotment option; and

gives effect to the amendment and restatement of our certificate of incorporation and bylaws upon the closing of this offering.

**Conflicts of Interest**

Theodore D. Roth, the President and an associated person of Roth Capital Partners, LLC, or Roth, one of the book-running managers and representatives of the underwriters in this offering, is also a director of BMR and, therefore, a conflict of interest may be deemed to exist with respect to Roth because Mr. Roth is deemed to control BMR (as a director of BMR) and BMR is deemed to control us (as an affiliate of a beneficial owner of in excess of 10% of our outstanding capital stock). Mr. Roth has agreed not to vote on any matter relating to us while serving as a director of BMR. In addition, a portion, constituting less than 5%, of the net proceeds of this offering may be used to

make required payments of interest and principal as they become due under our note payable to our largest stockholder, which is an affiliate of BMR. See Use of Proceeds.

**Table of Contents****Index to Financial Statements****Summary Financial Data**

The following summary financial data should be read together with our audited consolidated financial statements and accompanying notes and Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our summary statements of operations data for the nine months ended September 30, 2014 and 2013 and the selected balance sheet data as of September 30, 2014 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our summary statements of operations data for the years ended December 31, 2013 and 2012 are derived from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of results to be expected for any future period. The summary financial data in this section are not intended to replace our audited and unaudited consolidated financial statements and the related notes.

The pro forma balance sheet data as of September 30, 2014 gives effect to the automatic conversion to 631,947 shares of common stock of the principal and all unpaid and accrued interest on each convertible promissory note outstanding at September 30, 2014 at a price equal to 85% of the initial public offering price, upon the closing of this offering, resulting in our liability for such notes being reclassified to additional paid-in capital. The pro forma as adjusted balance sheet data as of September 30, 2014 gives effect to (1) the pro forma adjustments described above and (2) our receipt of estimated net proceeds of \$44.4 million from this offering, based on the initial public offering price of \$11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and our receipt of net proceeds of approximately \$14.5 million from the sale of shares of common stock to Lilly in the concurrent private placement, after payment by us of the private placement fee due to the representatives of the underwriters, as if each had occurred as of September 30, 2014. The pro forma as adjusted summary financial data are not necessarily indicative of what our financial position would have been if this offering had been completed as of the date indicated, nor are these data necessarily indicative of our financial position for any future date or period.

|  | <b>Nine Months<br/>Ended September 30,</b>  |              | <b>Year Ended<br/>December 31,</b> |               |
|--|---|--------------|------------------------------------|---------------|
|  | <b>2014</b>                                 | <b>2013</b>  | <b>2013</b>                        | <b>2012</b>   |
|  | <b>(unaudited)</b>                          |              |                                    |               |
|  | <b>(in thousands except per share data)</b> |              |                                    |               |
| <b>Statements of Operations Data:</b>      |   |              |                                    |               |
| Revenue:                                   |   |              |                                    |               |
| License fees revenue                       | \$ 1,819                                    | \$ 3,688     | \$ 4,250                           | \$ 9,250      |
| Collaborative development support services | 662   |              |                                    | 2,374         |
| <b>Total revenue</b>                       | <b>2,481</b>                                | <b>3,688</b> | <b>4,250</b>                       | <b>11,624</b> |
| Operating expenses:                        |   |              |                                    |               |
| Cost of license fees revenue               | 100   |              |                                    |               |
| Research and development                   | 8,230                                       | 4,760        | 7,637                              | 5,399         |
| General and administrative                 | 3,208                                       | 2,692        | 4,582                              | 3,077         |
| <b>Total operating expenses</b>            | <b>11,538</b>                               | <b>7,452</b> | <b>12,219</b>                      | <b>8,476</b>  |

Edgar Filing: Zosano Pharma Corp - Form 424B4

|  |           |           |            |          |
|--|-----------|-----------|------------|----------|
| Income (loss) from operations  | (9,057)   | (3,764)   | (7,969)    | 3,148    |
| Other (expense) income:  |           |           |            |          |
| Interest expense, net  | (1,261)   | (526)     | (760)      | (663)    |
| Other expense  | (143)     | (20)      |            |          |
| Warrant revaluation income   |           |           |            | 71       |
| Income (loss) before equity in gain (loss) of joint venture, gain on termination of joint venture, and gain on debt forgiveness      | (10,461)  | (4,310)   | (8,729)    | 2,556    |
| Equity in gain (loss) of joint venture   |           | 45        | (366)      | (738)    |
| Gain on termination of joint venture   |           |           | 3,487      |          |
| Gain on debt forgiveness   | 497       |           |            |          |
| Net income (loss)  | (9,964)   | (4,265)   | \$ (5,608) | \$ 1,818 |
| Net income (loss) per common share basic   | \$ (1.95) | \$ (0.84) | \$ (1.10)  | \$ 0.47  |
| Net income (loss) per common share diluted   | \$ (1.95) | \$ (0.84) | \$ (1.10)  | \$ 0.47  |
| Weighted-average shares outstanding basic  | 5,121     | 5,107     | 5,107      | 3,908    |
| Weighted-average shares outstanding diluted  | 5,121     | 5,107     | 5,107      | 3,908    |
| Pro forma net loss per common share-basic and diluted (unaudited) <sup>(1)</sup>   | \$ (1.68) |           | \$ (1.06)  |          |
| Weighted-average pro forma shares used in computing pro forma net loss per common share basic and diluted (unaudited) <sup>(1)</sup> | 5,696     |           | 5,211      |          |

Table of ContentsIndex to Financial Statements

|                                      | <b>As of September 30, 2014</b>  |                  |                                  |
|--------------------------------------|----------------------------------|------------------|----------------------------------|
|                                      | <b>Actual</b>                    | <b>Pro Forma</b> | <b>Pro Forma<br/>As Adjusted</b> |
|                                      | <b>(unaudited; in thousands)</b> |                  |                                  |
| <b>Balance Sheet Data:</b>           |                                  |                  |                                  |
| Cash and cash equivalents            | \$ 2,303                         | 2,303            | 61,163                           |
| Working capital (deficit)            | \$ (7,853)                       | (1,944)          | 58,359                           |
| Total assets                         | \$ 15,165                        | 15,165           | 72,582                           |
| Long-term debt                       | \$ 14,354                        | 14,354           | 14,354                           |
| Accumulated deficit                  | \$ (134,187)                     | (134,187)        | (134,187)                        |
| Total stockholders' equity (deficit) | \$ (9,222)                       | (3,313)          | 55,547                           |

- (1) Pro forma weighted-average shares outstanding and net loss per common share for the nine months ended September 30, 2014 reflect the conversion of the principal and all unpaid and accrued interest on each convertible promissory note outstanding at September 30, 2014 into shares of common stock at a conversion price equal to 85% of the initial public offering price, as if the conversion had occurred at the beginning of the period. Does not give effect to the issuance of shares from this initial public offering or the concurrent private placement or to the potential effect of dilutive securities, because the impact of such issuance would be anti-dilutive. See Note 2 to our audited consolidated financial statements included elsewhere in this prospectus.



---

Table of Contents

Index to Financial Statements

**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. Before you invest in our common stock, 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 prospectus. 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. When determining whether to invest, you should also refer to the other information contained in this prospectus, 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 losses. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.**

Since inception, we have incurred significant operating losses. For the year ended December 31, 2013 we had net losses of \$5.6 million, and for the nine months ended September 30, 2014 we had net losses of \$10.0 million. As of September 30, 2014, we had an accumulated deficit of \$134.2 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 to raise additional capital to operate our business, 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, 2013, we had total revenue of \$4.3 million, and for the nine months ended September 30, 2014, we had total revenue of \$2.5 million. Substantially all of our revenue to date 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. Further, after completing this offering and the concurrent private placement with Eli Lilly and Company, or Lilly, one of our collaborators, we do not have any committed external source of funds. The net proceeds from this offering and the concurrent private placement and our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund completion of clinical development of any of our product candidates. Accordingly, unless and until we generate revenues and become profitable, we will need to raise additional capital to continue to operate our business, including after the consummation of this offering and the concurrent private placement.

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.

**Table of Contents**

**Index to Financial Statements**

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.

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, or Hercules, and our secured note payable to our largest stockholder, an affiliate of BioMed Realty Trust, 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 and proceeds of this offering and the concurrent private placement with Lilly.**

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 intend to use a portion of the proceeds from this offering to make required payments of interest and principal as they become due under the loan facility with Hercules and the note payable to BMR. 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 and proceeds of this offering and the concurrent private

**Table of Contents**

**Index to Financial Statements**

placement with Lilly. 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 upon which to base an investment decision.**

Although our business was formed in 2006, we have had limited operations since that time. We do not currently have the ability to perform the sales, marketing and manufacturing functions necessary for the production and sale of our products on a commercial scale. 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.

**The report of our independent registered public accounting firm on our 2013 audited consolidated financial statements contains an explanatory paragraph regarding our ability to continue as a going concern.**

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern without additional debt or equity financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our audited consolidated financial statements for 2013 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and make it more difficult for us to obtain financing. If we are unable to obtain sufficient capital in this offering and the concurrent private placement, our business, financial condition and results of operations will be materially and adversely affected and we will need to obtain alternative financing or significantly modify our operational plans to continue as a going concern. Further, if we successfully complete and receive the net proceeds from this offering and the concurrent private placement, given

our planned expenditures for the next several years, including without limitation, expenditures in connection with our planned clinical trials of our lead product candidates, our independent registered public accounting firm may conclude, in connection with the preparation of our financial statements for 2014 or any subsequent period that there continues to be substantial doubt regarding our ability to continue as a going concern.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

Table of Contents

Index to Financial Statements

**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;

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 clinical 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.



---

**Table of Contents**

**Index to Financial Statements**

**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 a new drug application, or 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.

**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.

Table of Contents

Index to Financial Statements

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

If we are required to conduct additional clinical trials or other testing of our 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 an 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

**Table of Contents**

**Index to Financial Statements**

clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. In addition, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

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

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

**Table of Contents**

**Index to Financial Statements**

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.

**Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.**

The manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for our product candidates will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. The regulatory approvals for our product candidates may be subject to limitations on the indicated uses for which the products may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product candidate. The FDA closely regulates the post-approval marketing and promotion of drugs and drug delivery devices to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and, if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry. The FDA currently requires a REMS for Forteo® and will likely require a post-approval REMS for 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



**Table of Contents**

**Index to Financial Statements**

government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

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

restrictions on such product candidate, or manufacturing processes;

restrictions on the labeling or marketing of a product;

restrictions on product distribution or use;

requirements to conduct post-marketing clinical trials;

warning or untitled letters;

withdrawal of the products from the market;

refusal to approve pending applications or supplements to approved applications that we submit;

recall of products;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of marketing approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

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

**We or 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. In addition, we have recently entered into strategic partnership and license agreements with Lilly to commercialize Daily ZP-PTH and with Novo Nordisk A/S, or Novo Nordisk, to commercialize Novo Nordisk's proprietary GLP-1, in each case 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 Teribon<sup>™</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

**Table of Contents**

**Index to Financial Statements**

development program or ceases to market an approved or commercial product, we will not receive any future milestone payments or royalties relating to that program or product under our partnership agreement with that party.

**We are dependent on the successful development of our three leading product candidates.**

We are dependent on the successful development of our three leading product candidates, Daily ZP-PTH, ZP-Glucagon and ZP-Triptan. We cannot assure you that we will be able to complete the clinical trials required for each product candidate in a timely manner, or at all, and ultimately obtain regulatory approval for any of these product candidates. If we are unable to complete clinical trials of and obtain regulatory approval for our product candidates, our business will be significantly affected.

**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.

**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.

**Table of Contents**

**Index to Financial Statements**

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.

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.

Proceeds from this offering and the concurrent private placement in part will be used to develop and expand our internal manufacturing capabilities. 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.

**Table of Contents**

**Index to Financial Statements**

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

If approved for marketing, the commercial success of our products will depend upon their acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of any product candidate will depend on a number of factors, including:

demonstration of clinical safety and efficacy of our products generally;

relative convenience and ease of administration;

prevalence and severity of any adverse effects;

willingness of physicians to prescribe our product and of the target patient population to try new therapies and routes of administration;

efficacy and safety of our products compared to competing products;

introduction of any new products, including generics, that may in the future become available to treat indications for which our products may be approved;

new procedures or methods of treatment that may reduce the incidences of any of the indications in which our products may show utility;

pricing and cost-effectiveness;

effectiveness of our or any future collaborators' sales and marketing strategies;

limitations or warnings contained in FDA-approved labeling; and

our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain

profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

Even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place conditions on approvals including potential requirements or risk management plans and the requirement for a REMS to assure the safe use of the drug or a black-box warning (which is a warning required by the FDA that appears on the package insert for or in literature describing certain prescription drugs, signifying that medical studies indicate that the drug carries a significant risk of serious adverse effects). If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. A black-box warning will limit how we are able to market and advertise our product. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the



**Table of Contents**

**Index to Financial Statements**

initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

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

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

our customers' ability to obtain reimbursement for our product candidates in foreign markets;

our inability to directly control commercial activities because we are relying on third parties;

the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;

different medical practices and customs in foreign countries affecting acceptance in the marketplace;

import or export licensing requirements;

longer accounts receivable collection times;

longer lead times for shipping;

language barriers for technical training;

reduced protection of intellectual property rights in some foreign countries;

foreign currency exchange rate fluctuations; and

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

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

results of operations.

## **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 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.

**Table of Contents**

**Index to Financial Statements**

**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;

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.

---

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

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. 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 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 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

**Table of Contents**

**Index to Financial Statements**

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.

**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.

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

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



**Table of Contents**

**Index to Financial Statements**

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.

**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

**Table of Contents**

**Index to Financial Statements**

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.

**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,

**Table of Contents**

**Index to Financial Statements**

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 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.

**Table of Contents**

**Index to Financial Statements**

**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.

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



---

**Table of Contents**

**Index to Financial Statements**

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 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

**Table of Contents**

**Index to Financial Statements**

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 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

**Table of Contents**

**Index to Financial Statements**

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.

**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

**Table of Contents**

**Index to Financial Statements**

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.

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



**Table of Contents**

**Index to Financial Statements**

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.

**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.

**Table of Contents**

**Index to Financial Statements**

**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.

**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 effective as of the date of this prospectus, 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.

**Table of Contents**

**Index to Financial Statements**

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

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

the difficulty of integrating the operations and personnel of the acquired companies;

the potential disruption of our ongoing business and distraction of management;

potential unknown liabilities and expenses;

the failure to achieve the expected benefits of the combination or acquisition;

the maintenance of acceptable standards, controls, procedures and policies; and

the impairment of relationships with employees as a result of any integration of new management and other personnel.

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

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

We are highly dependent on our chief executive officer, 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**

**There is no public market for our common stock and an active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.**

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade upon the completion of this offering. Although our common stock has been approved for listing on The NASDAQ Capital Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price, if at all.

**Table of Contents**

**Index to Financial Statements**

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

Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;

results of clinical trials of our products or those of our competitors;

announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;

actual or anticipated variations in our operating results;

changes in financial estimates by us or by any securities analysts who might cover our stock;

conditions or trends in our industry;

changes in laws or other regulatory actions affecting us or our industry;

stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;

announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

capital commitments;

investors' general perception of our company and our business;

disputes concerning our intellectual property or other proprietary rights;

recruitment or departure of key personnel; and

sales of our common stock, including sales by our directors and officers or specific stockholders.

In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies whose shares trade in the stock market. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

**If 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 will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.



**Table of Contents**

**Index to Financial Statements**

**If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.**

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement with Lilly. Based on the initial public offering price of \$11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, you will experience immediate dilution of \$6.23 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement and the initial public offering price.

In addition, as of December 31, 2014, we had outstanding stock options to purchase an aggregate of 497,753 shares of common stock at a weighted average exercise price of \$1.59 per share and an outstanding warrant to purchase 31,674 shares of our common stock at an exercise price of \$8.84 per share. To the extent these outstanding options or warrant are exercised, there may be further dilution to investors in this offering.

**A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. Such sales, or the perception that such sales may occur, could negatively impact the market price of our common stock.**

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or if the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

Upon the completion of this offering and the concurrent private placement with Lilly, the 4,500,000 shares sold in this offering will be freely tradable to the extent purchased by nonaffiliates and substantially all of the remaining outstanding shares of common stock will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up agreements between some of our stockholders and the underwriters. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time, which would allow for earlier sales of shares in the public market.

In addition, following the completion of this offering, we intend to file one or more registration statements on Form S-8 registering the issuance of approximately 2.5 million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

**Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.**

Upon the completion of this offering and the concurrent private placement with Lilly, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates will, in the aggregate, beneficially own approximately 60.0% of our outstanding common stock, giving effect to the purchase by certain of our existing investors of \$550,000 of our common stock in this offering, giving effect to Lilly's purchase of 1,363,636 shares in the concurrent private placement and giving effect to the conversion of our outstanding

convertible promissory notes. Of the foregoing beneficial owners, Lilly will beneficially own 11.5% of our common stock. Additionally, funds controlled by one investor, New Enterprise Associates, or NEA, will beneficially own approximately 18.3% of our common stock, and funds controlled by a second investor, BMR, will beneficially own approximately 20.7% of our common stock. As a result, NEA and BMR, acting together, with or

**Table of Contents**

**Index to Financial Statements**

without Lilly, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

**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 these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th or (2) the date on which we have issued more than \$1.0 billion in non-convertible

debt during the prior three-year period.

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.

**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, 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

**Table of Contents**

**Index to Financial Statements**

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. This material weakness had not been remediated as of September 30, 2014.

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 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.

After the completion of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, 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 this offering, 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.**

Upon consummation of this offering, we will become subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or 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.

---

**Table of Contents**

**Index to Financial Statements**

**We will have broad discretion in the use of proceeds from this offering and the concurrent private placement with Lilly and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.**

We will have broad discretion over the use of proceeds from this offering and the concurrent private placement with Lilly. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering and the concurrent private placement to conduct clinical trials of Daily ZP-PTH and ZP-Glucagon, to fund the research and development of our preclinical pipeline, including ZP-Triptan, to make required payments of interest and principal as they become due under our loan facility with Hercules and our note payable to BMR, expand our manufacturing capability, and for working capital and general corporate purposes. Our failure to apply the net proceeds from this offering and the concurrent private placement effectively could compromise our ability to pursue our business strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. In addition, the net proceeds from this offering may not be sufficient for our anticipated uses, and we may need additional resources to progress our product candidates to the stage we expect. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

**Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.**

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of our existing and any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

**We will incur increased costs and demands upon management as a result of being a public company.**

As a public company, we will incur significant additional legal, accounting and other costs. These additional costs, which we estimate will be approximately \$1 million annually, will decrease our net income or increase our consolidated net loss. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The NASDAQ Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We will need to invest significant resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from revenue-generating activities to compliance activities. If we do not comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.





**Table of Contents**

**Index to Financial Statements**

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

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

providing for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board;

authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock;

limiting the liability of, and providing indemnification to, our directors;

limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;

requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;

controlling the procedures for the conduct and scheduling of board and stockholder meetings;

limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our board of directors then in office; and

providing that directors may be removed by stockholders only for cause.

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

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

**Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.**

As of December 31, 2013, we had \$133.1 million of federal and \$129.6 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has previously occurred or will occur as a result of this offering. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

Table of Contents

Index to Financial Statements

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, plan, potential predict, project or the negative of those terms or similar words. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. You should read these statements carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. These forward-looking statements include, among other things, statements about:

the anticipated timing, costs and conduct of our planned preclinical studies and clinical trials, 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;

our commercialization, marketing and manufacturing capabilities and strategy;

our intellectual property position;

our competitive position;

our expectations related to the use of proceeds from this offering and the concurrent private placement with Lilly; and

our estimates regarding expenses, future revenues, capital requirements and needs for additional financing. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the Risk Factors section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

The sections in this prospectus titled Business, Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as other items and sections in this prospectus, discuss some of the factors that could contribute to these differences.

You should read this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Table of Contents

Index to Financial Statements

**INDUSTRY AND MARKET DATA**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations, market position, market opportunity and market size, is based on information from various sources, including independent industry publications and market surveys by third parties privately commissioned by us that we believe to be reliable. In presenting this information, we have also made assumptions that we believe to be reasonable based on such data and other similar sources and on our knowledge of, and our experience to date in, the markets for our product candidates. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in [Risk Factors](#) and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. See [Cautionary Note Regarding Forward-Looking Statements](#).

Table of Contents

Index to Financial Statements

**USE OF PROCEEDS**

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately \$44.4 million, or approximately \$51.3 million if the underwriters exercise their over-allotment option in full, based on the initial public offering price of \$11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will also receive net proceeds of approximately \$14.5 million from our issuance and sale of shares of our common stock to Lilly in the concurrent private placement, after payment by us of the private placement fee due to the representatives of the underwriters.

We expect to use the net proceeds from this offering and the concurrent private placement, together with cash and cash equivalents on hand, to conduct planned clinical trials for our lead product candidates, fund research and development of our preclinical pipeline, service our debt obligations, expand and enhance our manufacturing capabilities and for working capital and general corporate purposes. Specifically, we intend to apply the net proceeds of this offering and the concurrent private placement as follows:

approximately \$7 million to complete our planned clinical development of our ZP-Glucagon product candidate;

approximately \$4 million to prepare for our planned Phase 3 clinical trial of our Daily ZP-PTH product candidate;

approximately \$4 million to complete a Phase 1 clinical trial and a Phase 2 clinical trial of our ZP-Triptan product candidate;

approximately \$3 million to expand and enhance our manufacturing capabilities by purchasing new equipment, enlarging our manufacturing facilities and refining our manufacturing processes and systems;

approximately \$3 million to make required payments of interest and principal as they become due under our term loan facility with Hercules Technology Growth Capital (which bears interest per annum at a floating 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%, and which matures in June 2017) and under our secured note payable to our largest stockholder, an affiliate of BioMed Realty Trust (which bears interest at the same rate as the Hercules loan while the Hercules loan is outstanding and otherwise at 8% per annum, and which matures in April 2016 but is not permitted to be repaid while the Hercules loan is outstanding); and

the remainder for working capital and general corporate purposes.

Our expected use of net proceeds from this offering and the concurrent private placement represents our current intentions based upon our present plans and business condition. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering and the concurrent private placement or the

amounts that we will actually spend on the uses set forth above. Many variables are inherent in the development of our lead product candidates at this time, such as the timing and results of preclinical animal studies and clinical trials and the timing of regulatory submissions and evolving regulatory requirements. The amount and timing of our actual expenditures will depend upon such variables and we cannot currently predict the stage of development we expect the net proceeds of this offering to achieve for our clinical trials and product candidates.

As a result, we will have broad discretion over the use of the net proceeds from this offering and the concurrent private placement, and investors will be relying on our judgment regarding the application of the net proceeds of this offering and the concurrent private placement. In addition, we might decide to postpone or not pursue certain clinical trials or preclinical activities if the net proceeds from this offering and the concurrent private placement and the other sources of cash are less than expected.

**Table of Contents**

**Index to Financial Statements**

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in any future financing instruments, provisions of applicable law and other factors the board deems relevant. See **Risk Factors** **Risks relating to an investment in our common stock** Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.



Table of ContentsIndex to Financial Statements**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2014 on:

An actual basis;

A pro forma basis giving effect to the automatic conversion of the principal and all unpaid and accrued interest on each convertible promissory note outstanding at September 30, 2014 into an aggregate of 631,947 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 additional paid-in capital, each upon the closing of this offering; and

A pro forma as adjusted basis, giving additional effect to the sale of 4,500,000 shares of our common stock offered in this offering at the initial public offering price of \$11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, the sale of 1,363,636 shares of our common stock to Lilly in the concurrent private placement, after payment by us of the private placement fee due to the representatives of the underwriters, and the filing and effectiveness of a restated certificate of incorporation upon the closing of this offering.

You should read the following table in conjunction with our financial statements and related notes, *Selected Consolidated Financial Data* and *Management's Discussion and Analysis of Financial Condition and Results of Operations* appearing elsewhere in this prospectus.

|   | <b>As of September 30, 2014</b>         |                  |                              |
|---|---|------------------|------------------------------|
|   | <b>Actual</b>                           | <b>Pro Forma</b> | <b>Pro Forma as Adjusted</b> |
|   | <b>(in thousands, except par value)</b> |                  |                              |
| Cash and cash equivalents   | \$ 2,303                                | 2,303            | 61,163                       |
| Short-term investment   | 343                                     | 343              | 343                          |
| Convertible promissory notes payable, current   | \$ 5,909                                |                  |                              |
| Freestanding warrant liability  | 114                                     | 114              | 114                          |
| Secured promissory note   | 3,896                                   | 3,896            | 3,896                        |
| Related party secured note payable  | 10,458                                  | 10,458           | 10,458                       |
| Stockholders' equity (deficit):   |   |                  |                              |
| Common stock, \$0.0001 par value; 30,000 shares authorized, actual and pro forma; 100,000 shares authorized, pro forma as adjusted; 5,140 shares, 5,772 shares, and 11,635 shares issued and outstanding, actual, pro forma, and pro forma as adjusted, respectively. | 1                                       | 1                | 2                            |
| Additional paid-in capital  | 124,964                                 | 130,873          | 189,732                      |

Edgar Filing: Zosano Pharma Corp - Form 424B4

|                                     |           |           |           |
|-------------------------------------|-----------|-----------|-----------|
| Accumulated deficit                 | (134,187) | (134,187) | (134,187) |
| Total stockholders equity (deficit) | (9,222)   | (3,313)   | 55,547    |
| Total capitalization                | \$ 11,155 | 11,155    | 70,015    |

The table above does not include the following potentially dilutive shares of common stock outstanding:

527,619 shares of our common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$1.58 per share as of September 30, 2014;

24,328 shares of our common stock reserved for future issuance under our 2012 stock incentive plan as of September 30, 2014; and

31,674 shares of our common stock issuable upon the exercise of a warrant outstanding as of September 30, 2014 at an exercise price of \$8.84 per share.

Table of ContentsIndex to Financial Statements**DILUTION**

If you invest in our common stock, your equity interest in our company will be diluted immediately to the extent of the difference between the initial public offering price per share you will pay in this offering and the pro forma as adjusted net tangible book value (deficit) per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 30, 2014 was \$(9.2 million), or \$(1.79) per share of common stock. Our adjusted historical net tangible book value (deficit) as of September 30, 2014 was \$11.2 million, or \$1.56 per share of common stock. Our adjusted net tangible book value (deficit) per share set forth below represents our total assets, excluding intangible assets, less our total liabilities, divided by the number of shares of our common stock outstanding on September 30, 2014, after giving effect to the sale of 1,363,636 shares of our common stock to Lilly in the concurrent private placement (after deducting the private placement fee payable by us) and the conversion of our convertible promissory notes outstanding at September 30, 2014 into 631,947 shares of common stock, resulting in the liability for such notes being reclassified to additional paid-in capital, upon the closing of this offering. For purposes of this calculation, we use a purchase price per share in the concurrent private placement equal to the initial public offering price and a conversion price for the principal and all unpaid and accrued interest on each convertible promissory note equal to 85% of the initial public offering price.

After giving effect to the sale of 4,500,000 shares of common stock in this offering at the initial public offering price of \$11.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value (deficit) as of September 30, 2014 would have been \$55.5 million, or \$4.77 per share. This represents an immediate increase in adjusted net tangible book value to existing stockholders of \$3.21 per share and an immediate dilution of \$6.23 per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this per share dilution:

|   |           |
|---|-----------|
| Initial public offering price   | \$ 11.00  |
| Historical net tangible book value (deficit) per share as of September 30, 2014                                 | \$ (1.79) |
| Increase attributable to concurrent private placement and conversion of convertible promissory notes            | 3.35      |
| Adjusted net tangible book value (deficit) per share as of September 30, 2014                                   | \$ 1.56   |
| Increase in adjusted net tangible book value per share attributable to investors participating in this offering | \$ 3.21   |
| Pro forma as adjusted net tangible book value per share after this offering                                     | \$ 4.77   |
| Pro forma as adjusted dilution per share to investors participating in this offering                            | \$ 6.23   |

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value (deficit) will increase to \$5.07 per share, representing an immediate increase in adjusted net tangible book value (deficit) to existing stockholders of \$3.51 per share and an immediate dilution of \$5.93 per share to new investors.

If any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.

The number of shares of our common stock reflected in the discussion and the table above is based on 5,139,630 shares of our common stock outstanding as of September 30, 2014, includes an additional 1,363,636 shares of our common stock that will be sold to Lilly in the concurrent private placement, and an additional 631,947 shares of our common stock that will be issued upon the automatic conversion of our convertible promissory notes outstanding as of September 30, 2014, based on the initial public offering price of \$11.00 per share, and excludes:

527,619 shares of common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan as of September 30, 2014, at a weighted average exercise price of \$1.58 per share;

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

24,328 shares of common stock available for future issuance under our 2012 Stock Incentive Plan as of September 30, 2014;

an additional 1,400,000 shares of our common stock that will be made available for future issuance under our 2014 Equity and Incentive Plan adopted in connection with the closing of this offering; and

31,674 shares of common stock issuable upon exercise of a warrant outstanding as of September 30, 2014 at an exercise price of \$8.84 per share.

The following table summarizes, on the pro forma as adjusted basis described above as of September 30, 2014, the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders (which, for purposes of this table, includes the shares purchased by Lilly in the concurrent private placement) and by new investors purchasing shares of common stock in this offering at the initial public offering price of \$11.00 per share, before the deduction of the underwriting discounts and commissions and estimated offering expenses payable by us:

|                       | Shares Purchased  |               | Total Consideration   |               | Average Price |
|-----------------------|-------------------|---------------|-----------------------|---------------|---------------|
|                       | Number            | %             | Amount                | %             | Per Share     |
| Existing stockholders | 7,135,213         | 61.3%         | \$ 145,349,000        | 74.6%         | \$ 20.37      |
| New investors         | 4,500,000         | 38.7          | 49,500,000            | 25.4          | \$ 11.00      |
| <b>Total</b>          | <b>11,635,213</b> | <b>100.0%</b> | <b>\$ 194,849,000</b> | <b>100.0%</b> |               |

If the underwriters' overallotment option is exercised in full, the number of shares held by new investors will increase to 5,175,000, or 42.0% of the total number of shares of common stock outstanding after this offering, and the percentage of shares held by existing stockholders will decrease to 58.0% of the total shares outstanding after this offering.

The number of shares purchased from us by existing stockholders is based on 5,139,630 shares of our common stock outstanding as of September 30, 2014, includes an additional 1,363,636 shares of our common stock that will be sold to Lilly in the concurrent private placement, based on the initial public offering price of \$11.00 per share, and an additional 631,947 shares of our common stock that will be issued upon the automatic conversion of our convertible promissory notes outstanding as of September 30, 2014, based on the initial public offering price of \$11.00 per share, and excludes:

527,619 shares of common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan as of September 30, 2014, at a weighted average exercise price of \$1.58 per share;

Edgar Filing: Zosano Pharma Corp - Form 424B4

24,328 shares of common stock available for future issuance under our 2012 Stock Incentive Plan as of September 30, 2014;

an additional 1,400,000 shares of our common stock that will be made available for future issuance under our 2014 Equity and Incentive Plan adopted in connection with the closing of this offering; and

31,674 shares of common stock issuable upon exercise of a warrant outstanding as of September 30, 2014 at an exercise price of \$8.84 per share.

Certain of our existing investors have agreed to purchase an aggregate amount of \$550,000 worth of our common stock in this offering at the initial public offering price. The foregoing discussion and tables do not reflect the purchases by these investors in the number of shares purchased by existing stockholders.

Table of ContentsIndex to Financial Statements**SELECTED CONSOLIDATED FINANCIAL DATA**

The following table summarizes our selected consolidated financial data for the periods and as of the dates indicated. Our selected statements of operations data for each of the years ended December 31, 2013 and 2012, and our selected balance sheet data as of December 31, 2013, have been derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. Our selected statements of operations data for the nine months ended September 30, 2014 and 2013, and our selected balance sheet data as of September 30, 2014, have been derived from our unaudited interim condensed consolidated financial statements and related notes included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to state fairly our financial position as of September 30, 2014 and the results of our operations for the nine months ended September 30, 2014 and 2013. Our selected financial data should be read together with the section entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations* and with our financial statements and their related notes, which are included elsewhere in this prospectus. Our historical results are not indicative of the results that may be expected in the future.

|   | <b>Nine Months<br/>Ended September 30,<br/>2014      2013<br/>(unaudited)</b> |                | <b>Year ended<br/>December 31,<br/>2013      2012</b> |               |
|---|---|----------------|---|---------------|
|   | <b>(in thousands, except per share amounts)</b>                               |                |   |               |
| <b>Statements of Operations Data:</b>   |   |                |   |               |
| License fees revenue  | \$ 1,819  | \$ 3,688       | \$ 4,250  | \$ 9,250      |
| Collaborative development support services  | 662   |                |   | 2,374         |
| <b>Total revenue</b>  | <b>2,481</b>  | <b>3,688</b>   | <b>4,250</b>  | <b>11,624</b> |
| <b>Operating expenses:</b>  |   |                |   |               |
| Cost of license fees revenue  | 100   |                |   |               |
| Research and development  | 8,230   | 4,760          | 7,637   | 5,399         |
| General and administrative  | 3,208   | 2,692          | 4,582   | 3,077         |
| <b>Total operating expenses</b>   | <b>11,538</b>   | <b>7,452</b>   | <b>12,219</b>   | <b>8,476</b>  |
| Income (loss) from operations   | (9,057)   | (3,764)        | (7,969)   | 3,148         |
| <b>Other income (expense):</b>  |   |                |   |               |
| Interest expense, net   | (1,261)   | (526)          | (760)   | (663)         |
| Other expense   | (143)   | (20)           |   |               |
| Warrant revaluation income  |   |                |   | 71            |
| <b>Income (loss) before equity in loss of joint venture, gain on termination of joint venture, and gain on debt forgiveness</b> | <b>(10,461)</b>   | <b>(4,310)</b> | <b>(8,729)</b>  | <b>2,556</b>  |
| Equity in gain (loss) of joint venture  |   | 45             | (366)   | (738)         |
| Gain on termination of joint venture  |   |                | 3,487   |               |

Edgar Filing: Zosano Pharma Corp - Form 424B4

|  |           |           |            |          |
|--|-----------|-----------|------------|----------|
| Gain on debt forgiveness   | 497       |           |            |          |
| Net income (loss)  | (9,964)   | (4,265)   | \$ (5,608) | \$ 1,818 |
| Net income (loss) per common share basic   | \$ (1.95) | \$ (0.84) | \$ (1.10)  | \$ 0.47  |
| Net income (loss) per common share diluted   | \$ (1.95) | \$ (0.84) | \$ (1.10)  | \$ 0.47  |
| Weighted-average shares used in computing net income (loss) per common share basic                             | 5,121     | 5,107     | 5,107      | 3,908    |
| Weighted-average shares used in computing net income (loss) per share diluted                                  | 5,121     | 5,107     | 5,107      | 3,908    |
| Pro forma net loss per common share basic and diluted <sup>(1)</sup>   | \$ (1.68) |           | \$ (1.06)  |          |
| Weighted-average shares used in computing pro forma net loss per common share basic and diluted <sup>(1)</sup> | 5,696     |           | 5,211      |          |



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

|   | <b>As of<br/>September 30,<br/>2014<br/>(unaudited)</b> | <b>As of December 31,<br/>2013                      2012</b> |           |
|---|---|--|-----------|
|   | <b>(in thousands)</b>                                   |  |           |
| <b><i>Balance Sheet Data:</i></b>         |   |  |           |
| Cash and cash equivalents                 | \$ 2,303  | \$ 5,913   | \$ 4,973  |
| Working capital (deficit)                 | \$ (7,853)  | (1,368)  | 1,925     |
| Total assets                              | \$ 15,165   | 22,084   | 19,628    |
| Long-term debt                            | \$ 14,354   | 9,711  | 9,026     |
| Accumulated deficit                       | \$ (134,187)  | (124,223)  | (118,615) |
| Total stockholders equity (deficit)       | \$ (9,222)  | 477  | 6,020     |
| Total liabilities and stockholders equity | \$ 15,165   | 22,084   | 19,628    |

- (1) Pro forma weighted-average shares outstanding and net loss per common share, basic and diluted, for the year ended December 31, 2013 and the nine months ended September 30, 2014 reflect the conversion of our convertible promissory notes outstanding at such dates into shares of common stock, as if the conversion had occurred at the beginning of the respective period. Does not give effect to the issuance of shares from this offering or the concurrent private placement or the potential effect of outstanding dilutive securities where the impact of such issuance would be anti-dilutive. See Note 2 to our audited consolidated financial statements included elsewhere in this prospectus.

---

**Table of Contents**

**Index to Financial Statements**

**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 the section entitled "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements." Our actual results may differ materially from those described below. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**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 intend to commence a Phase 2 clinical trial to evaluate the performance of ZP-Glucagon in the first quarter of 2015 and also complete the trial in the first 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 commence a Phase 1 trial in the first half 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

---

**Table of Contents**

**Index to Financial Statements**

currently have no sales, marketing or distribution capabilities and thus our ability to market our products in the future will depend in part on our ability to develop such capabilities either alone or with collaboration partners.

In 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 ended 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.

**Key Developments Important to Understanding Our Financial Statements**

The audited consolidated financial statements, unaudited interim condensed consolidated financial statements and the following discussion include the consolidated accounts of Zosano Pharma Corporation and subsidiaries, and our 100% interest in ZP Group LLC, the entity we operated as a joint venture with Asahi until its termination in December 2013. All intercompany balances and transactions have been eliminated in consolidation in our audited consolidated financial statements and our unaudited interim condensed consolidated financial statements.

***2012 recapitalization***

Since inception in 2006, we have been financed primarily by the sale of preferred stock and debt to private investors. In January 2012, Zosano Pharma Corporation was formed (under the name ZP Holdings, Inc.). In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of Zosano Pharma Corporation was merged with and into ZP Opco, Inc. (then named Zosano Pharma, Inc.), whereby ZP Opco, Inc. was the surviving entity and became a wholly-owned subsidiary of Zosano Pharma Corporation. As part of this reorganization, Zosano Pharma Corporation issued shares of its common stock to the stockholders and optionholders of ZP Opco, Inc. in exchange for the cancellation of all outstanding common and preferred stock and all outstanding stock options of ZP Opco, Inc. Also, in connection with this reorganization, all outstanding debt and related accrued interest of ZP Opco, Inc. held by investors was cancelled, and all outstanding warrants to purchase capital stock were terminated. The recapitalization included a stock purchase and loan restructuring agreement with two entities affiliated with BioMed Realty Trust, or BMR, under which we issued shares of our common stock to these two BMR affiliates and a secured promissory note to one of these BMR affiliates, as more fully described under the caption *Restructuring of lease agreement with BMR*

below. BMR, through its affiliated entities, is the landlord for our Fremont, California subsidiary and one of our stockholders and creditors.

***Restructuring of lease agreement with BMR***

Our operations are conducted in 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

---

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

April 2012, we amended the lease agreement with BMR to reduce future rent obligations to amounts ranging from approximately \$600,000 to \$891,000 per year over a new lease term of seven years. In addition, ZP Group LLC, the entity operating our previous joint venture with Asahi, signed the new lease as a sub-tenant. In consideration of these amendments, BMR waived all outstanding principal, accrued interest and unpaid rent as of April 2012. We issued a new four-year non-callable secured promissory note to BMR with an original principal amount of \$8.6 million bearing interest at the rate of 8% per annum, compounded annually. All principal and interest will become due and payable to BMR in April 2016. The note, which we refer to herein as the BMR secured promissory note, is secured by substantially all of our assets, including intellectual property. In June 2014, we amended the BMR 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, as described under the caption *Hercules loan* below, and to provide that any failure by us to pay any amount under the BMR secured promissory note during the period from the maturity date of the BMR secured promissory note through the date that the Hercules loan is repaid in full will not constitute a default under the BMR secured promissory note. In addition to the note, we issued shares of our common stock to two entities affiliated with BMR in connection with the lease restructuring. As a result, BMR affiliates hold approximately 39.4% of our outstanding shares as of December 31, 2014. In exchange for BMR's agreement to subordinate the BMR secured promissory note to the Hercules loan, we issued 31,250 shares of our common stock to the BMR affiliate that is the holder of the BMR secured promissory note.

***Asahi license and collaboration agreement***

In February 2011, we entered into a strategic partnership and license agreement with Asahi whereby we granted to Asahi an exclusive license to use our microneedle patch system for the treatment and prevention of osteoporosis in Japan, China, Taiwan and South Korea. As consideration for the license, Asahi paid us an upfront license fee of \$7.5 million and agreed to pay contingent payments, based upon the achievement of certain contractually specified milestones, and additional cash royalty payments on sales of future products to be commercialized by Asahi using our microneedle patch system. As of December 31, 2013, Asahi had paid us a total of \$16.5 million in additional milestone payments. As part of the collaboration, Asahi also agreed to reimburse us for costs to develop and commercialize our microneedle patch system for delivery of Asahi's Teribone product. Under the license agreement, we were responsible for all product development, including manufacturing of the clinical trial material in support of development activities and clinical trials planned to be conducted by Asahi in Japan.

In April 2012, we reached agreement with Asahi to amend the license agreement and transfer the manufacturing responsibilities from us to ZP Group LLC, a new entity created to grant increased management control to Asahi and its affiliates. ZP Group LLC was a joint venture of AKP USA, Inc., or AKPUS, an affiliate of Asahi, and us, with each holding 50% of the equity interests. We contributed fixed assets to ZP Group LLC necessary for production of clinical trial material. In addition, all of our manufacturing and engineering personnel and some other employees terminated their employment with us and became employees of ZP Group LLC. ZP Group LLC then served as a contract manufacturing organization to both Asahi and us.

As part of the agreement to form ZP Group LLC, the original license agreement with Asahi was amended to eliminate the product milestones and to reduce the future royalties payable to us on sales of products governed by the agreement. In addition, AKPUS provided ZP Group LLC with a line of credit for working capital needs, and we had the right to receive quarterly cash distributions from ZP Group LLC based on depreciation and utilization of the equipment assets contributed by us to the joint venture.

In connection with our collaboration, Asahi conducted Phase 1 clinical trials in Japan using our microneedle patch system to deliver a patch formulation of Asahi's Teribone product. One of Asahi's requirements for the Phase 1 clinical trials was that the patch formulation of Teribone delivered using our microneedle patch system demonstrate bioavailability equal to or greater than the existing Teribone injection. In the most recent Phase 1 clinical trial conducted by Asahi, which ended in the second half of 2013, our microneedle patch system did not demonstrate bioavailability of the coated drug formulation at or above these levels. These results brought into question the need for further studies to demonstrate the correlation, or lack thereof, between the bioavailability of Teribone and its efficacy, as measured by the increase in bone mineral density, or BMD. Despite our belief,

---

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

based in part on our previous 2008 Phase 2 clinical trial involving our daily dose of ZP-PTH, that there is no direct correlation between bioavailability of PTH and BMD, we came to an agreement with Asahi not to pursue further development of this program.

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. As a result, certain employees of ZP Group LLC were hired by us. 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 January 2014, also in connection with the termination agreement, our strategic partnership and license agreement was terminated, which included a termination of the exclusive license to Asahi to use our microneedle patch system for the treatment and prevention of osteoporosis in Japan, China, Taiwan and South Korea.

***Bridge financing***

In September 2013, we raised approximately \$3 million through the sale of convertible promissory notes to current investors, including affiliates of BMR, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P., and ProQuest Management LLC. In February 2014, we sold an additional \$2.5 million of the same series of convertible promissory notes to affiliates of BMR and New Enterprise Associates 12, Limited Partnership, and in December 2014, we sold an additional \$1.3 million of convertible promissory notes to New Enterprise Associates 12, Limited Partnership and an affiliate of BMR. The convertible promissory notes, which we refer to herein as the convertible bridge notes, are unsecured, subordinated notes which mature on September 9, 2014 (in the case of the September 2013 and February 2014 convertible bridge notes) and on June 1, 2017 (in the case of the December 2014 convertible bridge notes) and accrue simple interest at the rate of 8% per annum. In June 2014, we amended the September 2013 and February 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 will not constitute a default under the convertible bridge notes, and the December 2014 convertible bridge notes provide for the same. Upon the closing of a qualified financing, which is defined in the convertible bridge notes as an equity financing on or prior to March 31, 2015 in which we raise at least \$25 million (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly described below), the principal and all unpaid and accrued interest on each convertible bridge note will automatically convert into the equity security sold in the qualified financing, at price equal to 85% of the lowest per share price at which the equity security is sold in the qualified financing. In December 2014, we amended the September 2013 and February 2014 convertible bridge notes to extend the date by which a qualified financing must occur in order for the convertible bridge notes to convert into equity securities to March 31, 2015. The principal and all unpaid and accrued interest on each convertible bridge note will automatically convert into our common stock at a price equal to 85% of the initial public offering price, upon the closing of this offering if the closing occurs on or before March 31, 2015. Our selected consolidated financial data on page 52 reflects the impact, on a pro forma basis, of the conversion of these notes outstanding at December 31, 2013 and at September 30, 2014 on our net loss per common share, given certain assumptions described therein.

***Acquisition of Eco Planet Corp.***



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 ZP Holdings, 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 through the sale of additional common stock or other securities to institutional investors in a private

**Table of Contents**

**Index to Financial Statements**

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 and we are actively pursuing the sale of Zosano, Inc.

***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 new transdermal presentation 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. Initially, we will collaborate with Novo Nordisk on nonclinical experiments to verify delivery of semaglutide using our microneedle patch system.

Under the terms of the agreement, we have granted Novo Nordisk a worldwide, exclusive license to develop and commercialize Novo Nordisk's proprietary GLP-1 analogues using our microneedle patch system. Novo Nordisk will, pending successful outcomes of nonclinical and clinical testing, be responsible for commercialization of all products under the agreement. We received an upfront payment of \$1 million from Novo Nordisk upon entering into the strategic partnership and license agreement.

The agreement also provides for potential milestone payments upon achieving certain nonclinical, clinical, regulatory and sales milestones of \$60 million for the first product and \$55 million for each additional product. Novo Nordisk has also agreed to pay us royalties on sales of products in the low to mid single digits and we will receive development support, as well as reimbursement of all development and manufacturing costs relating to the Novo Nordisk program.

***Hercules loan***

In June 2014, we entered into a \$4 million term loan facility with Hercules Technology Growth Capital. 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%. 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.

The BMR secured promissory note and the convertible bridge notes are subordinated in right of payment to the Hercules loan, and BMR's security interest in substantially all of our assets under the BMR secured promissory note is subordinate to Hercules' security 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 BMR secured promissory note, even if the subordination with Hercules and BMR allows for the payment. Any such payment will give Hercules the

right to accelerate any or all of the Hercules loan. In exchange for BMR's agreement to subordinate the BMR secured promissory note to the Hercules loan, we issued 31,250 shares of our common stock to the BMR affiliate that is the holder of the BMR secured promissory note.

**Table of Contents**

**Index to Financial Statements**

***Collaboration with Eli Lilly and Company***

In November 2014, we entered into a strategic partnership and license agreement with 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. Lilly will be responsible, pending successful clinical trial outcomes and regulatory approval of our Daily ZP-PTH product candidate, 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. Under the terms of the license agreement, 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 November 2014, we entered into a stock purchase agreement with Lilly pursuant to which Lilly will purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price.

As a result of entering into our license agreement with Lilly, we have reprioritized our research and product development activities to focus on Daily ZP-PTH as our lead product candidate, rather than on our ZP-PTH product for weekly administration, or Weekly ZP-PTH, on which our research and development activities were focused prior to November 2014.

**Financial Operations Overview**

***Summary***

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 September 30, 2014, we had an accumulated deficit of approximately \$134.2 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization. We cannot assure you that we will receive additional 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 to increase as we continue to advance our product candidates through clinical and manufacturing 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.

After this offering, additional capital will be required to undertake our planned research and manufacturing development activities and to meet our operating requirements through 2015 and beyond. We intend to raise such capital through the issuance of additional equity through public or private offerings, borrowings of debt, and strategic alliances with partner companies. 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 and sell unsecured assets, 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.

---

**Table of Contents****Index to Financial Statements*****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 September 30, 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 nine months ended September 30, 2014, we recognized approximately \$694,000 of license fees revenue and approximately \$662,000 of collaborative development support services revenue from Novo Nordisk. As of December 31, 2013, we had received an aggregate of \$16.5 million under the license agreement with Asahi. Reimbursements for research and development expenses under our prior license agreement with Asahi for research and development and out-of-pocket expenses were based on expenses actually incurred and these payments were recognized as revenue on a time and material basis and recorded as service revenue in the consolidated statement of operations.

***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 \$100,000 due to ALZA is charged to expense in our condensed consolidated statement of operations for the nine months ended September 30, 2014.

***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 clinical research organizations, or 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 contract manufacturing organizations, or CMOs;

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

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, a Phase 2 trial to investigate the safety and efficacy of our ZP-Glucagon product candidate (expected to commence in the first quarter of 2015), and Phase 1 and Phase 2 trials of our ZP-Triptan product candidate (expected to commence in the first half of 2015 and the second half of 2015, respectively), and as we begin to enhance our manufacturing facilities in preparation of commercial launch.

We began tracking our external costs by project in 2006, and implemented a timesheet tracking system for personnel-related costs in the first quarter of 2011. The following table summarizes our research and development expenses incurred during the nine months ended September 30, 2014 and 2013, during the years ended December 31, 2013 and 2012, and from our inception to September 30, 2014:

|  | Nine Months<br>Ended September 30, |                 | Year Ended<br>December 31, |                 | From Inception<br>in October 2006<br>to<br>September 30, 2014 |
|--|------------------------------------|-----------------|----------------------------|-----------------|---|
|  | 2014                               | 2013            | 2013                       | 2012            |   |
|  | (in thousands)                     |                 |                            |                 |   |
| Product candidate:   |                                    |                 |                            |                 |   |
| ZP-PTH <sup>(1)</sup>  | \$ 528                             | \$ 756          | \$ 1,757                   | \$              | \$ 38,663   |
| ZP-Glucagon <sup>(2)</sup>                                   | 959                                | 1,667           | 2,886                      | 139             | 3,985   |
| ZP-Triptan <sup>(3)</sup>                                    | 865                                | 33              | 142                        |                 | 1,007   |
| Collaborative development support <sup>(4)</sup>             | 392                                |                 |                            | 1,882           | 2,274   |
| Other research projects <sup>(5)</sup>                       | 1,245                              | 926             | 972                        | 1,881           | 9,286   |
| Unallocated research and development expenses <sup>(6)</sup> | 4,241                              | 1,379           | 1,879                      | 1,497           | 63,087  |
| <b>Total research and development expenses</b>               | <b>\$ 8,230</b>                    | <b>\$ 4,761</b> | <b>\$ 7,636</b>            | <b>\$ 5,399</b> | <b>\$ 118,302</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. 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

**Table of Contents**

**Index to Financial Statements**

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 primarily of salaries and related expenses for executive, finance, human resources management and other administrative personnel, legal and accounting fees, business insurance, allocation of facilities-related costs, costs of maintaining our intellectual property portfolio and other corporate expenses. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administration and professional services.

***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 2012 consists of interest paid to Silicon Valley Bank for the debt facility we paid off in connection with our recapitalization in April 2012 and accrued interest on the BMR secured promissory note. For 2013, interest expense reflects accrued interest on both the convertible bridge notes issued in September 2013 and the BMR secured promissory note as well as interest on the line of credit. For the nine months ended September 30, 2014, interest expense reflects accrued interest on the convertible bridge notes issued in September 2013 and February 2014, accrued interest on the BMR secured promissory note, and accrued interest related to the Hercules loan.

***Other expense***

Other expense consists of certain miscellaneous expenses that are not included in the categories described above. For the nine months ended September 30, 2014, other expense consisted primarily of expense related to the fair value of 31,250 shares of common stock that were issued to BMR in June 2014 as an inducement for the subordination of debt in connection with the Hercules loan.

***Warrant revaluation income***

Warrant revaluation income in 2012 resulted from the re-measurement of our preferred stock warrant liability associated with the warrants to purchase preferred stock issued to lenders under our debt facilities and certain of the former preferred stockholders of ZP Opco, Inc. prior to the 2012 reorganization. We recorded changes to the estimated fair value of the preferred stock warrants as income or loss at each balance sheet date until they were exercised, expired or converted into shares of our common stock. All then outstanding warrants were retired in connection with our 2012 recapitalization.

*Equity in loss of joint venture*

Equity in loss of joint venture reflects our share of ZP Group LLC's net loss for the applicable reporting period. Through December 20, 2013, 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 depreciation expense on our contributed capital equipment.

**Table of Contents**

**Index to Financial Statements**

***Gain on termination of joint venture***

We recorded a one-time gain 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 provides 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 \$497,000 in the first quarter of 2014.

**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. 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.

***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.

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

**Table of Contents**

**Index to Financial Statements**

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 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 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.

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.

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

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 are subject to the 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.

We estimate the fair value of our stock options and awards and the related compensation expense using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) estimated period of time outstanding, or expected term, of the options granted, (2) volatility, (3) risk-free interest rate and (4) expected dividend yield. Because stock-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeiture rates differ from those estimates. We have estimated expected forfeitures of stock options based on our historical employment turnover rate and expected turnover in developing a future forfeiture rate. If our actual forfeiture rate varies from our estimates, additional adjustments to compensation expense may be required in future periods. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates, but the estimates involve inherent uncertainties and the application of management judgment. As a result, if facts change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

Information pertaining to the Black-Scholes valuation assumptions used for stock options granted to employees and to employees of our previous joint venture, ZP Group LLC, during 2014, 2013 and 2012 is as follows:

| For valuation of employees and joint venture employees grants: | Nine Months Ended  |                    |                              |                              |
|--|--------------------|--------------------|------------------------------|------------------------------|
|  | September 30, 2014 | September 30, 2013 | Year Ended December 31, 2013 | Year Ended December 31, 2012 |
| Assumptions:   |                    |                    |                              |                              |
| Expected volatility  | 89.00%             | 89.00%             | 89.00%                       | 89.00%                       |
| Expected term in years   | 6.08               | 6.08               | 6.08                         | 6.08                         |
| Risk-free interest rate  | 2.02%-2.12%        | 1.74%              | 1.74%                        | 0.97%                        |
| Expected dividend yield  | 0.00%              | 0.00%              | 0.00%                        | 0.00%                        |

Information pertaining to the Black-Scholes valuation of common stock options granted to non-employees during 2014, 2013 and 2012 is as follows:

**Year Ended December 31,**



**Nine Months Ended  
September 30,**

| <b>For valuation of non-employee grants:</b> | <b>2014</b> | <b>2013</b> | <b>2013</b> | <b>2012</b> |
|--|-------------|-------------|-------------|-------------|
| <b>Assumptions:</b>                          |             |             |             |             |
| Expected volatility                          | 89.00%      | 89.00%      | 89.00%      | 89.00%      |
| Expected term in years                       | 10.00       | 10.00       | 10.00       | 10.00       |
| Risk-free interest rate                      | 2.66%-2.89% | 3.01%       | 3.01%       | 1.78%       |
| Expected dividend yield                      | 0.00%       | 0.00%       | 0.00%       | 0.00%       |

**Table of Contents**

**Index to Financial Statements**

The dividend yield is based upon the assumption that we will not declare a dividend over the life of the options. We have been unable to use historical employee exercise and option expiration data to estimate the expected term assumption for the Black-Scholes grant-date valuation. We have therefore utilized the simplified method, as prescribed by the SEC's Staff Accounting Bulletin No. 107, Share-Based Payment, to estimate on a formula basis the expected term of our stock options considered to have plain vanilla characteristics. The risk-free interest rate is based on the U.S. Treasury strip rate on the date of the grant. We compute volatility under the guideline public company method by utilizing the average of a peer group comprised of publicly-traded companies and expect to continue to do so until we have adequate historical data regarding the volatility of our traded stock price. The peer group was determined based upon companies considered to be direct competition or having been presented by independent parties as a comparable company based upon market sector. In determining a comparable, we have excluded large-cap entities. Forfeitures are estimated at the time of the grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Share-based compensation expense recognized in the statement of operations for the years ended December 31, 2012 and 2013 does not record tax-related effects on stock-based compensation given our historical and anticipated operating losses and offsetting changes in its valuation allowance that fully reserves against potential deferred tax assets.

Table of ContentsIndex to Financial Statements*Stock option and restricted stock award grants during 2012, 2013 and through September 30, 2014*

The following summarizes all stock options and restricted stock awards granted during the years ended December 31, 2012 and 2013:

| Type of Grant    | Grant Date        | Reason For Grant                              | Shares Underlying Grants | Exercise Price of Shares (in \$) | Fair Value                  |                         | Total Stock-Based Compensation (in \$ in thousands) |
|------------------|-------------------|---|--------------------------|----------------------------------|-----------------------------|-------------------------|---|
|                  |                   |   |                          |                                  | Share at Grant Date (in \$) | Value Per Share (in \$) |   |
| Stock options    | June 15, 2012     | Awards to founder                             | 70,753                   | 1.40                             | 1.40                        | 1.03                    | 73  |
| Stock options    | July 1, 2012      | Awards to founding CEO                        | 141,506                  | 1.54 <sup>(1)</sup>              | 1.40                        | 1.01                    | 143   |
| Stock options    | July 25, 2012     | Awards to employees                           | 42,071                   | 1.40                             | 1.40                        | 1.03                    | 43  |
| Stock options    | July 25, 2012     | Awards to non-employee advisor and consultant | 2,418                    | 1.40                             | 1.40                        | (2)                     | (2)   |
| Stock options    | July 25, 2012     | Awards to employees of joint venture          | 30,103                   | 1.40                             | 1.40                        | (3)                     | (3)   |
| Stock options    | December 11, 2012 | Awards to employees                           | 22,916                   | 1.40                             | 1.40                        | 1.03                    | 24  |
| Restricted stock | December 11, 2012 | Awards to officer employees                   | 12,500                   |                                  | 1.40                        | 1.40                    | 18  |
| Stock options    | December 11, 2012 | Awards to employees of joint venture          | 2,750                    | 1.40                             | 1.40                        | (3)                     | (3)   |
| Stock options    | December 11, 2012 | Awards to non-employee advisor and consultant | 2,418                    | 1.40                             | 1.40                        | (2)                     | (2)   |

**Total number of shares granted in 2012** **327,435**

|               |                   |   |        |      |      |      |     |
|---------------|-------------------|---|--------|------|------|------|-----|
| Stock options | February 15, 2013 | Awards to employees                           | 18,858 | 1.40 | 1.40 | 0.97 | 18  |
| Stock options | February 15, 2013 | Awards to employees of joint venture          | 10,569 | 1.40 | 1.40 | (3)  | (3) |
| Stock options | April 19, 2013    | Awards to a director                          | 28,301 | 1.40 | 1.40 | 0.97 | 27  |
| Stock options | May 24, 2013      | Awards to employees                           | 55,112 | 1.40 | 1.40 | 0.97 | 53  |
| Stock options | June 19, 2013     | Awards to employees                           | 7,500  | 1.40 | 1.40 | 0.97 | 7   |
| Stock options | June 19, 2013     | Awards to employees of joint venture          | 1,000  | 1.40 | 1.40 | (3)  | (3) |
| Stock options | July 12, 2013     | Awards to employees                           | 79,603 | 1.40 | 1.40 | 0.97 | 77  |
| Stock options | July 12, 2013     | Awards to employees of joint venture          | 500    | 1.40 | 1.40 | (3)  | (3) |
| Stock options | July 12, 2013     | Awards to non-employee advisor and consultant | 2,500  | 1.40 | 1.40 | (2)  | (2) |

**Total number of shares granted in 2013** **203,943**



Table of ContentsIndex to Financial Statements

The following summarizes all stock options and restricted stock awards granted subsequent to December 31, 2013 through September 30, 2014:

| Type of Grant | Grant Date     | Reason For Grant    | Shares<br>Underlying<br>Grants | Exercise<br>Price<br>of<br>Shares<br>(in \$) | Fair Value                                     |   | Total<br>Stock-<br>Based<br>Compensation<br>Expense<br>(\$ in thousands) |
|---------------|----------------|---------------------|--------------------------------|--|--|---|--|
|               |                |                     |                                |  | Common<br>Share<br>at<br>Grant Date<br>(in \$) | Fair<br>Value<br>Per<br>Award<br>Share<br>(in \$) |  |
| Stock options | April 15, 2014 | Awards to employees | 57,625                         | 1.28   | 1.28   | 0.95  | 55   |
| Stock options | April 30, 2014 | Awards to employees | 44,858                         | 1.28   | 1.28   | 0.95  | 43   |
| Stock options | July 10, 2014  | Award to director   | 28,301                         | 4.52   | 4.52   | 3.36  | 95   |

**Total number of shares granted in 2014** **130,784**

- (1) Incentive stock option granted to a 10% stockholder. Pursuant to Section 422 of the Internal Revenue Code, incentive stock options granted to 10% stockholders must have an exercise price no less than 110% of fair value.
- (2) We account for stock options issued 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.
- (3) We account for stock options granted to employees of our previous 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 options is subject to re-measurement over the vesting period at each reporting date based upon the valuation of our common stock at that time.

*Exercise price and fair value of common stock*

All options have been granted at exercise prices determined by our board of directors to be not less than the fair value of the underlying common shares on the date of grant. The fair value of the shares of common stock that underlie the stock options we have granted has historically been estimated by our board of directors based upon information available to it at the time of grant, as further discussed below.

We recorded total non-cash stock-based compensation expense of approximately \$65,000 and \$63,000 for the years ended December 31, 2013 and 2012, respectively. We recorded total non-cash stock-based compensation expense of approximately \$122,000 and \$55,000 for the nine-month periods ended September 30, 2014 and 2013, respectively. As of September 30, 2014, we had approximately \$357,000 of total unrecognized employee stock-based compensation expense, net of estimated forfeitures, related to stock option grants. We expect the amount of our share-based compensation expense for stock options granted to employees and non-employees to increase in future periods due to increases in headcount and, potentially, to increases in the value of our common stock.

*Significant factors used in determining the fair value of our common stock*

The fair value of the shares of common stock that underlie the stock options we have granted has historically been determined by our board of directors based upon information available to it at the time of grant. Our board of directors, with the assistance of management, developed these valuations using significant judgment and taking into account numerous factors, including progress in our research and development programs, status of clinical trials and preclinical studies relating to our product candidates, operation and financial performance, the lack of liquidity of our capital stock, the likelihood of achieving a liquidity event for the shares of common stock underlying these stock options, general and industry specific economic outlook, and independent third-party valuations of our common stock performed in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. As we have been a private enterprise, a discount for lack of

**Table of Contents**

**Index to Financial Statements**

marketability has been applied to derive the final fair value of our common stock for use in stock option grants. The board has generally considered the most persuasive evidence of fair value to be the prices at which our securities were exchanged in actual arms length transactions.

In determining a fair value for our common stock after the April 2012 reorganization, on two separate occasions we engaged an independent third party valuation firm to assess our enterprise value. In each report prepared by the valuation firm, two valuation approaches were considered to determine the enterprise value of our business: the income approach and the market approach.

The income approach estimates the fair enterprise value of a company based on the present value of the company's future estimated cash flows and the residual value of the company beyond the forecast period. These future cash flows, including the cash flows beyond the forecast period for the residual value, are discounted to their present values using an appropriate discount rate, to reflect the risks inherent in the company achieving these estimated cash flows and taking into account the risk-free rate for the use of funds and the expected rate of inflation over the applicable period. The discount rate used in our third-party valuations was based on rates of return available for alternative investments of similar type and quality.

There are different acceptable methods of applying the market approach. The valuations considered by our board of directors all employ the guideline public company analysis, whereby estimates for the fair enterprise value of a company are calculated by applying market multiples of comparable publicly traded companies, in our case in the biotechnology and pharmaceutical industries. The market multiples are based on key metrics implied by the enterprise values of our comparable publicly-traded peers.

The equity values determined by these valuation approaches were then weighted to determine the aggregate equity value of our business. The resulting equity values were then allocated to the common stock using the option pricing method, or OPM. The OPM treats common stock and convertible preferred stock as call options on a business, with exercise prices based on the liquidation preference. The common stock is modeled to be a call option with a claim on the business at an exercise price equal to the remaining value immediately after any senior security is liquidated. The OPM uses the Black-Scholes option-pricing model to value the call option. The OPM is appropriate to use when, as in our case, the range of possible future outcomes is so difficult to predict that lattice or scenario modeling would be highly speculative.

*Valuation performed as of May 31, 2012*

In conducting our valuation as of May 31, 2012, the board took into consideration the following company-specific events:

The board believed the April 2012 reorganization, in which all of our previously authorized Series A, B, and C preferred stock were converted into common stock at a price that was acceptable to each series of preferred stockholders, would constitute an exchange at arms length.

Also in connection with the April 2012 reorganization, all convertible unsecured promissory notes originally issued prior to the reorganization were converted into common and all outstanding warrants were terminated.

These facts further led the board to believe that the fair value determined in connection with the organization represented a fair value exchange in an arms length transaction.

There had been no significant clinical, manufacturing and regulatory milestones during 2012 and 2013 until December 2013 when our joint venture with Asahi was terminated.

Further, management engaged a third-party valuation firm to perform a valuation of our common stock. The valuation firm applied both the market approach and the income approach to arrive at an estimated enterprise valuation of our equity. The guideline public company analysis performed for the market approach resulted in a fair value indication for our company of \$10 million on a minority, marketable basis. The discounted cash flow analysis performed for the income approach resulted in a fair value indication for our company of \$10.4 million



**Table of Contents**

**Index to Financial Statements**

on a minority, marketable basis. The market approach and income approach were then equally weighted at 50% to arrive at an estimate enterprise value of our equity. The final step employed by the valuation firm involved allocating our estimated enterprise equity to the common stock using the OPM, to arrive at the estimate of fair value per share of common stock of our company. The OPM assumptions were as follows: a time to liquidity event of 3 years, a risk-free rate of 0.35%, dividend yield of 0%, and volatility of 85% over the time to a liquidity event, which was calculated based on the volatility of the common stock of our comparable publicly-traded peers. The valuation firm then applied a marketability discount of approximately 28%, based on the Finnerty Model, which assumes that the marketability discount on a privately-held security could be approximated by the value of an average-strike put option. Based on this analysis, the valuation firm determined the fair value of our common stock to be \$1.40 per share as of May 31, 2012.

Based on the company-specific factors discussed above, as supported by the third-party valuation specialists' report, the board determined that \$1.40 per share was not less than the fair value per share of our common stock as of May 31, 2012. At the time of each of the stock awards granted on each date subsequent to May 31, 2012 and through July 12, 2013, the board of directors determined that there had been no significant clinical, manufacturing or regulatory milestones attained that would warrant an increase in the estimate of fair value.

*Valuation performed as of December 31, 2013*

The Board considered the following factors in estimating the fair value of our common stock as of December 31, 2013:

The collaboration with Asahi is no longer a source of revenue for us.

In the fourth quarter of 2013, encouraged by our findings that higher dosage of PTH can be delivered by our microneedle patch system, we commenced a Phase 1 clinical trial to evaluate the pharmacokinetics, safety and tolerability in healthy post-menopausal women of a single application of one or two Weekly ZP-PTH transdermal patches.

Also in the fourth quarter of 2013, we initiated a Phase 1 clinical trial to evaluate the pharmacokinetics and safety in healthy individual for the application of ZP-Glucagon transdermal patches.

Further, beginning in the second quarter of 2013 and particularly in the third and fourth quarters of 2013, the volume of initial public offerings by biotechnology companies accelerated significantly. More importantly, for the first time, these included offerings by companies in the early stages of development. As a result of these developments, we believed that investors would have interest in our clinical stage, transdermal drug delivery technology.

We also engaged a third-party valuation firm to evaluate the fair value of our common stock as of December 31, 2013, prepared on a minority, non-marketable interest basis. In conducting its valuation, the valuation firm applied both the market approach and the income approach to arrive at an estimated enterprise valuation of our equity. The guideline public company analysis performed for the market approach resulted in a fair value indication for our company of

\$16.4 million on a minority, marketable basis. The discounted cash flow analysis performed for the income approach resulted in a fair value indication for our company of \$9.3 million on a minority, marketable basis. The valuation firm did not give any weight to the market approach and instead used the more conservative value produced by the income approach to estimate enterprise value of our equity. The final step employed by the valuation firm involved allocating our estimated enterprise equity to the common stock using the OPM, to arrive at the estimate of fair value per share of common stock of our company. The OPM assumptions were as follows: a time to liquidity event of 1.8 years, a risk-free rate of 0.31%, dividend yield of 0%, and volatility of 90% over the time to a liquidity event, which was calculated based on the volatility of the common stock of our comparable publicly-traded peers. The valuation firm then applied a marketability discount of approximately 25%, based on the Finnerty Model. Based on this analysis, the valuation firm determined the fair value of our common stock to be \$1.28 per share as of December 31, 2013.

**Table of Contents**

**Index to Financial Statements**

Based on the above factors as supported by the third-party valuation specialists' report, the board determined that the fair value of our common stock was not greater than \$1.28 per share as of December 31, 2013. The board also considered that this valuation provided further support for its prior determination that the fair value of our common stock at the time of grant of all previous awards during 2012 and 2013 was not greater than \$1.40 per share.

The valuations described above were made solely for the purposes of valuing the common stock underlying our stock option grants for financial reporting purposes and involved significant judgments and estimates, including assumptions regarding our future performance and the success of our pre-clinical studies and planned clinical trials. If we had made different assumptions, our stock-based compensation expense could have been different. The valuation methodologies we have historically used in estimating the fair value of our common stock are not the only methodologies available and they will not be used to value our common stock once this offering is complete. We cannot predict or offer any assurance with regard to the future value of our common stock. Accordingly, investors are cautioned not to place undue reliance on the valuation methodologies we describe above as an indicator of our future stock prices. Before investing in our common stock, you should carefully read this entire prospectus and consider, among other things, the matters described under Risk Factors.

*Developments subsequent to the December 31, 2013 valuation*

We believe that the increase in the estimated fair value of our common stock from \$1.40 per share as of December 31, 2013 to \$4.52 per share on July 10, 2014, when we most recently granted a stock-based award, is due to the following principal factors:

In January 2014, we completed Phase 1 clinical trials of Weekly ZP-PTH, which was then our lead product candidate, and of our ZP-Glucagon product candidate, with encouraging results.

In January 2014, we entered into a strategic partnership and license agreement with Novo Nordisk A/S to develop a new transdermal presentation of semaglutide for treatment of diabetes, and we received an upfront payment of \$1 million from Novo Nordisk.

In February 2014, we secured additional bridge financing in the form of \$2.5 million of convertible promissory notes issued to affiliates of BMR and New Enterprise Associates 12, Limited Partnership.

In June 2014, we obtained a \$4 million term loan facility with Hercules Technology Growth Capital. In connection with our option award on July 10, 2014, we also engaged a third-party valuation firm to evaluate the fair value of our common stock as of June 30, 2014, prepared on a minority, non-marketable interest basis. In conducting its valuation, the valuation firm considered both the market approach and the income approach to arrive at an estimated enterprise valuation of our equity. The analysis performed for the market approach resulted in a fair value indication for our company of \$20.0 million on a minority, marketable basis. The discounted cash flow analysis performed for the income approach resulted in a fair value indication for our company of \$32.1 million on a minority, marketable basis. The valuation firm did not give any weight to the market approach and instead used the higher value produced by the income approach to estimate enterprise value of our equity. The final step employed by the valuation

firm involved allocating our estimated enterprise equity to the common stock using the OPM, to arrive at the estimate of fair value per share of common stock of our company. The OPM assumptions were as follows: a time to liquidity event of 0.5 years, a risk-free rate of 0.06%, dividend yield of 0%, and volatility of 90% over the time to a liquidity event, which was calculated based on the volatility of the common stock of our comparable publicly-traded peers. The valuation firm then applied a marketability discount of approximately 22%, based on the Finnerty Model. Based on this analysis, the valuation firm determined the fair value of our common stock to be \$4.52 per share as of June 30, 2014.

**Table of Contents**

**Index to Financial Statements**

*Initial public offering price*

The initial public offering price for the shares of common stock offered by this prospectus is \$11.00 per share and was determined by negotiation between the underwriters and us. Among the factors that were considered in determining the initial public offering price were the following:

an analysis of the typical valuation ranges seen in recent initial public offerings for companies in our industry;

the general condition of the securities markets and the recent market prices of, and the demand for, publicly traded common stock of generally comparable companies;

an assumption that there would be a receptive public trading market for pre-commercial drug delivery companies such as us; and

an assumption that there would be sufficient demand for our common stock to support an offering of the size contemplated by this prospectus.

The initial public offering price of \$11.00 per share reflects a significant increase over the estimated valuation as of June 30, 2014 at \$4.52 per share. Investors should be aware of this difference and recognize that the initial public offering price is in excess of our prior valuations. We believe the difference may be due to the following factors:

The fact that in November 2014, we entered into a strategic partnership and license agreement with Lilly to develop one or more ZP-PTH microneedle patch products, and Lilly agreed to purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering.

The fact that whereas the initial public offering price necessarily assumes that this offering has occurred and a public market for our common stock has been created, the valuation of our common stock as of June 30, 2014 assumed a time to liquidity of 0.5 years and a marketability discount of 22%.

The fact that capital market conditions have continued to support offerings by biotech companies in the early stages of development, leading us to believe that investors would have interest in our clinical stage, transdermal drug delivery technology.

We also believe that investors in the public markets may apply more qualitative and subjective valuation criteria to our product candidates and business than the quantitative valuation methods we have previously applied, although there can be no assurance that this is the case. Further, the initial public offering price was

not derived using a quantitative determination of fair value, but rather was determined by negotiation between us and the underwriters. In particular, our estimates of the fair value of our common stock as of December 31, 2013 and June 30, 2014 were not considered by us or the underwriters as a factor in determining the initial public offering price.

***Income taxes***

We are subject to income tax under the U.S. federal jurisdiction and the State of California. We file U.S. federal income tax returns and California state income tax returns. To date, we have not been audited by the Internal Revenue Service or any state income tax authority.

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

---

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

As of December 31, 2013, we had net deferred tax assets of \$56.5 million. The deferred tax assets primarily consisted of federal and state tax net operating losses and research and development tax credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these tax assets, a full valuation allowance has been established to offset our deferred tax assets. As of December 31, 2013, we 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 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, 2013, we 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.

***JOBS Act***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can 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, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we intend to rely on certain of these exemptions, including those that will relieve us of responsibility for (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) complying 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, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

**Internal control over financial reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. 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. Because of its inherent limitations, internal control



**Table of Contents**

**Index to Financial Statements**

over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Furthermore, our controls and procedures can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control, and misstatements due to error or fraud may occur and not be detected on a timely basis.

Our management has determined that as of December 31, 2013, 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. This material weakness had not been remediated as of September 30, 2014.

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.

Notwithstanding the existence of this material weakness, our management has concluded that the consolidated financial statements included elsewhere in this prospectus present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with U.S. GAAP.

If we fail to fully remediate this material weakness or fail to maintain 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.

**Results of Operations**

**Comparison of the nine months ended September 30, 2014 and 2013**

**Revenue**

|  | <b>Nine Months Ended<br/>September 30,</b> |             | <b>Change</b> |          |
|--|--|-------------|---------------|----------|
|  | <b>2014</b>                                | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|  | <b>(in thousands)</b>                      |             |               |          |
| <b>Revenue:</b>                            |  |             |               |          |
| License fees revenue                       | \$ 1,819                                   | \$ 3,688    | \$ (1,869)    | (51%)    |
| Collaborative development support services | 662  |             | 662           | N/A      |
| Total revenue                              | \$ 2,481                                   | \$ 3,688    | \$ (1,207)    | (33%)    |

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

We have not made any commercial product sales. We have generated revenue from collaboration and license agreements for the development and commercialization of our transdermal microneedle patch technology. Total revenue decreased \$1.2 million, or 33%, for the nine months ended September 30, 2014 as compared to the same period in 2013. The decrease in revenue was primarily due to approximately \$2.6 million of contract revenue we earned from our license and collaboration 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 \$694,000 of license fee revenue earned from our collaboration with Novo Nordisk beginning in 2014 and approximately \$662,000 of related development support service revenue.

***Cost of license fees revenue***

|                              | <b>Nine Months Ended</b> |             | <b>Change</b> |          |
|------------------------------|--------------------------|-------------|---------------|----------|
|                              | <b>September 30,</b>     |             | <b>Amount</b> | <b>%</b> |
|                              | <b>2014</b>              | <b>2013</b> |               |          |
|                              | <b>(in thousands)</b>    |             |               |          |
| 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 increased \$100,000 for the nine months ended September 30, 2014 as compared to the same period in 2013 due to the increased royalty attributable to our receipt of a \$1.0 million license fee from Novo Nordisk upon execution of a license agreement with Novo Nordisk during the first nine months of 2014.

***Research and development expenses***

|                          | <b>Nine Months Ended</b> |             | <b>Change</b> |          |
|--------------------------|--------------------------|-------------|---------------|----------|
|                          | <b>September 30,</b>     |             | <b>Amount</b> | <b>%</b> |
|                          | <b>2014</b>              | <b>2013</b> |               |          |
|                          | <b>(in thousands)</b>    |             |               |          |
| Research and development | \$ 8,230                 | \$ 4,760    | \$ 3,470      | 73%      |

Research and development expenses increased \$3.5 million, or 73%, for the nine months ended September 30, 2014 as compared to the same period in 2013. Of this increase, approximately \$2.9 million was due to an increase in equipment depreciation expense following the return of equipment to us and the rehiring of key personnel with critical manufacturing know-how upon the termination of our joint venture with Asahi in ZP Group LLC, approximately \$832,000 was due to the non-clinical study in preparation for our ZP-Triptan Phase 1 clinical trial to be commenced in the first half of 2015, approximately \$392,000 related to servicing our collaboration and license agreement with Novo Nordisk, and approximately \$319,000 related to other research projects, partially offset by an approximately \$936,000 reduction in spending on our former Weekly ZP-PTH lead product candidate and our ZP-Glucagon product candidate follow the completion of our Phase 1 clinical trials.

***General and administrative expenses***

**Nine Months Ended**  
**September 30,**  
**2014                      2013**                      **Change**  
**Amount                      %**  
**(in thousands)**

|                            | 2014     | 2013     | Amount | %   |
|----------------------------|----------|----------|--------|-----|
| General and administrative | \$ 3,208 | \$ 2,692 | \$ 516 | 19% |

General and administrative expenses increased \$516,000, or 19%, for the nine months ended September 30, 2014 as compared to the same period in 2013. The increase in general and administrative expenses was primarily due to approximately \$309,000 in costs related to executive hiring and severance, an approximately \$296,000 increase in facility related expenses as a result of the termination of our facility sharing arrangement in the joint

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

venture with Asahi in ZP Group LLC, and an approximately \$165,000 increase in general and administrative expenses, partially offset by a reduction in market research spending of approximately \$274,000.

***Interest expense, net***

|                       | <b>Nine Months Ended</b> |                      | <b>Change</b> |          |
|-----------------------|--------------------------|----------------------|---------------|----------|
|                       | <b>September 30,</b>     | <b>September 30,</b> | <b>Amount</b> | <b>%</b> |
|                       | <b>2014</b>              | <b>2013</b>          |               |          |
|                       | <b>(in thousands)</b>    |                      |               |          |
| Interest expense, net | \$ 1,261                 | \$ 526               | \$ 735        | 140%     |

Interest expense, net, increased \$735,000, or 140%, for the nine months ended September 30, 2014 as compared to the same period in 2013. The increase was primarily due to the incremental interest expense incurred in connection with our bridge financings in September 2013 and February 2014, as well as interest on the Hercules loan entered into in June 2014.

***Other expense***

|               | <b>Nine Months Ended</b> |                      | <b>Change</b> |          |
|---------------|--------------------------|----------------------|---------------|----------|
|               | <b>September 30,</b>     | <b>September 30,</b> | <b>Amount</b> | <b>%</b> |
|               | <b>2014</b>              | <b>2013</b>          |               |          |
|               | <b>(in thousands)</b>    |                      |               |          |
| Other expense | \$ 143                   | \$ 20                | \$ 123        | 615%     |

Other expense increased \$123,000 for the nine months ended September 30, 2014 as compared to the same period in 2013. The increase was primarily related to the fair value of the 31,250 shares of common stock that were issued to an affiliate of BMR in June 2014 as an inducement for its subordination of debt in connection with the Hercules loan, including the change in fair value as remeasured at each financial reporting period.

***Equity in gain of joint venture***

|                                 | <b>Nine Months</b>    |                      | <b>Change</b> |          |
|---------------------------------|-----------------------|----------------------|---------------|----------|
|                                 | <b>Ended</b>          |                      | <b>Amount</b> | <b>%</b> |
|                                 | <b>September 30,</b>  | <b>September 30,</b> |               |          |
|                                 | <b>2014</b>           | <b>2013</b>          |               |          |
|                                 | <b>(in thousands)</b> |                      |               |          |
| Equity in gain of joint venture | \$                    | \$ 45                | \$ (45)       | (100%)   |

Equity in gain of joint venture reflects our share of ZP Group LLC's net gain for the applicable reporting period. Equity in gain of joint venture decreased \$45,000, or 100%, for the nine months ended September 30, 2014 as compared to the same period in 2013. This decrease was due to the termination of our joint venture investment in ZP Group LLC in December 2013.

*Gain on debt forgiveness*

|                          | <b>Nine Months<br/>Ended<br/>September 30,</b> |             | <b>Change</b> |          |
|--------------------------|--|-------------|---------------|----------|
|                          | <b>2014</b>                                    | <b>2013</b> | <b>Amount</b> | <b>%</b> |
|                          | <b>(in thousands)</b>                          |             |               |          |
| Gain on debt forgiveness | \$ 497   | \$          | \$ 497        | N/A      |

Pursuant to the provisions of our joint venture termination agreement with Asahi, we recorded a \$497,000 one-time gain on debt forgiveness during the nine months ended September 30, 2014, resulting from the cancellation of ZP Group LLC's revolving line of credit with Asahi.

**Table of Contents****Index to Financial Statements****Comparison of the years ended December 31, 2012 and 2013*****Revenue***

|  | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|--|--------------------------------|-------------|---------------|----------|
|  | <b>2013</b>                    | <b>2012</b> | <b>Amount</b> | <b>%</b> |
|  | <b>(in thousands)</b>          |             |               |          |
| <b>Revenue:</b>                            |                                |             |               |          |
| License fees revenue                       | \$ 4,250                       | \$ 9,250    | \$ (5,000)    | (54%)    |
| Collaborative development support services |                                | 2,374       | (2,374)       | (100%)   |
| Total revenue                              | \$ 4,250                       | \$ 11,624   | \$ (7,374)    | (63%)    |

We have not made any commercial product sales. We have generated revenue from collaboration and license agreements for the development and commercialization of our technology. Total revenue decreased \$7.4 million, or 63%, for the year ended December 31, 2013 as compared to the same period in 2012. The decrease in revenue was primarily due to an approximately \$7.2 million of payments we received from our license and collaboration with Asahi in 2012 that was not received in 2013. Specifically, we received \$5.0 million in license fees from Asahi in 2012 and approximately \$2.2 million of collaborative development support services revenue in 2012, which were not received in 2013, in part as a result of the transfer of our manufacturing obligations under our license agreement with Asahi to ZP Group LLC upon forming our joint venture in April 2012.

***Research and development expenses***

|                                   | <b>Year Ended December 31,</b> |             | <b>Change</b> |          |
|-----------------------------------|--------------------------------|-------------|---------------|----------|
|                                   | <b>2013</b>                    | <b>2012</b> | <b>Amount</b> | <b>%</b> |
|                                   | <b>(in thousands)</b>          |             |               |          |
| Research and development expenses | \$ 7,637                       | \$ 5,399    | \$ 2,238      | 41%      |

Research and development expenses increased \$2.2 million, or 41%, for the year ended December 31, 2013 as compared to the same period in 2012. Of this increase, approximately \$2.7 million was attributable to research and development expenses related to the completion of our final formulation and the initiation of a Phase 1 clinical trial of ZP-Glucagon and approximately \$1.8 million was due to the initiation of a Phase 1 clinical trial involving our former Weekly ZP-PTH lead product candidate during the second half of 2013. These increases were partially offset by an approximately \$1.9 million reduction in research and development and manufacturing spending in support of our collaboration and license agreement with Asahi during the first quarter of 2012 due to the formation of our joint venture entity (ZP Group LLC) with Asahi which assumed the responsibility for servicing the collaboration, and an approximately \$908,000 reduction in other research and development projects.

***General and administrative expenses***

|                                     | Year Ended December 31, |          | Change   |     |
|-------------------------------------|-------------------------|----------|----------|-----|
|                                     | 2013                    | 2012     | Amount   | %   |
|                                     | (in thousands)          |          |          |     |
| General and administrative expenses | \$ 4,582                | \$ 3,077 | \$ 1,505 | 49% |

General and administrative expenses increased \$1.5 million, or 49%, for the year ended 2013 as compared to the same period in 2012. The increase in general and administrative expenses was primarily due to \$520,000 increase in personnel cost related to the addition of key executive management personnel, a \$758,000 increase in legal fees in connection with our bridge financing and the acquisition of our short-term investment in Zosano, Inc. and related consulting and accounting fees.



**Table of Contents****Index to Financial Statements*****Interest expense, net***

|                       | Year Ended December 31, |        | Change |     |
|-----------------------|-------------------------|--------|--------|-----|
|                       | 2013                    | 2012   | Amount | %   |
|                       | (in thousands)          |        |        |     |
| Interest expense, net | \$ 760                  | \$ 663 | \$ 97  | 15% |

Interest expense, net, increased \$97,000, or 15%, for the year ended December 31, 2013 as compared to the same period in 2012. The increase was primarily due to the full-year effect of accrued interest on our BMR secured promissory note and the interest expense incurred in connection with our bridge notes issued in September 2013.

***Warrant revaluation income***

|                            | Year Ended December 31, |       | Change  |        |
|----------------------------|-------------------------|-------|---------|--------|
|                            | 2013                    | 2012  | Amount  | %      |
|                            | (in thousands)          |       |         |        |
| Warrant revaluation income | \$                      | \$ 71 | \$ (71) | (100)% |

Warrant revaluation income resulted from the re-measurement of our preferred stock warrant liability associated with the warrants to purchase preferred stock issued to lenders under our debt facilities and certain of our former preferred stockholders prior to our 2012 recapitalization. In 2012, we recorded income of \$71,000 reflecting a decrease in fair value of the underlying security based upon the fair value re-measured on the date of the warrant retirement. After our recapitalization in 2012, these warrants are no longer outstanding.

***Equity in loss of joint venture and gain on termination of joint venture***

|                                      | Year Ended December 31, |          | Change   |       |
|--------------------------------------|-------------------------|----------|----------|-------|
|                                      | 2013                    | 2012     | Amount   | %     |
|                                      | (in thousands)          |          |          |       |
| Equity in loss of joint venture      | \$ (366)                | \$ (738) | \$ (372) | (50)% |
| Gain on termination of joint venture | 3,487                   |          | 3,487    | N/A   |

Equity in loss of joint venture reflects our share of ZP Group LLC's net loss for the applicable reporting period. Equity in loss of joint venture decreased \$372,000, or 50%, for the year ended December 31, 2013 as compared to the same period in 2012, primarily due to the manufacturing services revenue generated by the joint venture through ZP Group LLC's contract manufacturing arrangement with us.

Our strategic partnership with Asahi through the joint venture investment in ZP Group LLC was terminated in December 2013. As a result, we recorded a one-time gain on termination of the joint venture of \$3.5 million, which represents payments from Asahi for 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.

## **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 September 30, 2014, had an accumulated deficit of \$134.2 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.

---

**Table of Contents**

**Index to Financial Statements**

Our primary uses of cash are to fund operating expenses, which have historically been primarily related to research and development and manufacturing activities. From inception through September 30, 2014, we have raised an aggregate of approximately \$120 million to finance our business through the sale of preferred stock and \$30.3 million from the issuance of debt to private investors. As of September 30, 2014 and December 31, 2013 and 2012, our principal sources of liquidity were our cash and cash equivalents, which totaled \$2.3 million, \$5.9 million and \$5.0 million, respectively.

Our recurring operating losses from operations and our need for additional sources of capital to fund our ongoing operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 with respect to this uncertainty. We have no current source of revenue to sustain our present activities other than our license and collaborative agreements with Novo Nordisk and Lilly, and we do not expect to generate substantial revenue for the foreseeable future. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations and there can be no assurance that additional financing will be available to us or that such financing will be available on terms favorable to us, if at all. We intend to raise additional capital through public or private offerings of our equity securities, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, or a combination of such.

There can be no assurance that we will be able to raise sufficient financing to fund our operations. To the extent that we raise additional capital through the sale of our equity or equity-linked 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 stockholder. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Debt financing may not be available to us, and, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Certain of our existing investors have provided us with unsecured bridge financing through the issuance of our convertible bridge notes. Upon the closing of a qualified financing, which is defined under the terms of the convertible bridge notes as an equity financing on or before March 31, 2015 where we raise at least \$25.0 million (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest on each note shall 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. We sold these notes in three tranches, in September 2013, February 2014 and December 2014, and raised an aggregate of \$6.9 million to sustain our operations. In June 2014, we entered into a \$4 million secured term loan facility with Hercules Technology Growth Capital to sustain our operations. The Hercules loan is secured by a senior security interest in substantially all of our assets. The convertible bridge notes are subordinated in right of payment to the Hercules loan.

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately \$44.4 million, based on the initial public offering price of \$11.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will also receive net

proceeds of approximately \$14.5 million from our issuance and sale of shares of our common stock to Lilly in the concurrent private placement, after payment by us of the private placement fee due to the representatives of the underwriters. We anticipate that these estimated net proceeds, along with our existing cash and cash equivalents of \$2.3 million as of September 30, 2014, should be sufficient to meet our anticipated cash

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

requirements for at least the next twelve months. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors, including the factors discussed in Risk Factors. See Cautionary Note Regarding Forward-Looking Statements.

***Summary of cash flows***

The following table shows a summary of our cash flows for the nine months ended September 30, 2014 and 2013, and for the years ended December 31, 2013 and 2012:

|                                       | <b>Nine Months Ended September 30, Year Ended December 31,</b> |                 |               |                 |
|---------------------------------------|--|-----------------|---------------|-----------------|
|                                       | <b>2014</b>  | <b>2013</b>     | <b>2013</b>   | <b>2012</b>     |
|                                       | <b>(unaudited)</b>   |                 |               |                 |
|                                       | <b>(in thousands)</b>  |                 |               |                 |
| <b>Cash generated from (used in):</b> |  |                 |               |                 |
| Operating activities                  | \$ (9,001)   | \$ (4,424)      | \$ (3,724)    | \$ 501          |
| Investing activities                  | (1,031)  | 707             | 1,139         | 1,984           |
| Financing activities                  | 6,422  | 3,034           | 3,525         | (1,112)         |
| <b>Total cash (used) generated</b>    | <b>\$ (3,610)</b>  | <b>\$ (683)</b> | <b>\$ 940</b> | <b>\$ 1,373</b> |

*Operating Cash Flow:* Net cash used in operating activities was \$9.0 million during the nine months ended September 30, 2014, as compared to \$4.4 million for the same period in 2013. Net cash used during the first nine months of 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. Net cash used during the first nine months of 2013 was primarily due to operating expenses of approximately \$6.4 million, partially offset by the receipt of a \$2.0 million license fee payment from Asahi in connection with our collaboration and license agreement.

Net cash used in operating activities was \$3.7 million in 2013, as compared to net cash generated from operating activities of \$501,000 for the same period in 2012. 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 and excess termination expense reimbursement from Asahi in connection with the termination of our joint venture. Net cash generated in 2012 was primarily the result of the receipt of \$5.0 million license fees and in collaboration funding from Asahi, partially offset by net cash used in normal operating activities such as personnel cost, outside services, professional and administrative fees. We expect that our net cash used in operating activities will increase significantly in each of the next several years in order to support our operations and complete the development and commercialization of our product candidates.

*Investing Cash Flow:* Net cash used in investing activities was \$1.0 million during the nine months ended September 30, 2014, as compared to net cash generated from investing activities of \$707,000 for the same period in 2013. Net cash used in investing activities during the first nine months of 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 the first nine months of 2013, cash generated from investing activities was primarily due to a \$1.2 million cash distribution received for the depreciation of our contributed equipment capital to ZP Group LLC, partially offset by a \$506,000 purchase of manufacturing equipment.

Net cash generated from investing activities was \$1.1 million and \$2.0 million in 2013 and 2012, respectively. Net cash generated from investing activities included a cash distribution of \$2.4 million and \$1.5 million for 2013 and 2012, respectively, from ZP Group LLC for the reimbursement of depreciation charges

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

associated with the equipment we contributed to ZP Group LLC during the formation of our joint venture with Asahi. In 2013, cash generated from investing activities was partially offset by the purchase of property and equipment for \$897,000 and cost of acquiring equity invested in Zosano, Inc., for \$365,000. We expect that we will continue to make investments in property, equipment and leasehold improvements as we expand our operations in the future.

*Financing Cash Flow:* Net cash generated from financing activities was \$6.4 million during the nine months ended September 30, 2014, as compared to \$3.0 million for the same period in 2013. Net cash generated from financing activities during the first nine months of 2014 was provided through \$3.9 million of net proceeds from our debt financing with Hercules and \$2.5 million from the issuance of bridge notes to certain of our existing investors. Net cash generated from financing activities during the first nine months of 2013 was provided through \$3.0 million of net proceeds from the issuance of bridge notes to certain of our existing investors.

Net cash generated from financing activities in 2013 was provided through \$3.0 million from the issuance of our bridge notes and \$491,000 from reimbursements received from ZP Group LLC, funded through the revolving line of credit facility provided by AKPUS to ZP Group LLC. Net cash used in financing activities in 2012 was related to the payment of certain prior equipment financing in connection with the recapitalization.

**Contractual Obligations**

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

|  | Total            | Payments Due by Period |                  |               | More than<br>5 Years |
|--|------------------|------------------------|------------------|---------------|----------------------|
|  |                  | Less than<br>One Year  | 1-3 Years        | 3-5 Years     |                      |
| <b>Contractual Obligations</b>   |                  |                        |                  |               |                      |
| Short and long-term debt obligations (including interest) <sup>(1)</sup> | \$ 24,979        | \$ 7,991               | \$ 16,988        | \$            | \$                   |
| Operating lease obligations <sup>(2)</sup>                               | 2,767            | 688                    | 1,264            | 815           |                      |
| Purchase commitments <sup>(3)</sup>                                      | 46               | 46                     |                  |               |                      |
| <b>Total contractual obligations</b>                                     | <b>\$ 27,792</b> | <b>\$ 8,725</b>        | <b>\$ 18,252</b> | <b>\$ 815</b> | <b>\$</b>            |

**(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 bear 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 1933 Securities Act. We may 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 a qualified financing, which is 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 (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest on each note shall 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



---

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

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 will 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 bear 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, unless the note is converted into equity securities in connection with this offering. We may 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 a qualified financing, as defined above, the principal and all unpaid and accrued interest on each note shall 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.

*Secured financing with BMR*

In connection with our recapitalization in April 2012, we renegotiated a new lease agreement with 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 an affiliate of BMR and all previously accrued interest, unpaid rent, future rent obligations and other fees due to BMR were either rolled into the note or eliminated. The note payable to BMR 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 are due and payable to BMR 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 June 2014, we amended the BMR 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 BMR note during the period from the maturity date of the BMR note through the date that the Hercules loan is repaid in full will not constitute a default under the BMR note. In exchange for BMR's agreement to subordinate the BMR secured promissory note to the Hercules loan, we issued 31,250 shares of our common stock to the BMR affiliate that is the holder of the BMR secured promissory note. We intend to use a portion of the proceeds from this offering to make required payments of interest and principal as they become due under the BMR note, as further explained in the section titled "Use of Proceeds."

The BMR 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.

*Line of credit with AKP USA, Inc.*

In April 2013, ZP Group LLC obtained a \$25 million credit facility under a revolving line of credit arrangement with AKP USA, Inc., or AKPUS, an affiliate of Asahi. The facility bore an interest rate of

---

**Table of Contents**

**Index to Financial Statements**

1.15% per year, and ZP Group LLC was obligated to pay interest on the principal outstanding on the last day of each month until any outstanding principal was paid in full.

Our joint venture with Asahi was terminated in December 2013. Pursuant to the termination agreement, the entire outstanding principal and unpaid and accrued interest shall was discharged, released and forgiven by AKPUS on March 14, 2014.

*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.

The BMR secured promissory note and the convertible bridge notes are subordinated in right of payment to the Hercules loan, and BMR's security interest in substantially all of our assets under the BMR secured promissory note is subordinate to Hercules' security 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 BMR secured promissory note, even if the subordination with Hercules and BMR allows for the payment. Any such payment will give Hercules the right to accelerate any or all of the Hercules loan. In exchange for BMR's agreement to subordinate the BMR secured promissory note to the Hercules loan, we issued 31,250 shares of our common stock to the BMR affiliate that is the holder of the BMR secured promissory note. We intend to use a portion of the proceeds from this offering to make required payments of interest and principal as they become due under the Hercules loan, as further explained in the section entitled Use of Proceeds.

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. 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 September 30, 2014, the prepaid rent of approximately \$5.2 million is offset against the deferred rent liability of approximately \$5.4 million resulting in a net deferred rent liability of approximately \$166,000.

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.

**Table of Contents**

**Index to Financial Statements**

**(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.

**Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks principally relate to interest rates. We had cash and cash equivalents of \$2.3 million as of September 30, 2014, and \$5.9 million and \$5.0 million as of December 31, 2013 and 2012, 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. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

**Off-balance Sheet Arrangements**

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

**Recently Issued Pronouncements**

In July 2013, Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2013-11, *Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* (a consensus of the FASB Emerging Issues Task Force). The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. We are currently assessing the impact of this ASU on our financial statements.

In February 2013, the FASB issued guidance which addresses the presentation of amounts reclassified from accumulated other comprehensive income. This guidance does not change current financial reporting requirements, instead an entity is required to cross-reference to other required disclosures that provide additional detail about amounts reclassified out of accumulated other comprehensive income. The adoption of this guidance did not have a material impact on our consolidated financial statements.

---

**Table of Contents****Index to Financial Statements****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.

**Daily ZP-PTH** is our proprietary formulation of teriparatide, a synthetic form of parathyroid hormone, PTH 1-34, or PTH, which regulates serum calcium, to be administered daily for the treatment of severe osteoporosis in women.

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, or WHO, and the International Osteoporosis Foundation, or IOF, 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. According to the National Osteoporosis Foundation, or NOF, approximately 700,000 adults in the United States suffer from severe osteoporosis.

We believe that anti-resorptive agents, which are typically administered orally and are one of the two main types of osteoporosis drugs currently available in the United States, have significant disadvantages. Bisphosphonates, the

current standard of care and a type of anti-resorptive agent, have been associated with infrequent but serious adverse events. We also believe that the other main type of osteoporosis drug currently available in the United States, an anabolic agent administered by injection, often times provides patients with a less than optimal treatment administration experience. The only anabolic agent approved in the United States for the treatment of severe osteoporosis is Eli Lilly and Company's Forteo®. Forteo® is administered by injection daily, has a two-year lifetime limitation on use and is unstable at room temperature and must be refrigerated. Market research suggests that the daily injections required with the current formulation of Forteo® leads to low compliance rates among patients. We commissioned a market survey in 2010, which estimates that in 2010 only 6% of the treated patients with severe osteoporosis in the United States received prescriptions for Forteo®. Nevertheless, worldwide sales of Forteo® in 2013 exceeded \$1.2 billion.

---

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

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, Mexico and Argentina in 2008. In 2009, we held End-of-Phase 2 meetings with the United States Food and Drug Administration, or FDA, to consider the proposed Phase 3 clinical trial and identify any additional information necessary to support a marketing application for the use of Daily ZP-PTH to treat osteoporosis in postmenopausal women. We also held similar meetings with European regulatory authorities in 2009. These meetings provided us with guidance for Phase 3 development of Daily ZP-PTH which we believe will help speed the regulatory approval process for Daily ZP-PTH. We plan to conduct a Phase 3 trial designed as a non-inferiority study compared to Forteo<sup>®</sup>, and intend to seek regulatory approval of Daily ZP-PTH pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or the 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 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 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.

In November 2014, we entered into a stock purchase agreement with Lilly pursuant to which Lilly will purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price. In addition, under the terms of the license agreement, 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. Lilly has the right to terminate the license agreement prior to regulatory approval of Daily ZP-PTH in the event 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 believe there is a significant opportunity for our Daily ZP-PTH product candidate, given what we believe to be its relatively low risk profile:

Our planned Phase 3 clinical trial of Daily ZP-PTH is a larger and longer version of our previously completed Phase 2 clinical trial. The Phase 3 trial is expected to be a one-year study with 1,200 patients with spine BMD as the primary endpoint, while the Phase 2 trial was a six-month study with 165 patients with spine BMD as the primary endpoint.



Edgar Filing: Zosano Pharma Corp - Form 424B4

We have completed End-of-Phase 2 meetings and Type C meetings with the FDA and have conducted similar meetings with European regulatory authorities, and intend to seek regulatory approval of Daily ZP-PTH pursuant to Section 505(b)(2) of the FDCA.

Under the terms of our licensing agreement with Lilly, Lilly will be responsible for commercialization of our Daily ZP-PTH product candidate. Given that Lilly markets the only currently approved anabolic agent in the United States for the treatment of osteoporosis and has an experienced sales force that for

---

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

over a decade has focused on prescribing physicians, we believe that Lilly is well suited for commercialization of a new anabolic agent such as Daily ZP-PTH.

We also believe there is an opportunity for product differentiation with Daily ZP-PTH:

*Dry formulation.* Our dry formulation provides enhanced convenience, portability and ease of use, potentially facilitating more effective treatment and improved patient compliance.

*Room temperature stability.* Our internal studies of Daily ZP-PTH demonstrated Daily ZP-PTH's ability to be room temperature stable, obviating the need for refrigeration and allowing for a potentially improved patient experience with administration.

Our Phase 2 trial of Daily ZP-PTH included 13 clinical sites in three countries—the United States (in connection with which we submitted an investigational new drug application, or IND, to the FDA), Mexico and Argentina, and was a six-month, outpatient, randomized, placebo-controlled, positive control study with daily self-administration. The study tested a total of 165 postmenopausal women in five groups (three groups with 20 µg, 30 µg, and 40 µg doses of Daily ZP-PTH patches, respectively, one group with a Forteo® injection and one placebo group), with 33 patients per group. The primary endpoint was spine BMD and the secondary endpoint was hip BMD. The study demonstrated a rapid increase in serum concentration of PTH, quickly followed by a rapid decrease. We believe that this pulsatile pattern, which occurred with all Daily ZP-PTH patch doses, is important for efficacy of an anabolic agent. The study results also demonstrated dose proportionality and high 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 no serious adverse events. The Daily ZP-PTH patch doses illustrated comparable spine BMD and hip BMD compared to the Forteo® injection. The study also demonstrated comparable safety and adverse event profile of Daily ZP-PTH patch doses compared to the Forteo® injection. Because these results warranted further development of our Daily ZP-PTH product candidate, we held an End-of-Phase 2 meeting and Type C meetings with the FDA and similar meetings with several European regulatory agencies.

These meetings provided us with guidance for Phase 3 development of Daily ZP-PTH, and we plan to begin Phase 3 clinical development with a trial designed as a non-inferiority study compared to Forteo® in accordance with the development plan under our license agreement with Lilly. We also intend to seek regulatory approval of Daily ZP-PTH pursuant to Section 505(b)(2) of the FDCA, and scale up manufacturing activities.

Before we entered into our license agreement with Lilly, our lead product candidate was Weekly ZP-PTH, 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 in women. In January 2014, we completed a Phase 1 clinical trial in Australia to evaluate the pharmacokinetics, safety and tolerability of Weekly ZP-PTH patches in a range of doses. The study results demonstrated a rapid increase in serum concentration of PTH, quickly followed by a rapid decrease. We believe that this pulsatile pattern, which occurred with all patch doses, is important for efficacy of an anabolic agent. The study results also demonstrated dose proportionality and high 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 no serious adverse events. We held a pre-IND meeting with the FDA, a meeting required for the filing of an IND, in July 2014 to discuss the clinical trial design for our planned Phase 2 and Phase 3 trials of Weekly ZP-PTH. As our Phase 1 clinical trial was conducted in Australia, the trial was conducted in compliance with applicable Australian regulations, and we were not required to file any IND in connection with the Phase 1 trial. Our license agreement with Lilly permits, but

does not require, us to pursue development of Weekly ZP-PTH at our own expense. Under the agreement, Lilly has exclusive, worldwide rights 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.

**ZP-Glucagon** is our proprietary formulation of glucagon, a hormone that raises blood glucose levels, intended for the emergency treatment of life-threatening severe hypoglycemia.

**Table of Contents**

**Index to Financial Statements**

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. Based on a market survey of the hypoglycemia market commissioned by us in 2013, which we refer to as our 2013 hypoglycemia market survey, 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.

The current standard of care in a severe hypoglycemic event is administration of glucagon by injection or infusion. The two glucagon products currently marketed in the United States are Lilly's Glucagon Emergency Kit and Novo Nordisk's GlucaGen®, which together accounted for \$120 million in sales in United States in 2012. These products, which are both injectables, have unstable formulations and require a time-consuming, multi-step reconstitution process prior to injection.

***Our ZP-Glucagon solution is intuitive and ready-to-use***

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 based on our existing 3 cm<sup>2</sup> patch and the reusable applicator (although this applicator is expected to only be used one time). We expect our Generation 2 product to be an integrated patch and applicator system on a 6 cm<sup>2</sup> patch with a single-use applicator. While we have developed prototypes for both the 6 cm<sup>2</sup> patch and the single-use applicator, we have yet to conduct clinical trials using these versions of our products.

We believe that our stable 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. Additionally, 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.

***Demonstrated high stability of our ZP-Glucagon formulation enables the ready-to-use feature of our product and is a significant source of differentiation compared to current marketed products***

In the treatment of severe hypoglycemia, we believe that the practical advantages afforded by the room-temperature stability of our microneedle patch system may be as important as the therapeutic benefits of rapid

**Table of Contents**

**Index to Financial Statements**

onset. We have therefore undertaken and completed multiple preclinical, clinical and stability studies designed to select the appropriate formulation to take into further human clinical development.

We have performed stability studies on four formulations of glucagon. Because the purity of an unstable compound typically deteriorates over time, our goal in these studies was to maintain a high purity level. In our most recent stability studies with those formulations 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.

In January 2014, we completed a Phase 1 trial of ZP-Glucagon designed to assess relative bioavailability with our microneedle patch system at various application sites compared to a currently available form of glucagon administered by intramuscular injection. As our Phase 1 clinical trial was conducted in Australia, the trial was conducted in compliance with applicable Australian regulations, and we were not required to file any IND in connection with the Phase 1 trial. With each of the ZP-Glucagon treatments, we achieved a 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) during the first 30 minutes following application compared to the glucagon injection. Additionally, application of our microneedle patch with our easy-to-use applicator avoids the delay in treatment associated with reconstitution of the currently available injectable products. We believe these attributes will provide significant advantages in the emergency rescue of a potentially comatose patient.

We intend to conduct a Phase 2 trial in Australia to evaluate the performance of our ZP-Glucagon product candidate 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 expect to commence, or treat the first patient in, this Phase 2 trial in the first quarter of 2015 and also complete the trial in the first quarter of 2015.

**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.

---

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

Migraine is a debilitating neurological disease that affects approximately 29 million adults in the United States according to a 2014 study by Global Data Pharma Point, or GlobalData. Symptoms of migraine include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. According to the Migraine Research Foundation, most patients who suffer from migraine experience attacks once or twice per month, and 14 million people, or about 4% of the U.S. population, experience chronic daily headache in which attacks occur at least 15 days per month.

According to GlobalData, 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, administered orally or by several alternative delivery systems, including nasal sprays, iontophoresis-based transdermal devices (which are devices that deliver medicine through the skin by a low electrical current) and subcutaneous injection. We believe that each of the currently available methods of administering triptans 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 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 a  $T_{MAX}$  of nine minutes 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 demonstrated rapid onset and bioavailability comparable to intravenous delivery. In 2014, we continued further confirmatory development of ZP-Triptan with additional preclinical studies. We intend to commence Phase 1 and Phase 2 clinical trials in the first half of 2015 and the second half of 2015, respectively, using an active injectable comparator to assess the relative speed of onset of ZP-Triptan compared to an injectable. The Phase 1 trial will be designed to compare the pharmacokinetic and safety/tolerability profiles of ascending patch doses of zolmitriptan and 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.

***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 using our system 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

**Table of Contents**

**Index to Financial Statements**

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.

**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

**Table of Contents**

**Index to Financial Statements**

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 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. 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.

The stability of a drug formulation is determined by whether 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>.

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.

Our research and development group has 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.

**Table of Contents**

**Index to Financial Statements**

We operate a current good manufacturing practices, or cGMP, manufacturing facility in Fremont, California, and we believe we have sufficient manufacturing and test capabilities to produce the microneedle patch system for our contemplated preclinical and Phase 1, Phase 2 and pivotal trials for our products.

**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 number of other indications beyond those on which we are currently focused, where fast onset, room-temperature stability, and ease of use will fill a significant unmet need.

After our lead product candidates, the 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.

**Table of Contents**

**Index to Financial Statements**

**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. We believe we will be able to compete effectively and profitably in these markets by offering an efficacious and lower cost alternative to existing treatments. We also believe that by continuing to focus on indications that can be treated with generic molecules with known safety and efficacy, for which we can develop our own proprietary formulations, we will be able to reduce our clinical and regulatory risk and development costs and accelerate our time to commercialization.

***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 have developed significant experience in the design and conduct of clinical trials and have established strong relationships with clinical teams, contract research organizations, or CROs, and key specialists and opinion leaders in our field that we believe have enabled us to rapidly and cost effectively advance our product candidates and reduce our regulatory risk early in the development process. 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. We believe this will be important to support the late-stage development, launch and commercial production of our product candidates, to establish and maintain high gross margins and to make other indications more economically viable.

***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. Our goal is to develop a cost-effective commercial infrastructure that will enable us to retain and maximize the commercial opportunity presented by our proprietary products.

***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 believe that our microneedle patch system can be used to deliver treatments for a wide variety of indications in addition to those on which we have initially focused. We believe that the potential for third parties to offer their own proprietary drugs in a more effective or easier to use form, as well as to significantly extend the product life

cycle of a profitable drug with limited remaining patent protection, will be attractive to potential collaborators. 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 Lilly 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.

**Table of Contents**

**Index to Financial Statements**

**Our product candidates**

The expected development timeline for our product candidates is summarized below:

The information provided in the table above is a forward-looking statement and is only intended to describe our expectations for the development time frame of our product candidates as of the date of this prospectus, assuming consummation of this offering and based on our expected use of the net proceeds of this offering, as described in "Use of Proceeds" on page 47. It is possible that we will not achieve the progress that we expect with respect to the clinical trials of our product candidates because the actual costs and timing of conducting clinical trials are difficult to predict and are subject to substantial risks and delays. In addition, the expected net proceeds of this offering will not be sufficient for us to complete the development of all of the product candidates described above and we will need to raise substantial additional capital to complete the development of any product candidate, other than ZP-Glucagon. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

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

Our product candidate Daily ZP-PTH is our proprietary formulation of PTH, to be administered daily for the treatment of severe osteoporosis. We believe that the main types of osteoporosis drugs currently available in the United States 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 IND to the 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 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 with a trial designed as a non-inferiority study compared to Forteo®, and intend to seek regulatory approval of Daily ZP-PTH pursuant to Section 505(b)(2) of the FDCA. 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. 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

---

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

commercial supplies of Daily ZP-PTH to Lilly. 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.

The license agreement permits, but does not require, us to pursue development of Weekly ZP-PTH at our own expense. 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. We also entered into a stock purchase agreement with Lilly in November 2014 pursuant to which Lilly will purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price.

The term of the license agreement with Lilly will expire on a country-by-country basis upon the expiration of all of Lilly's royalty payment obligations. Additionally, 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 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. Either party may terminate the agreement upon failure of the other party to cure a material breach of the agreement.

***Osteoporosis market is large and attractive***

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which can lead to an increase in bone fractures. It mainly affects adults age 50 and older. The 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. Assuming osteoporosis and low bone mass prevalence remain unchanged, the NOF projects that by 2020, 10.7 million adults will have osteoporosis and 58.2 million will have low bone mass. 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. As the United States population age 50 and older increases, the NOF projects that the incidence of osteoporosis will also increase. The NOF expects that the number of bone fractures due to osteoporosis will rise to three million by 2025 resulting in an estimated \$25.3 billion in costs. A patient has severe osteoporosis when he or she has a T-score  $\leq -2.5$  plus one or more fragility fractures. Approximately 700,000 adults in the United States suffer from severe osteoporosis.

***Significant unmet needs with existing treatments***

There are two main types of osteoporosis drugs 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. Both types of drug are typically prescribed by specialists, including gynecologists, endocrinologists, rheumatologists, orthopedists and geriatricians.

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 (which is 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 (which is a condition that shuts down the body's



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

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 and is 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 Forteo® in the osteoporosis market. There may be potential for synergies with the branding, patient support and physician education already in place for Forteo®. 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.

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

*Phase 2 trial with Daily ZP-PTH treatment showed a pulsatile delivery leading to a high BMD gain versus Forteo®*

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 design consisted of a six-month, randomized, placebo-controlled, positive control, multi-dose daily administration study with 165 patients enrolled. The study contained five arms: three arms of Daily ZP-PTH (20 µg, 30 µg, 40 µg) and a placebo patch, all self-administered daily with a 30-minute wear time, and a teriparatide 20 µg injection administered daily. Our Phase 2 trial demonstrated that at six months, the Daily ZP-PTH patch at 40 µg increased lumbar spine bone mineral density by a mean of 4.97%, compared to a loss of bone mineral density of a mean of 0.33% with a placebo, and increased hip bone mineral density by a mean of 1.33%, compared to an increase of a mean of 0.09% with teriparatide 20 µg injection and a loss of a mean of 0.63% with placebo (see tables below). In the tables immediately below, the 95% 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.

**Table of Contents**

**Index to Financial Statements**

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 bone mass density illustrated above. 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.

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 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>.

**Table of Contents**

**Index to Financial Statements**

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

The stability of a drug formulation is determined by whether 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>.

***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.

The Phase 3 trial is expected to be a 12-month, randomized, double-blind, double-dummy, multi-center global study comparing the safety and efficacy of Daily ZP-PTH to Forteo<sup>®</sup> for the treatment of postmenopausal osteoporosis, with a six-month safety extension. The trial will have three arms, with approximately 400 patients per arm (Daily ZP-PTH 30 µg, Daily ZP-PTH 40 µg and Forteo<sup>®</sup>).

*Study objectives.* The objectives of this trial are 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<sup>®</sup>, 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<sup>®</sup>.

*Primary efficacy endpoint.* The primary efficacy endpoint will be the percent change in lumbar spine BMD (L1-L4) over 12 months.

*Secondary efficacy endpoints.* The secondary efficacy endpoints will be 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.

**Table of Contents**

**Index to Financial Statements**

*Safety endpoints.* The safety endpoints will be maximal change in serum calcium within the first 10 hours of an administration (evaluated in a subgroup) and incidence of adverse events.

*Study design.* The study is randomized, double-blind, double-dummy, active-controlled parallel group one-year multi-center study, with a six-month safety extension. The planned 1200 eligible patients will be randomized equally to receive one of the following for one year:

One patch of Daily ZP-PTH 30 µg dose and one placebo injection;

One patch of Daily ZP-PTH 40 µg dose and one placebo injection; and

Daily administration of Forteo® (20 µg) subcutaneous injection and one placebo patch.

*Study powering.* The study will be powered to illustrate a non-inferiority margin of 1.5% of active comparator to Forteo®.

*Blinding.* Patients in the control group will receive sucrose-coated patches that are identical in gross appearance to the Daily ZP-PTH patches. Patients in the test (investigational treatment) group will receive a pen identical or similar to the Forteo® pen for daily injections. The active and placebo pens will have identical labels. If the pens are not identical, patients will be instructed in its use by a designated person at each site who is not involved in any of the study assessments.

**Our hypoglycemia opportunity ZP-Glucagon**

Our product candidate ZP-Glucagon is our proprietary formulation of glucagon, for the emergency rescue of patients suffering from life-threatening, severe hypoglycemia. 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 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 intend to commence a Phase 2 trial in Australia to evaluate the performance of ZP-Glucagon 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 expect to commence this Phase 2 trial in the first quarter of 2015 and also complete the trial in the first quarter of 2015.

***Severe hypoglycemia market is attractive and underserved***

Severe hypoglycemia is a life-threatening potential complication of diabetes treatment. It is characterized by very low level of blood sugar, often resulting from insulin overdose, which can cause loss of consciousness, seizure, coma and death. Timely treatment is critical. Severe hypoglycemia is treated by restoring blood glucose to normal levels by

administering a glucagon injection or infusion. The treatment is typically provided by a third party, caregiver or a bystander, as the patient is unable to self-administer the injection. Despite the risks involved with hypoglycemia, many insulin-dependent patients do not carry glucagon rescue kits.

There are 21 million diagnosed diabetes patients in the United States, of whom 26% are insulin-dependent. Insulin-dependent patients have on average 1.2 severe hypoglycemic events per year. There are currently two glucagon products marketed in the United States, Glucagon Emergency Kit by Lilly and GlucaGen<sup>®</sup> by Novo Nordisk. Based on our 2013 hypoglycemia survey, 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.

---

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

Sales of glucagon are driven by a combination of new glucagon prescriptions and refills of expired prescriptions after the end of the shelf life. Prescriptions for glucagon are most commonly written by diabetes specialists, including adult and pediatric endocrinologists. Pediatric use and use by the elderly in long-term care facilities comprise approximately 45% of the total prescriptions sold. Both of these segments need an intuitive and easy-to-use system for administration of glucagon.

We believe that ZP-Glucagon also has the potential to address the needs of type 2 insulin-dependent diabetics. There are approximately 2.9 million patients in this segment who, because they become insulin-dependent later in their adult life, do not have the same level of training or education on insulin dosing as type 1 diabetics. We believe that a user-friendly device such as our microneedle patch system for administration of ZP-Glucagon will be an attractive offering for this market segment.

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

There are currently two products marketed in the United States for severe hypoglycemia, Glucagon Emergency Kit by Lilly and GlucaGen® by Novo Nordisk. 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. To our knowledge, most competitors marketing or developing products for severe hypoglycemia offer injectable products.

***Clinical development of ZP-Glucagon***

Glucagon is indicated for use in emergency rescue of severely hypoglycemic patients with a recommended dose of 1 mg for adults and 0.5 mg for children under 44 pounds. We have conducted preclinical studies and clinical trials with a 0.5 mg dose using our existing 3 cm<sup>2</sup> patch and the reusable applicator.

Our ZP-Glucagon development program consists of studies designed to systematically reduce the development risk as the studies are completed. Our 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. A Phase 2 trial, also to be conducted in Australia, will be followed by a Phase 3 trial. The Phase 3 trial will be designed as a non-inferiority study compared to commercial glucagon administered by intramuscular injection, with submission in accordance with the 505(b)2 regulatory guidelines. After approval of our Generation 1 product, we will subsequently 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) for launch of our Generation 2 product with a 6cm<sup>2</sup> patch and a single-use applicator.

The endpoints in a glucagon trial are the responder rate and the time to normalization of glucose levels. Both endpoints are objective and measurable within a very short period of time after administration of glucagon.

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

Our first Phase 1 trial was completed in January 2014. It was designed to assess relative bioavailability with our microneedle patch system on a 3cm<sup>2</sup> patch compared to GlucaGen® which is 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.

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 is shown in the graphs

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

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.

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

Note: AUC measured in ng\*hr/mL

***Planned clinical development of ZP-Glucagon*****Planned Phase 2 trial**

We expect to commence our Phase 2 clinical trial in the first quarter of 2015. 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.

This study is expected to investigate the safety and efficacy of ZP-Glucagon in the treatment of insulin-induced hypoglycemia in diabetic patients (as opposed to healthy volunteers used in our Phase 1 trial). We expect this study to (i) inform our target dose for the pivotal Phase 3 trial and (ii) give us guidance to adequately power the pivotal study.

This trial is expected to be a four-way crossover study with 16 diabetic patients, each of whom would be administered the following four doses:



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

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

Intramuscular injections of 1.0 mg commercial glucagon; and

Intramuscular injections of 0.5 mg commercial glucagon.

The primary endpoints in this study are expected to be 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;

**Table of Contents**

**Index to Financial Statements**

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.

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.

Based on smaller trial sizes, easy enrollment and short time to results, we expect to complete all human trials and develop the Generation 1 ZP-Glucagon within approximately two years from the start of the clinical program. We expect to commence our planned Phase 3 clinical trial by the end of 2015.

We intend to complete a bridging study in order to launch the Generation 2 ZP-Glucagon product with a 6 cm<sup>2</sup> patch and a single use applicator after approval of the Generation 1 product.

**Our migraine opportunity ZP-Triptan**

Our product candidate ZP-Triptan is our proprietary formulation of zolmitriptan, used for the treatment of migraine. 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 intend to commence a Phase 1 trial in the first half 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 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.

**Table of Contents**

**Index to Financial Statements**

***Migraine is a large and attractive market***

According to the Migraine Research Foundation, migraine affects 36 million men, women and children in the United States. Symptoms of migraine include moderate to severe headache pain, nausea and vomiting, photophobia (abnormal sensitivity to light), and phonophobia (abnormal sensitivity to sound). 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.

***Existing treatments triptans, which comprise significant proportion of total migraine, have significant disadvantages***

According to a 2014 study by GlobalData, 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, 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***

According to a 2005 article by published in Headache, clinical trials have demonstrated that at least 30% of migraine patients fail to respond consistently to oral triptans. Based on data from multiple published third party clinical trials, including those described in a 2005 article by published in Headache, a peer-reviewed medical journal, we believe patients' failure to respond consistently results from a variety of causes, including a slower onset of action (typically ranging between one and three hours) and low and inconsistent absorption of oral medication because of reduced gastric motility in migraine patients.

In published studies, migraine sufferers often cite faster onset of pain relief as a key therapeutic attribute they would like from their migraine medication.

The following table compares the time to maximum drug concentration in blood, or Tmax, 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:

**Table of Contents****Index to Financial Statements****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.

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.

Sumatriptan injection forms have shown improved efficacy profiles over oral and nasal forms which may be attributable to a shorter  $T_{max}$ . Nasal forms, while claimed by some to be fast-acting, have drug absorption profiles similar to oral forms because a large portion of the administered dose may be swallowed prior to absorption. Given that  $T_{max}$  closely correlates to speed of onset of pain relief and pain freedom over time, and because of our preclinical results, we believe that ZP-Triptan may provide differentiated treatment from oral and nasal triptan products, which all have much slower onset of action.

Migraines may also be associated with nausea and/or vomiting. Twenty-nine percent of patients reported vomiting as a symptom of migraine attacks, according to the American Migraine Study II, and epidemiological studies in migraine reveal that the vast majority of patients (more than 90%) have experienced nausea during a migraine attack and more than 50% have nausea with the majority of attacks, according to an article published in *Drugs* in 2003 (Volume 63, Issue 21). Depending on the type of migraine episode, a treatment may be more or less effective. For example, oral treatments may be of little value in a patient who is vomiting or who is experiencing migraine-associated gastric stasis. There is also clinical evidence that oral agents may be less effective when taken at a later stage of a migraine attack, rather than at an earlier stage. Consequently, rapid onset migraine and waking with a migraine attack may reduce the benefits to patients of oral triptans, because both represent fully-developed attacks.

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

Because ZP-Triptan has demonstrated a  $T_{max}$  of nine minutes in preclinical studies, and does not depend on gastrointestinal absorption, we believe it has the potential for superior efficacy compared to currently marketed oral triptans. Our single-use disposable device is ready to apply after opening the packaging, is 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, NuPathe), 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.



**Table of Contents**

**Index to Financial Statements**

*Our ZP-Triptan solution offers high bioavailability*

ZP-Triptan, being delivered through the bloodstream, 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.

*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 hairless guinea pig model is a standard animal model that we have used for various development products because the skin is very similar to human skin.

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.

**Table of Contents**

**Index to Financial Statements**

In 2014, we continued further confirmatory development of ZP-Triptan with additional preclinical studies. Based on our preclinical results, we plan to commence a Phase 1 clinical trial of ZP-Triptan in the first half of 2015.

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

***Clinical development strategy for 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 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 trial involves an active comparator or placebo.

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

Our planned Phase 1 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. The results of the ZP-Triptan Phase 1 trial will guide the dose selection for the ZP Triptan Phase 2 trial.



**Table of Contents**

**Index to Financial Statements**

***Planned Phase 2 trial of ZP-Triptan***

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. 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 conduct our planned Phase 2 trial of ZP-Triptan after completion of our planned Phase 1 trial of ZP-Triptan, and we expect to conduct our planned Phase 3 trial of ZP-Triptan after completion of the Phase 2 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, 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 administered weekly 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.

***Further pipeline opportunities***

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. 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.

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.

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

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. The following table lists products that we believe may or will compete in the United States against Daily ZP-PTH, should Daily ZP-PTH receive approval for sale:

| <b>Manufacturer</b> | <b>Product</b>             | <b>Method of Treatment</b>             |
|---------------------|----------------------------|--|
| Amgen               | Romozosumab <sup>(1)</sup> | Injection (monthly)                    |
| Lilly               | Forteo <sup>®</sup>        | Injection in thigh or abdomen (daily)  |
| Lilly               | Blosozumab <sup>(1)</sup>  | Injection (twice monthly)              |
| Radius              | BA058 <sup>(1)</sup>       | Transdermal patch or injection (daily) |

(1) Currently undergoing clinical testing.

Companies marketing products that treat severe hypoglycemia that may compete with our ZP-Glucagon product candidate include Novo Nordisk and Lilly. The following table sets forth selected products that we believe would potentially compete against ZP-Glucagon, should this product receive approval for sale:

| <b>Manufacturer</b> | <b>Product</b>         | <b>Method of Treatment</b>  |
|---------------------|------------------------|---|
| Novo Nordisk        | GlucaGen <sup>®</sup>  | Injection   |
| Lilly               | Glucagon Emergency Kit | Injection   |
| Biodel              |                        | Stable liquid formulation delivered via pen injector <sup>(1)</sup> |
| Xeris               | G-Pen and G-Pen Mini   | Stable liquid formulation delivered via pen injector <sup>(1)</sup> |
| AMG Medical         |                        | Glucagon powder delivered intranasally <sup>(1)</sup>               |

(1) Currently undergoing clinical testing.

Companies marketing products that treat migraine that may compete with our ZP-Triptan product candidate include Teva, Zogenix, GlaxoSmithKline, AstraZeneca and Allergan. The following table sets forth selected products that we believe would potentially compete against ZP-Triptan, should this product receive approval for sale:

| <b>Manufacturer</b> | <b>Product</b>      | <b>Method of Treatment</b> |
|---------------------|---------------------|----------------------------|
| Teva                | Zecuity             | sumatriptan patch          |
| Zogenix             | Sumavel DosePro     | sumatriptan injection      |
| GlaxoSmithKline     | Imitrex Nasal Spray | sumatriptan nasal spray    |
| AstraZeneca         | Zomig Nasal Spray   | zolmitriptan nasal spray   |
| Allergan            | Levadex             | dihydroergotamine inhaler  |

*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.

**Table of Contents**

**Index to Financial Statements**

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 have adequate manufacturing capabilities and capacity to produce our microneedle patch system for preclinical and Phase 1, Phase 2 and pivotal trials of our products. We follow current good manufacturing practices, or cGMP, in our Fremont, California manufacturing facility. 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.

*Manufacturing Process*

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. We generally expect to retain commercial rights in the United States for our current product candidates other than Daily ZP-PTH, all of which are still in preclinical or clinical development. 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.

We focus on indications that have patient populations large enough to provide us with an attractive commercial opportunity, and where there is currently limited competition and premium pricing. We believe we will be able to compete effectively and profitably in these markets by offering a more effective and lower cost alternative. We also

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. We intend to develop a small, cost-effective commercial infrastructure that will enable us to retain and maximize the commercial opportunity.

**Table of Contents**

**Index to Financial Statements**

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 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.

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

The patents and patent applications we own or hold under license as of December 31, 2014 are as follows:

| <b>United States</b>     | <b>Europe</b>               | <b>Japan</b>              | <b>China</b>                | <b>Patent</b>            |
|--------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|
| <b>Patent Number</b>     | <b>Patent Number</b>        | <b>Patent Number</b>      | <b>Patent Number</b>        | <b>Patent</b>            |
| <b>(Expiration Date)</b> | <b>(Expiration Date)</b>    | <b>(Expiration Date)</b>  | <b>(Expiration Date)</b>    | <b>(Expiration Date)</b> |
| 4/466,461***;            |                             |                           |                             |                          |
| US14/52326***;           |                             |                           |                             |                          |
| ,556,821 (18-Mar-2025);  | EP 1 744 683**;             | JP 5007427 (18-Mar-2025); |                             |                          |
| ,361,022 (18-Mar-2025);  | EP 2 001 453**;             | JP 5309203 (18-Mar-2025); |                             |                          |
| ,633,159 (15-Feb-2027);  |                             |                           |                             |                          |
| 008/0039775**;           |                             |                           |                             |                          |
| 010/0119568** ;          |                             |                           |                             |                          |
| ,537,795 (31-May-2023);  | EP 1 333 880 (26-Oct-2021); | JP 4659336 (26-Oct-2021); | CN 100548228 (21-Oct-2024); | KR 10081209              |
| ,579,013 (29-Jun-2024);  | EP 1 392 389 (20-Apr-2022); | JP 5388415 (21-Oct-2024); | CN 1842320 (29-Jun-2024);   |                          |
| ,963,935 (23-May-2027);  | EP 1 638 523 (29-Jun-2024); | JP 5456234 (29-Jun-2024); | CN 100566669 (18-Mar-2025); |                          |
| ,663,155 (24-Jun-2023);  |                             |                           | CN 1239212 (26-Oct-2021);   |                          |
| 010/0221305**;           |                             |                           | CN 100349632 (20-Apr-2022); |                          |
| 014/0260096**;           |                             |                           | CN 100421653 (6-Sep-2021);  |                          |
| ,050,988 (9-Dec-2018);   | EP 1 037 686 (9-Dec-2018);  | JP 4012252 (17-Jun-2017); | CN 1170603 (9-Dec-2018);    |                          |
| ,083,196 (9-Dec-2018);   | EP 1 037 687 (9-Dec-2018);  | JP 4061022 (9-Dec-2018);  | CN 1161164 (9-Dec-2018);    |                          |
| ,322,808 (9-Dec-2018);   |                             |                           |                             |                          |
| ,184,826 (17-Jun-2017);  |                             |                           |                             |                          |
| ,855,131 (26-Oct-2021);  | EP 1 239 917 (7-Dec-2020);  | JP 4104975 (12-Oct-2021); | CN 100402106 (7-Dec-2020);  |                          |
| ,753,318 (10-Apr-2026);  | EP 1 341 452 (12-Dec-2021); | JP 4312407 (7-Dec-2020);  |                             |                          |



,953,589 (9-Dec-2018); EP 1 035 889 (9-Dec-2018);  
 4/306,854\*\*\*;  
 ,087,035 (12-Mar-2022); EP 1 239 916 (7-Dec-2020); JP 4198985 (12-Oct-2021); CN 1250171 (12-Oct-2021); KR 10081854  
 ,097,631 (27-Jan-2025); EP 1 341 442 (12-Oct-2021); JP 4659332 (12-Oct-2021); CN 100571643 (21-Oct-2024);  
 ,131,960 (13-Apr-2022); EP 1 341 453 (12-Oct-2021); JP 4682144 (21-Oct-2024); CN 100391404 (12-Oct-2021);  
 ,419,481 (13-Mar-2022); EP 1 680 154 (21-Oct-2024); JP 2008-534152\*\*;  
 ,798,987 (13-Sep-2025);  
 4/447,309\*\*\*;  
 007/0027427\*\*;  
 006/0095061\*\*;  
 US14/48932\*\*\*;  
 ,855,372 (10-Nov-2022); EP 1 981 547\*\*; JP 5438872 (1-Jun-2026); CN 101189031\*\*;  
 ,435,299 (18-Jan-2025); JP 2009-522288\*\*;  
 ,632,801 (31-May-2023);

\* Patents are for the benefit of all formulations

\*\* Publication Number (pending)

\*\*\* Application Number (pending)

## **Table of Contents**

### **Index to Financial Statements**

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, 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 conduct of the preclinical tests and formulation of the compounds for testing must comply

---

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

with federal regulations and requirements. 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. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 1 trials are usually conducted in healthy individuals. However, Phase 1b trials may be conducted in healthy volunteers or in patients diagnosed with the disease or condition for which the study drug is intended, who demonstrate some biomarker, surrogate, or possibly clinical outcome that could be considered for proof of concept. Proof of concept in a Phase 1b trial typically confirms the hypothesis that the current prediction of biomarker, or outcome benefit is compatible with the mechanism of action. Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage, (ii) identify possible adverse effects and safety risks, and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Several different doses of the drug may be looked at in Phase 2 to see which dose has the desired effects. Patients are monitored for side effects and for any improvement in their illness, symptoms, or both. Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. A Phase 3 trial usually compares how well the study drug works compared with an inactive placebo and/or another approved medication. One group of patients may receive the new drug being tested, while another group of patients may receive the comparator drug (already-approved drug for the disease being studied), or placebo. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA

approval for new or improved formulations of previously approved 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 testing and approval process

**Table of Contents**

**Index to Financial Statements**

requires substantial time, effort and financial resources. 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.

The FDA has various programs, including fast track, priority review and accelerated approval that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those intended to treat serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. A company cannot be sure that any of its drugs will qualify for any of these programs, or if a drug does qualify, that the review time will be reduced.

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 NDA are required to (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements

---

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

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. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. 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. The court may shorten or lengthen the 30 month stay period 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. Thus,



the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. 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.

**Table of Contents**

**Index to Financial Statements**

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.

*Centralized Procedure*

Under the centralized procedure, after the European Medicines Agency, or EMA, issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

*National Authorization Procedures*

There are also two other possible routes to authorize medicinal products in several countries, which are available for products that fall outside the scope of the centralized procedure:

*Decentralized Procedure*

Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of a medicinal product that has not yet been authorized in any European Union country and that does not fall within the mandatory scope of the centralized procedure.

*Mutual Recognition Procedure*

In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Thereafter, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In light of the fact that there is no policy at the EU level governing pricing and reimbursement, the EU Member States each have developed their own, often varying, approaches. In many EU Member States, pricing negotiations must take

place between the holder of the marketing authorization and the competent national authorities before the product is sold in their market with the holder of the marketing authorization required to provide evidence demonstrating the pharmaco-economic superiority of its product in comparison with directly and indirectly competing products. 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.

**Table of Contents**

**Index to Financial Statements**

*Good Manufacturing Practices*

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.

*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

**Table of Contents**

**Index to Financial Statements**

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*

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

We may also be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the recently enacted Patient Protection and Affordable Care Act, or the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes, so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA permits the government to assert that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment, to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing.

Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the

increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.

## **Table of Contents**

### **Index to Financial Statements**

Similar rigid restrictions are imposed on the promotion and marketing of medicinal products in the EU and other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have implications for us.

### *Other Governmental Regulations and Environmental Matters*

We will be subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the SEC and, if any of our capital stock becomes listed on the NASDAQ Capital Market or another exchange, we will be subject to the regulations of the NASDAQ Capital Market or another exchange, respectively. In addition, the Financial Accounting Standards Board, or the FASB, the SEC and other bodies that will have jurisdiction over the form and content of our accounts, our financial statements and other public disclosure are constantly discussing and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

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, CROs, 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 full-time employees, and 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.

## **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.

## **Legal Proceedings**



We are not currently involved in any material legal proceedings.

Table of ContentsIndex to Financial Statements**MANAGEMENT****Executive Officers, Directors and Key Employees**

Our executive officers, directors and key employees, their current positions and their ages as of December 31, 2014 are set forth below:

| <b>Name</b>  | <b>Age</b> | <b>Position(s)</b>                              |
|--|------------|---|
| Bruce D. Steel <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>            | 48         | Chairman of Board of Directors                  |
| M. James Barrett <sup>(1)</sup> <sup>(2)</sup> <sup>(3)</sup>          | 72         | Director  |
| Troy Wilson <sup>(3)</sup> <sup>(4)</sup> <sup>(5)</sup>               | 46         | Director  |
| Kleanthis G. Xanthopoulos <sup>(2)</sup> <sup>(3)</sup> <sup>(4)</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   | 52         | Chief Operating Officer                         |
| Winnie W. Tso  | 53         | Chief Financial Officer                         |

- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee, effective on the date of this prospectus.
- (4) Member of the audit committee, effective on the date of this prospectus.
- (5) Member of the compensation committee, effective on the date of this prospectus.

**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

---

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

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 managers of Avidity NanoMedicines LLC, a private biopharmaceutical company, since November 2012 and the 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. He 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 Santé 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 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.

---

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

**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® Internal Venture at Johnson & Johnson. Previously, Dr. Daddona was Vice President of Macroflux® 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.

**Board Composition**

Our board of directors currently consists of six members, all of whom were elected as directors pursuant to a stockholders agreement that we have entered into with certain holders of our common stock. The stockholders agreement will terminate upon the closing of this offering and there will be no further contractual obligations regarding the election of our directors. Our directors and officers hold office until their successors have been elected and qualified, or until their earlier death, resignation or removal.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of the board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 66  $\frac{2}{3}$ % of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of

**Table of Contents**

**Index to Financial Statements**

directors, including a vacancy resulting from an enlargement of our board of directors, may be filled either by vote of a majority of our directors then in office even though less than a quorum or by a stockholder vote pursuant to a resolution approved by the board of directors.

Under our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

the class I directors will be Vikram Lamba and Peter E. Daddona, and their initial term will expire at the annual meeting of stockholders to be held in 2015;

the class II directors will be M. James Barrett and Bruce D. Steel, and their initial term will expire at the annual meeting of stockholders to be held in 2016; and

the class III directors will be Troy Wilson and Kleantlis G. Xanthopoulos, and their initial term will expire at the annual meeting of stockholders to be held in 2017.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be nominated for re-election for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through an established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

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

**Director Independence**

Our common stock has been approved for listing 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 of the completion of an initial public offering. In addition, the rules of The NASDAQ Stock Market require that (i) on the date of the completion of the offering, at least one member of each of a listed company's audit, compensation and nominating and corporate governance committees be independent, (ii) within 90 days of the date of the completion of the offering, a majority of the members of such committees be independent and (iii) within one year of the date of the completion of the offering, all the members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or 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 that 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.

**Table of Contents**

**Index to Financial Statements**

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. 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 within 90 days of the effective date of this prospectus, and a second within one year from such date. 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 and a compensation committee. We have also established a nominating and corporate governance committee, effective as of the date of this prospectus. Each of these committees, which are the only standing committees of our board of directors, will operate under a charter that has been approved by our board of directors.

*Audit Committee.* The current members of our audit committee are Dr. Barrett and Mr. Steel. Effective as of the date of this prospectus, our audit committee will consist of Dr. Barrett, 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 intend to add at least one additional independent director to our audit committee. 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. 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.

*Compensation Committee.* The current members of our compensation committee are Dr. Barrett, Mr. Steel and Dr. Xanthopoulos. Effective as of the date of this prospectus, our compensation committee will consist of Dr. Barrett, Mr. Steel, Dr. Wilson and Dr. Xanthopoulos, of whom each of Dr. Wilson and Dr. Xanthopoulos is an independent director. We intend to add at least one additional independent director to our compensation committee. The compensation committee:

approves the compensation and benefits of our executive officers;

## **Table of Contents**

### **Index to Financial Statements**

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.* Effective as of the date of this prospectus, the members of our nominating and corporate governance committee will be Dr. Barrett, Mr. Steel, Dr. Wilson and Dr. Xanthopoulos, of whom each of Dr. Wilson and Dr. Xanthopoulos is an independent director. We intend to add at least one additional independent director to our nominating and corporate governance committee. The nominating and corporate governance committee will:

identify individuals qualified to become board members;

recommend to the board of directors nominations of persons to be elected to the board; and

advise the board regarding appropriate corporate governance policies and assists the board in achieving them.

### **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.

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

We have adopted a written code of business conduct and ethics that applies to our directors, executive officers and employees, effective as of the date of this prospectus. Following this offering, a copy of the code will be posted on the Corporate Governance section of our website, which is located at [www.zosanopharma.com](http://www.zosanopharma.com). If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

### **Director Compensation**

Prior to this offering, 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.

Following the closing of this offering, our non-employee directors will receive compensation as follows:

an annual cash fee of \$25,000, and non-statutory stock options to purchase shares of our common stock (at a per share exercise price equal to fair market value on the date of grant) vesting in equal monthly installments over a period of four years, with full acceleration of vesting upon a change of control.

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.

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

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](#) 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</b> <sup>(1)</sup> <sup>(2)</sup> | <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 prospectus.
- (2) Represents a non-statutory option to purchase 28,301 shares of common stock granted in July 2014.

Table of ContentsIndex to Financial Statements**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>Bonus</b>           | <b>Option awards <sup>(3)</sup></b> | <b>Total</b> |
|--|-------------|---------------|------------------------|-------------------------------------|--------------|
| Vikram Lamba<br><i>Chief Executive Officer</i>   | 2014        | \$ 412,000    | \$ (1)                 | \$                                  | \$ 412,000   |
| Peter Daddona<br><i>Chief Scientific Officer</i> | 2013        | 412,000       | 185,400 <sup>(2)</sup> |                                     | 597,400      |
| Nandan Oza<br><i>Chief Operating Officer</i>     | 2014        | 329,815       | (1)                    |                                     | 329,815      |
|  | 2013        | 334,750       | 120,510 <sup>(2)</sup> |                                     | 455,260      |
|  | 2014        | 203,333       | (1)                    | 4,766                               | 208,099      |

- (1) Cash bonus amount in respect of 2014 is not calculable through the latest practicable date, and is expected to be determined by our compensation committee and board of directors during the first quarter of 2015.
- (2) Represents cash bonus amounts awarded in respect of 2013, payment of which is contingent upon the completion of this offering. 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.

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 this offering, our compensation committee will approve 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



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

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.

**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          | Option Awards   |   |                            |                        |                   |
|---------------|---|---|----------------------------|------------------------|-------------------|
|               | Number of Securities Underlying Unexercised Options (#) exercisable | Number of Securities Underlying Unexercised Options (#) unexercisable | Option Exercise Price (\$) | Option Expiration Date | Option Grant Date |
| Vikram Lamba  | 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         |
|               | <sup>(2)</sup>  | 5,000   | \$ 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 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,

---

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

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. Also, upon a change in control, as defined in the employment agreement, all shares of Mr. Lamba's founder's stock will be released from our repurchase option described below, and if within a year after a change of control 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. In January 2012, in connection with the incorporation of Zosano Pharma Corporation (then named ZP Holdings, Inc.), we issued and sold to Mr. Lamba 625,000 shares of our common stock as founder's stock pursuant to a Restricted Stock Purchase Agreement dated as of January 26, 2012 between us and Mr. Lamba. Following the April 2012 reorganization, we entered into a Stock Repurchase Option Agreement dated as of May 15, 2012 with Mr. Lamba which provides us an option to repurchase certain shares of Mr. Lamba's founder's stock upon certain terminations of Mr. Lamba's employment with us, and also provides for the release of the shares from this repurchase option upon a change of control as described above.

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. Also, upon a change in control, as defined in the employment agreement, all unvested shares of Dr. Daddona's founder's stock will be released from our repurchase option described below, and if within a year after a change of control 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. In January 2012, in connection with the incorporation of Zosano Pharma Corporation (then named ZP Holdings, Inc.), we issued and sold to Dr. Daddona 312,500 shares of our common stock as founder's stock pursuant to a Restricted Stock Purchase Agreement dated as of January 26, 2012 between us and Dr. Daddona. Following the April 2012 reorganization, we entered into a Stock Repurchase Option Agreement dated as of May 15, 2012 with Dr. Daddona which provides us an option to repurchase certain shares of Dr. Daddona's founder's stock upon certain terminations of Dr. Daddona's employment with us, and also provides for the release of the shares from this repurchase option upon a change of control as described above.

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. Also, 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.

**Stock Incentive and Equity Compensation Plans**

We believe that equity-based awards are important vehicles by which to align the interest of our employees with the financial interests of our stockholders, and we historically have awarded stock options broadly to our employees, including our named executive officers. The material terms and conditions of our stock incentive and equity compensation plans are described below.

We have the following equity incentive plans: (i) 2012 Stock Incentive Plan; and (ii) 2014 Equity and Incentive Plan. Following the closing of this offering, our 2014 Equity and Incentive Plan will be the only effective equity compensation plan pursuant to which we will make new awards.

***2012 Stock Incentive Plan***

Our 2012 Stock Incentive Plan provides for the grant of equity-based awards, denominated in shares of our common stock, including incentive stock options, non-statutory stock options and restricted stock awards. We will not make any new awards under the 2012 Stock Incentive Plan following the completion of this offering.

**Table of Contents**

**Index to Financial Statements**

The material features of our 2012 Stock Incentive Plan are summarized below. The complete text of our 2012 Stock Incentive Plan is filed as an exhibit to the registration statement of which this prospectus forms a part.

*General.* The maximum number of shares of common stock which may be issued under our 2012 Stock Incentive Plan is 566,027. Any shares subject to an award granted under our 2012 Stock Incentive Plan to any person are counted against this limit.

*Purposes.* The purpose of our 2012 Stock Incentive Plan is to encourage and enable our officers and employees and other persons providing services to us and our subsidiaries to acquire a proprietary interest in our business. We believe that by providing such persons with a direct stake in our welfare will assure a closer identification of their interests with our interests and the interests of our shareholders, thereby stimulating their efforts on our behalf and strengthening their desire to remain with us.

*Administration.* Our 2012 Stock Incentive Plan has been administered by our board of directors, and, following the closing of this offering, will be administered by the compensation committee of our board of directors. Subject to the terms of our 2012 Stock Incentive Plan, the board of directors may determine the types of awards and the terms and conditions of such awards, interpret provisions of our 2012 Stock Incentive Plan and select participants to receive awards.

*Source of shares.* The shares of common stock issued or to be issued under our 2012 Stock Incentive Plan consist of authorized but unissued shares and shares that we have reacquired. Shares of common stock underlying any awards issued under the 2012 Stock Incentive Plan that are forfeited, cancelled, reacquired by us or otherwise terminated (other than by exercise) will be added back to the shares of common stock with respect to which awards may be granted under the 2012 Stock Incentive Plan.

*Eligibility.* Awards may be granted under the 2012 Stock Incentive Plan to our and our subsidiaries' respective officers, directors, employees, and to consultants and advisors to and us and/or our subsidiaries.

*Amendment or termination of our stock incentive plan.* Our board of directors may terminate or amend the 2012 Stock Incentive Plan at any time. No amendment or termination may adversely impair the rights of grantees with respect to outstanding awards without the affected participant's consent to such amendment. In addition, an amendment will be contingent on approval of our stockholders to the extent required by law. Unless terminated earlier, our 2012 Stock Incentive Plan will terminate in April 2022, but will continue to govern unexpired awards.

*Options.* Our 2012 Stock Incentive Plan permits the granting of options to purchase shares of common stock intended to qualify as incentive stock options under the Internal Revenue Code, and options that do not qualify as incentive stock options, which are referred to as non-statutory stock options. We may grant non-statutory stock options to our employees, directors, officers, consultants or advisors in the discretion of our board of directors. Incentive stock options will only be granted to our employees.

The exercise price of each incentive stock option and non-statutory stock option may not be less than 100% of the fair market value of shares of our common stock on the date of grant. If we grant incentive stock options to any 10% stockholder, the exercise price may not be less than 110% of the fair market value of shares of our common stock on the date of grant. The term of each option may not exceed 10 years from the date of grant, except that the term of any incentive stock option granted to any 10% stockholder may not exceed five years from the date of grant. At the time of grant of the award, our board of directors determines at what time or times each option may be exercised and the

period of time, if any, after retirement, death, disability or termination of employment during which options may be exercised. Options may be made exercisable in installments. The vesting and exercisability of options may be accelerated by the board of directors.

In general, an optionee may pay the exercise price of an option by cash or check or, if so provided in the applicable option agreement and with the written consent of the board of directors, by tendering shares of our

**Table of Contents**

**Index to Financial Statements**

common stock having a fair market value equal to the aggregate exercise price of the options being exercised, by a personal recourse note issued by the optionee in a principal amount equal to the aggregate exercise price of the options being exercised, by a cashless exercise through a broker supported by irrevocable instructions to the broker to deliver sufficient funds to pay the applicable exercise price, by reducing the number of shares otherwise issuable to the optionee upon exercise of the option by a number of shares having a fair market value equal to the aggregate exercise price of the options being exercised, or by any combination of these methods of payment.

Incentive stock options granted under our 2012 Stock Incentive Plan may not be transferred or assigned other than by will or under applicable laws of descent and distribution. Our board of directors may determine the extent to which a non-statutory option shall be transferable.

*Restricted stock awards.* Restricted stock awards entitle the recipient to acquire, for a purchase price determined by the board of directors, shares of common stock subject to such restrictions and conditions as the board of directors may determine at the time of grant, including continued employment and/or achievement of pre-established performance goals and objectives.

*Adjustments upon changes in capitalization.* We will make appropriate and proportionate adjustments in outstanding awards and the number of shares available for issuance under the 2012 Stock Incentive Plan to reflect recapitalizations, reclassifications, stock dividends, stock splits, reverse stock splits and other similar events.

*Effect of a change in control.* Upon the occurrence of a change in control transaction (as defined in the 2012 Stock Incentive Plan), unless otherwise provided in any stock option agreement or restricted stock agreement, our board of directors (or the board of directors of any corporation assuming the obligations of our company), may, in its discretion, take any one or more of the following actions as to some or all outstanding stock options or restricted stock awards:

provide that such stock options will be assumed, or equivalent stock options substituted, by the acquiring or succeeding corporation (or an affiliate thereof);

upon written notice to the optionees, provide that all unexercised stock options will terminate immediately prior to the consummation of the change in control transaction unless exercised by the optionee to the extent otherwise then exercisable within a specified period following the date of such notice;

upon written notice to the grantees, provide that all unvested shares of restricted stock will be repurchased at cost;

make or provide for a cash payment to the optionees equal to the difference between (x) the fair market value of the per share consideration (whether cash, securities or other property or any combination thereof) the holder of a share of our common stock will receive upon consummation of the change in control transaction times the number of shares of common stock subject to outstanding vested stock options (to the extent then exercisable at prices not equal to or in excess of such per share consideration) and (y) the aggregate exercise

price of such outstanding vested stock options, in exchange for the termination of such stock options; or

provide that all or any outstanding stock options will become exercisable and all or any outstanding restricted stock awards will vest in part or in full immediately prior to the change in control transaction.

To the extent that any stock options are exercisable at a price equal to or in excess of the per share consideration in the change in control transaction, our board of directors may provide that such stock options will terminate immediately upon the consummation of the change in control transaction without any payment being made to the holders of such stock options.



**Table of Contents**

**Index to Financial Statements**

***2014 Equity and Incentive Plan***

Our board of directors has adopted, and our stockholders have approved, our 2014 Equity and Incentive Plan. A total of 1,400,000 shares of our common stock will initially be reserved for issuance under our 2014 Equity and Incentive Plan, subject to automatic annual increases as set forth in the plan. The 2014 Equity and Incentive Plan provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of our 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.

*Purpose.* The purpose of our 2014 Equity and Incentive Plan is to (i) provide long-term incentives and rewards to those employees, officers, directors and other key persons (including consultants) of the company and its subsidiaries who are in a position to contribute to the long-term success and growth of the company and its subsidiaries, (ii) to assist the company and its subsidiaries in attracting and retaining persons with the requisite experience and ability, and (iii) to more closely align the interests of such employees, officers, directors and other key persons with the interests of the company's stockholders.

*Administration.* Our 2014 Equity and Incentive Plan will be administered by the compensation committee of our board of directors. The compensation committee is generally granted broad authority to administer the plan, including the power to determine and modify the terms and conditions, not otherwise inconsistent with the terms of the plan, of any award. All decisions and interpretations of the compensation committee shall be binding on all persons subject to the plan including the company and plan grantees.

*Sources of shares.* The shares of common stock to be issued under the 2014 Equity and Incentive Plan consist of authorized but unissued shares and shares that we have reacquired. Shares of common stock underlying any award issued under the 2014 Equity and Incentive Plan that are forfeited, canceled, satisfied without issuance of stock, otherwise terminated or, for shares of stock issued pursuant to any unvested full value award, reacquired by the company shall be added back to the shares of common stock with respect to which awards may be granted under the plan.

*Eligibility.* Incentive stock options may only be granted to our employees. All other awards may be granted to our employees, officers, directors and key persons (including consultants and prospective employees).

*Amendment or termination of our 2014 Equity and Incentive Plan.* Subject to requirements of law or any stock exchange or similar rules which would require a vote of our stockholders, our board of directors may, at any time, amend or discontinue the plan and the compensation committee may, at any time, amend or cancel any outstanding award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding award without the holder's consent.

*Options.* Our 2014 Equity and Incentive Plan permits the granting of options to purchase common stock that are intended to qualify as incentive stock options under the Code, and options that do not qualify as incentive stock options, which are referred to as non-statutory stock options. We may grant non-qualified stock options to our employees, directors, officers, consultants or advisors in the discretion of our board of directors. Incentive stock options will only be granted to our employees. The exercise price of each incentive stock option may not be less than 100% of the fair market value of shares of our common stock on the date of grant. If we grant incentive stock options to any person holding 10% or more of the outstanding voting stock of the company, the exercise price may not be less than 110% of the fair value of shares of our common stock on the date of grant. The exercise price of any

non-qualified stock option will be determined by our board of directors and may not be less than the fair value of shares of our common stock.

The term of each option may not exceed 10 years from the date of grant, and no option shall be transferable by the optionee other than by will or by the laws of descent and distribution. Notwithstanding the foregoing, the

**Table of Contents**

**Index to Financial Statements**

compensation committee, in its sole discretion, may provide in the award agreement regarding a given option, or may agree in writing with respect to an outstanding option, that the optionee may transfer their non-statutory stock options to members of their immediate family, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the company to be bound by all of the terms and conditions of this plan and the applicable option.

In general, an optionee may pay the exercise price of an option by cash or, if so provided in the applicable option agreement, by tendering shares of our common stock, by a cashless exercise through a broker supported by an irrevocable instruction to such broker to deliver sufficient funds to pay the applicable exercise price, by reducing the number of shares otherwise issuable to the optionee upon exercise of the option by a number of shares having a fair market value equal to the aggregate exercise price of the options being exercised or by any other method permitted by the compensation committee.

*Stock appreciation rights.* Pursuant to the 2014 Equity and Incentive Plan, we may grant stock appreciation rights, or an award entitling the recipient to receive cash or shares of our common stock having a value on the date of exercise calculated as follows: (i) the exercise price of a share of common stock on the grant date is less the fair market value of the common stock on the date of exercise and (ii) multiplied by the number of shares of stock with respect to which the stock appreciation right shall have been exercised. The exercise price of a stock appreciation right shall not be less than 100% of the fair market value of our common stock on the date of grant, and the terms and conditions of the stock appreciation rights shall be determined from time to time by the compensation committee.

*Restricted stock awards.* Pursuant to the 2014 Equity and Incentive Plan, we may grant restricted stock awards entitling the recipient to acquire, at such a price as determined by the compensation committee, shares of common stock subject to such restrictions and conditions as the compensation committee may determine at the time of grant. Conditions may be based on continuing employment or achievement of pre-established performance goals and objectives. A holder of a restricted stock award may exercise voting rights upon (i) execution of a written instrument setting forth the award and (ii) payment of any applicable purchase.

*Restricted stock units.* Pursuant to the 2014 Equity and Incentive Plan, we may grant restricted stock units which entitle the holder, upon vesting of the right, to a number of shares of common stock as determined in the award agreement. The compensation committee shall determine the restrictions and conditions applicable to each restricted stock unit at the time of grant, and a holder of a restricted stock unit shall only have exercisable rights as a stockholder upon settlement of restricted stock units. Unless otherwise provided in the award agreement, a holder's rights in all restricted stock units that have not vested shall automatically terminate immediately following the holder's termination of employment with the company for any reason.

*Unrestricted stock awards.* Pursuant to the 2014 Equity and Incentive Plan, we may grant unrestricted awards of shares of common stock free of any restrictions under the plan. The right to receive shares of unrestricted stock awards on a deferred basis may not be sold, assigned, transferred, pledged or otherwise encumbered, other than by will or the laws of descent and distribution.

*Performance share awards.* Pursuant to the 2014 Equity and Incentive Plan, we may grant performance share awards entitling the recipient to acquire shares of common stock upon the attainment of specified performance goals; provided, however, that the compensation committee, in its discretion, may provide either at the time of grant or at the time of settlement that a performance share award will be settled in cash. The period during which performance is to be measured for performance share awards shall not be less than one year, and such performance share awards, and all

rights with respect to such awards, may not be sold, assigned, transferred, pledged or otherwise encumbered.

*Dividend equivalent rights.* Pursuant to the 2014 Equity and Incentive Plan, we may grant dividend equivalent rights entitling the recipient to receive credits based on cash dividends that would be paid on the

## **Table of Contents**

### **Index to Financial Statements**

shares of stock specified in the dividend equivalent right (or other award to which it relates). Dividend equivalent rights may be settled in cash or shares of stock or a combination thereof, in a single installment or installments. A dividend equivalent right granted as a component of another award may provide that such dividend equivalent right shall be settled upon exercise, settlement, or payment of, or lapse of restrictions on, such other award, and that such dividend equivalent right shall expire or be forfeited or annulled under the same conditions as such other award.

*Cash awards.* The compensation committee, in its discretion, may provide for cash payments to be made under the 2014 Equity and Incentive Plan. Such cash awards may be made subject to such terms, conditions and restrictions as the compensation committee considers necessary or advisable.

*Effect of a change in control.* If we experience a change in control, as defined in the 2014 Equity and Incentive Plan, the compensation committee may in its discretion, at the time an award is made or at any time thereafter, take one or more of the following actions: (i) provide for the acceleration of any time period relating to the exercise or payment of the award; (ii) provide for termination of any awards not exercised prior to the occurrence of a change in control; provided that the holder of any such award is given written notice of such prospective action by the administrator at least ten calendar days prior to the effective date of the change in control; (iii) provide for payment to the holder of the award of cash or other property with a fair market value equal to the amount that would have been received upon the exercise or payment of the award had the award been exercised or paid upon the change in control in exchange for cancellation of the award; (iv) adjust the terms of the award in a manner determined by the compensation committee to reflect the change in control; (v) cause the award to be assumed, or new rights substituted therefor, by another entity; or (vi) make such other provision as the compensation committee may consider equitable to the holders of awards and in our best interests.

### **401(k) Retirement Plan**

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Code. In general, all of our employees, upon meeting certain requirements, are eligible to participate in the 401(k) plan. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit and have the amount of the reduction contributed to the 401(k) plan. Employee contributions are held and invested by the plan's trustee. The 401(k) plan also permits the Company to make discretionary matching contributions. The Company did not make any matching contribution for the years ended December 31, 2014, 2013 or 2012.

### **Limitation of Liability and Indemnification**

Our amended and restated certificate of incorporation includes provisions that will limit or eliminate the personal liability of our directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breaches of their fiduciary duties as directors, except liability for:

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or

any transaction from which the director derived an improper personal benefit.

These limitations do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies, including injunctive relief or rescission. If Delaware law is amended to authorize the further elimination or limiting of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law as so amended.

**Table of Contents**

**Index to Financial Statements**

As permitted by Delaware law, our certificate of incorporation and bylaws that will be effective as of the closing date of this offering will also provide that:

we will indemnify our directors and officers to the fullest extent permitted by law;

we may indemnify our other employees and other agents to the same extent that we indemnify our officers and directors, unless otherwise determined by our board of directors; and

we will advance expenses to our directors and officers in connection with legal proceedings in connection with a legal proceeding to the fullest extent permitted by law.

The indemnification provisions contained in our certificate of incorporation that will be effective as of the closing date of this offering are not exclusive.

We believe that these provisions are necessary to attract and retain qualified persons as directors and officers. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we understand that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

In addition, we have entered into indemnification agreements with each of our directors and maintain standard policies of insurance under which coverage is provided to our directors and officers against losses arising from claims made by reason of breach of duty or other wrongful act, and to us with respect to payments which may be made by us to such directors and officers pursuant to the above indemnification provisions or otherwise as a matter of law.

---

**Table of Contents****Index to Financial Statements****RELATED PERSON TRANSACTIONS**

The following is a description of transactions since January 1, 2012 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 the *Executive Compensation* section of this report. 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.

**Issuance of Founder's Shares**

In January 2012, in connection with our incorporation, we issued and sold to Vikram Lamba, our President and Chief Executive Officer and a director, 625,000 shares of our common stock as founder's stock for an aggregate purchase price of \$250 pursuant to a restricted stock purchase agreement between us and Mr. Lamba, and we issued and sold to Peter Daddona, our Chief Scientific Officer and a director, 312,500 shares of our common stock as founder's stock for an aggregate purchase price of \$125 pursuant to a restricted stock purchase agreement between us and Dr. Daddona. Following the April 2012 recapitalization, we entered into a stock repurchase option agreement with Mr. Lamba pursuant to which we have an option to repurchase certain shares of Mr. Lamba's founder's stock in the event of Mr. Lamba's termination without cause or resignation for good reason (as these terms are defined in Mr. Lamba's employment agreement). Of the 625,000 shares, 1/3 of the shares were released from the repurchase option on May 15, 2012 and the remainder are released in equal monthly installments over three years beginning on January 26, 2012, provided that an additional 2/9 of the total shares are released from the repurchase option upon Mr. Lamba's death or termination due to disability and all shares are released from the repurchase option upon a qualified sale (as defined in the stock repurchase option agreement) involving the Company. Following the April 2012 recapitalization, we also entered into a stock repurchase option agreement with Dr. Daddona pursuant to which we have an option to repurchase certain shares of Dr. Daddona's founder's stock in the event of Dr. Daddona's termination without cause or resignation for good reason (as these terms are defined in Dr. Daddona's employment agreement). Of the 312,500 shares, 1/3 of the shares were released from the repurchase option on May 15, 2012 and the remainder are released in equal annual installments over three years beginning on January 26, 2012, provided that all shares are released from the repurchase option upon a qualified sale (as defined in the stock repurchase option agreement) involving the Company.

**Secured Loan and Real Property Lease with BMR**

In April 2012, in connection with our April 2012 recapitalization, described in further detail in the *Management's Discussion and Analysis of Financial Condition and Results of Operations - Key Developments Important to Understanding Our Financial Statements 2012 recapitalization* section of this prospectus, 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 BMR in July 2011 and cancellation of a stock



purchase warrant issued to BMR Holdings in July 2011.

The BMR 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 BMR secured promissory note, and (iii) the date that any distribution is made to our stockholders, as defined in the BMR secured promissory note. We may prepay the BMR secured promissory note, in whole or in part, at any time without prepayment penalty or premium. Further, we are required

---

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

to prepay the BMR 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 BMR 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 prospectus, the aggregate outstanding principal and accrued interest under the BMR secured promissory note is approximately \$10.8 million. In June 2014, we amended the BMR 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 BMR secured promissory note during the period from the maturity date of the BMR secured promissory note through the date that the Hercules loan is repaid in full will not constitute a default under the BMR 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 BMR 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, the BMR affiliate that is the holder of the BMR secured promissory note agreed to subordinate the BMR secured promissory note to the Hercules loan, and we issued 31,250 shares of our common stock to this BMR affiliate in June 2014.

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 prospectus 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

---

**Table of Contents**

**Index to Financial Statements**

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

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 accrue simple interest at the annual rate of 8%. As of December 31, 2014, the aggregate outstanding principal and accrued interest under the 2013 bridge notes is approximately \$3.4 million. Upon the closing of a qualified financing, which is 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 (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest on each note shall 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 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 prospectus 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 accrue simple interest at the annual rate of 8%. As of December 31, 2014, the aggregate outstanding principal and accrued interest under the February 2014 bridge notes is approximately \$2.7 million. Upon the closing of a qualified financing, which is 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 (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest on each note shall 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 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.

**Table of Contents**

**Index to Financial Statements**

**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 prospectus 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 mature on June 1, 2017 and accrue simple interest at the annual rate of 8%. As of December 31, 2014, the aggregate outstanding principal and accrued interest under the December 2014 bridge notes is approximately \$1.3 million. Upon the closing of a qualified financing, which is 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 (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest on each note shall 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.

**Agreement with Our Stockholders**

In April 2012, in connection with our April 2012 recapitalization, we entered into a stockholder rights and voting agreement, which we refer to as the stockholders agreement, with certain holders of our common stock, including Vikram Lamba, our President and Chief Executive Officer and a holder of more than 5% of our voting securities, Peter Daddona, our Chief Scientific Officer and a holder of more than 5% of our voting securities, BMR, then a holder of more than 5% of our voting securities, BioMed Realty, L.P., then a holder of more than 5% of our voting securities (together with its affiliate BMR), New Enterprise Associates 12, Limited Partnership, a holder of more than 5% of our voting securities, NEA Ventures 2006, Limited Partnership, a holder of more than 5% of our voting securities (together with New Enterprise Associates 12, Limited Partnership), ProQuest Investments IV, L.P., then a holder of more than 5% of our voting securities, and Nomura Phase4 Ventures L.P., then a holder of more than 5% of our voting securities. In December 2012, BMR and BioMed Realty, L.P. assigned its rights under the stockholders agreement to BMV Direct SOTRS LP and BMV Direct SO LP, respectively. Each of BMV Direct SOTRS LP and BMV Direct SO LP owns more than 5% of our voting securities. The stockholders agreement provides each of the stockholders that is a party to the agreement with a secondary right of first refusal in respect of sales of securities by certain holders of our capital stock, and contains provisions with respect to the election of our board of directors and its composition. The stockholders agreement will terminate upon the closing of this offering.

**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.

**Table of Contents**

**Index to Financial Statements**

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 this Offering**

Certain of our existing investors have agreed to purchase an aggregate amount of \$550,000 worth of our common stock in this offering at the initial public offering price. The shares purchased by these investors will be subject to lock-up restrictions described in Shares Eligible for Future Sale.

**Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation and amended and restated bylaws that will be effective as of the closing date of this offering 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. See the *Executive Compensation Limitation of Liability and Indemnification* section of this prospectus for a further discussion of these arrangements.

**Policies and Procedures for Related Person Transactions**

While we have not historically had a written policy with respect to the review and approval of transactions with our directors, officers and principal stockholders, it has been the practice of our board of directors to review all interested party transactions and not to authorize any such transaction unless the board of directors, excluding any interested directors, determines that the terms of the proposed transaction are as favorable or more favorable to our company than would be available from an unrelated party in an arms length negotiation. Pursuant to the charter of our audit committee that we expect to become effective upon the closing of this offering, our audit committee will be 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.



Table of Contents

Index to Financial Statements

**PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information with respect to beneficial ownership of our common stock, as of December 31, 2014, 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 December 31, 2014, shares of common stock issuable upon automatic conversion of our convertible promissory notes held by that person, and the shares of common stock issuable in the concurrent private placement (in the case of Lilly) are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name. Except as otherwise indicated, the address of each of the persons in this table is c/o Zosano Pharma Corporation, 34790 Ardentech Court, Fremont, California 94555.

Each stockholder's percentage ownership before the offering is determined in accordance with Rule 13d-3 under the Exchange Act and is based on 5,165,123 shares of our common stock outstanding as of December 31, 2014. Each stockholder's percentage ownership after the offering assumes the issuance of the 4,500,000 shares of our common stock offered hereby and assumes no exercise of the underwriters' over-allotment option. Shares beneficially owned before and after the offering also assume the issuance of 1,363,636 shares of common stock that will be sold to Lilly in the concurrent private placement and 787,353 shares of common stock that will be issued upon the closing of this offering in connection with the automatic conversion of our outstanding convertible promissory notes outstanding at December 31, 2014, in each case based on the initial public offering price of \$11.00 per share.

Certain of our existing investors have agreed to purchase an aggregate amount of \$550,000 worth of our common stock in this offering at the initial public offering price. The information set forth below does not reflect any purchases by these investors.

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

| Name of Beneficial Owner <sup>(1)</sup>  | Shares<br>Beneficially<br>Owned<br>Prior to<br>the<br>Offering | Percentage<br>Prior to the<br>Offering | Shares<br>Beneficially<br>Owned<br>After the<br>Offering | Percentage<br>After<br>the<br>Offering |
|--|--|--|--|--|
| <i>5%+ Stockholders</i>  |  |  |  |  |
| BMV Direct SOTRS LP <sup>(2)</sup>   | 2,413,551  | 43.53%                                 | 2,413,551  | 20.43%                                 |
| 17190 Bernardo Center Drive  |  |  |  |  |
| San Diego, CA 92128  |  |  |  |  |
| New Enterprise Associates 12,<br>Limited Partnership <sup>(3)</sup>                | 2,133,000  | 38.75%                                 | 2,133,000  | 18.05%                                 |
| Chevy Chase, MD 20815  |  |  |  |  |
| 5425 Wisconsin Avenue, Suite 800   |  |  |  |  |
| Eli Lilly and Company <sup>(4)</sup>   | 1,363,636  | 20.89%                                 | 1,363,636  | 11.54%                                 |
| Lilly Corporate Center   |  |  |  |  |
| Indianapolis, IN 46285   |  |  |  |  |
| <i>Directors and Named Executive Officers:</i>                                     |  |  |  |  |
| Vikram Lamba <sup>(5)</sup>  | 722,639  | 13.75%                                 | 722,639  | 6.12%                                  |
| Peter Daddona <sup>(6)</sup>   | 365,956  | 7.02%                                  | 365,956  | 3.10%                                  |
| Nandan Oza <sup>(7)</sup>  | 18,573   | *                                      | 18,573   | *                                      |
| M. James Barrett   | 5  | *                                      | 5  | *                                      |
| Bruce Steel  |  | *                                      |  | *                                      |
| Troy Wilson <sup>(8)</sup>   | 4,717  | *                                      | 4,717  | *                                      |
| Kleanthis Xanthopoulos <sup>(9)</sup>  | 13,561   | *                                      | 13,561   | *                                      |
| Current Directors and Executive Officers as a Group<br>(8 persons) <sup>(10)</sup> | 1,125,451  | 21.07%                                 | 1,125,451  | 9.52%                                  |

\* 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 prior to the offering includes 1,579,573 shares of common stock owned by BMV Direct SOTRS LP, 454,243 shares of common stock owned by BMV Direct SO LP, 315,462 shares of common stock that will be issued to BMV Direct SOTRS LP upon automatic conversion of our convertible promissory notes (based on the initial public offering price of \$11.00 per share) and 64,273 shares of common stock that will be issued to

- BMV Direct SO LP upon automatic conversion of our convertible promissory notes (based on the initial public offering price of \$11.00 per share). Shares owned after the offering includes 1,895,035 shares of common stock owned by BMV Direct SOTRS LP and 518,516 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 prior to the offering includes 1,793,881 shares of common stock owned by New Enterprise Associates 12, Limited Partnership, or NEA 12, 4 shares of common stock owned by NEA Ventures 2006, Limited Partnership, or Ven 2006, and 339,115 shares of common stock that will be issued to NEA 12 upon automatic conversion of our convertible promissory notes (based on the initial public offering price of

---

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

\$11.00 per share). Shares owned after the offering includes 2,132,996 shares of common stock owned by NEA 12 and 4 shares of common stock owned by Ven 2006. 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) Consists of 1,363,636 shares of our common stock that will be purchased by Lilly in the concurrent private placement (based on the initial public offering price of \$11.00 per share).
- (5) Includes options to purchase 91,389 shares of our common stock anticipated to be exercisable within 60 days after December 31, 2014.
- (6) Includes options to purchase 47,169 shares of our common stock anticipated to be exercisable within 60 days after December 31, 2014.
- (7) Consists of options to purchase 18,573 shares of our common stock anticipated to be exercisable within 60 days after December 31, 2014.
- (8) Consists of options to purchase 4,717 shares of our common stock anticipated to be exercisable within 60 days after December 31, 2014.
- (9) Consists of options to purchase 13,561 shares of our common stock anticipated to be exercisable within 60 days after December 31, 2014.
- (10) Includes options to purchase 175,409 shares of our common stock anticipated to be exercisable within 60 days after December 31, 2014.

---

**Table of Contents**

**Index to Financial Statements**

**DESCRIPTION OF CAPITAL STOCK**

*The following is a summary of all material characteristics of our capital stock as set forth in our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the consummation of this offering. The summary does not purport to be complete and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, all of which are incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and the applicable provisions of Delaware law. The numbers of outstanding shares of common stock set forth in the summary below give effect to a 1-for-4 reverse split of our common stock effected on July 11, 2014.*

**General**

Upon the completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated. As of December 31, 2014, we had 5,165,123 shares of common stock issued and outstanding, outstanding stock options to purchase 497,753 shares of common stock, and 787,353 shares of common stock that will be issued upon the automatic conversion of our outstanding convertible promissory notes. The terms of the convertible promissory notes provide that upon the closing of a qualified financing, which is defined as an equity financing on or before March 31, 2015 where we raise at least \$25.0 million (which, for purposes of this definition as it relates to this offering, will include the gross proceeds of the concurrent private placement with Lilly described below), the principal and all unpaid and accrued interest on each note shall 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 addition, in November 2014, we entered into a stock purchase agreement with Lilly under which Lilly has agreed to purchase \$15 million worth of our common stock in a separate private placement concurrent with the closing of this offering, at a price per share equal to the initial public offering price.

**Common Stock**

*Voting rights.* Holders of our common stock are entitled to one vote per share held of record on all matters to be voted upon by our stockholders. The election of directors by our stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Other matters subject to a vote by our stockholders are decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our common stock does not have cumulative voting rights.

*Dividend rights.* Subject to preferences that may be applicable to the holders of any outstanding shares of our preferred stock, the holders of our common stock are entitled to receive such lawful dividends as may be declared by our board of directors.

*Liquidation and dissolution.* In the event of our liquidation, dissolution or winding up, and subject to the rights of the holders of any outstanding shares of our preferred stock, the holders of shares of our common stock will be entitled to receive pro rata all of our remaining assets available for distribution to our stockholders.

*Other rights and restrictions.* Our certificate of incorporation does not permit us to redeem shares of our common stock at our election, provide for a sinking fund with respect to our common stock or provide for the granting of preemptive rights to any stockholder. All outstanding shares are fully paid and nonassessable.

**Preferred Stock**

Prior to this offering, our certificate of incorporation did not provide for any preferred stock. Upon the closing of this offering, pursuant to our amended and restated certificate of incorporation, our board of directors will be authorized, without stockholder approval, from time to time to issue up to 5,000,000 shares of preferred

**Table of Contents**

**Index to Financial Statements**

stock in one or more series, each of the series to have such rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as the board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that we may issue in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for others to acquire, or of discouraging others from attempting to acquire, a majority of our outstanding voting stock. We have no current plans to issue any shares of preferred stock.

**Options**

As of December 31, 2014, options to purchase 497,753 shares of our common stock were outstanding under our 2012 Stock Incentive Plan, at a weighted average exercise price of \$1.59 per share.

As of December 31, 2014, we had an outstanding warrant to purchase 31,674 shares of our common stock at an exercise price of \$8.84 per share.

**Anti-Takeover Effects of Provisions of Delaware Law and Our Charter and By-laws**

Provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult to acquire us by means of a tender offer, a proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

We must comply with Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to an interested stockholder. An interested stockholder includes a person who, together with affiliates and associates, owns, or did own within three years before the determination of interested stockholder status, 15% or more of the corporation's voting stock. The existence of this provision generally will have an anti-takeover effect for transactions not approved in advance by the board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Upon the closing of this offering, our amended and restated certificate of incorporation and our amended and restated bylaws will require that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of the stockholders and may not be effected by a consent in writing. In addition, upon the closing of this offering, special meetings of our stockholders may be called only by the board of directors and some of our officers. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that, effective upon the closing of this offering, our board of directors will be divided into three

classes, with each class serving staggered three-year terms. These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or management.

**Listing on the NASDAQ Capital Market**

Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol ZSAN.



**Table of Contents**

**Index to Financial Statements**

**Authorized but Unissued Shares**

The authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the NASDAQ Listing Rules. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A.

Table of Contents

Index to Financial Statements

**SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no public market for our common stock, and a liquid public trading market for our common stock may not develop or be sustained after this offering. Future sales of significant amounts of our common stock, including shares issued upon exercise of outstanding options or warrants or in the public market after this offering, or the anticipation of those sales, could adversely affect the public market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities. Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol ZSAN.

Upon the closing of this offering and the concurrent private placement with Lilly, and after giving effect to the issuance of the 4,500,000 shares of our common stock offered in this offering, the issuance of 1,363,636 shares of common stock to Lilly in the concurrent private placement and the conversion of our convertible promissory notes outstanding at December 31, 2014 into 787,353 shares of common stock upon the closing of this offering, we will have outstanding an aggregate of 11,816,112 shares of common stock, assuming no exercise of outstanding options. Of these shares, the 4,500,000 shares sold by us (assuming that the underwriters do not exercise their over-allotment option) in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement, and shares purchased by our existing investors, which will be subject to lock-up agreements as described below.

The remaining 7,316,112 shares of common stock will be restricted securities, as that term is defined in Rule 144 under the Securities Act, and substantially all of these shares will further be subject to either restrictions on transfer under the lock-up agreements described below or restrictions on transfer for a period of 180 days from the effectiveness of the registration statement of which this prospectus forms a part under stock option agreements entered into between us and the holders of those shares. Following the expiration of these restrictions, these shares will become eligible for public sale if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

In addition, of the 497,753 shares of common stock that were issuable pursuant to stock options outstanding under our 2012 Stock Incentive Plan as of December 31, 2014, options to purchase 212,512 shares of common stock had vested and were exercisable as of December 31, 2014. Upon exercise, these shares will be eligible for sale, subject to the lock-up agreements and securities laws described below. As of December 31, 2014, an outstanding warrant was exercisable for 31,674 shares of common stock, and upon issuance these shares will be eligible for sale, subject to the securities laws described below.

**Rule 144**

*Affiliate Resales of Restricted Securities*

In general, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in broker's transactions or certain riskless principal transactions or to market makers, a number of shares within any three-month period that does not exceed the greater of:

Edgar Filing: Zosano Pharma Corp - Form 424B4

1% of the number of shares of our common stock then outstanding, which will equal approximately 118,161 shares immediately after this offering and the concurrent private placement; or

the average weekly trading volume in our common stock on the NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

## **Table of Contents**

### **Index to Financial Statements**

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and the NASDAQ Stock Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus forms a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchased shares from us in connection with a compensatory stock or option plan or other written agreement entered into before the effective date of our initial public offering is entitled to sell such shares without further restriction under the Securities Act.

### **Lock-up Agreements**

All of our executive officers and directors and the holders of substantially all of our outstanding stock have agreed with the underwriters, 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 for a period through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives of the underwriters.

The representatives of the underwriters currently do not anticipate shortening or waiving any of the lock-up agreements and do not have any pre-established conditions for such modifications or waivers. The representatives of the underwriters may, however, release for sale in the public market all or any portion of the shares subject to the lock-up agreements.

### **Stock Options and Warrant**

As of December 31, 2014, we had outstanding options to purchase 497,753 shares of common stock, of which options to purchase 212,512 shares of common stock were vested and exercisable. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of common stock subject to outstanding options and options and other awards issuable pursuant to our 2012 Stock Incentive Plan and 2014 Equity and Incentive Plan.

As of December 31, 2014, we also had an outstanding and exercisable warrant to purchase 31,674 shares of our common stock at an exercise price of \$8.84 per share. Any shares purchased by the non-affiliate warrant holder pursuant to the cashless exercise feature of the warrant will be freely tradable under Rule 144(b)(1), and any shares purchased through the exercise of the warrant for cash will be eligible for sale subject to the securities laws described above.

Table of Contents

Index to Financial Statements

**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS**

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their purchase, ownership and disposition of shares of our common stock. This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, within the meaning of Section 1221 of the Code (generally, property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address, except to the limited extent provided below with respect to estate tax, any aspects of U.S. federal estate or gift taxes, and state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

insurance companies;

integral parts or controlled entities of a foreign sovereign;

tax-exempt organizations;

banks or other financial institutions;

brokers or dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

regulated investment companies or real estate investment trusts;

individual retirement accounts, tax-deferred accounts or pension plans;

controlled foreign corporations or passive foreign investment companies;

hybrid entities;

corporations that accumulate earnings to avoid U.S. federal income tax;

persons who own (or are deemed to own) more than 5% of our common stock (except to the extent specifically set forth below);

persons subject to the alternative minimum tax or the 3.8% Medicare tax on net investment income;

owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and

certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities, or persons who hold our common stock through partnerships or other pass-through entities, for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

**Table of Contents**

**Index to Financial Statements**

We have not sought and will not seek any ruling from the Internal Revenue Service, which we refer to as the IRS, with respect to the statements made and the conclusions reached in the following discussion. There can be no assurance that the IRS will not challenge one or more of the tax consequences described herein, or that any such challenge would not be sustained by a court.

NON-U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL TAX LAWS TO THEIR PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE LAWS OF ANY STATE, LOCAL, FOREIGN OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

**Non-U.S. Holder Defined**

For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that, for U.S. federal income tax purposes, is an individual, corporation, estate or trust that is not a U.S. person. For purposes of this discussion, a U.S. person is:

an individual who is a citizen or resident of the United States (as determined under U.S. federal income tax rules);

a corporation, or any other organization taxable as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States, any political subdivision thereof, any state thereof or the District of Columbia;

an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

a trust if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect to be treated as a U.S. person.

**Distributions on Our Common Stock**

As described in the section entitled "Dividend Policy," we have not made distributions on our common stock and do not plan to make any distributions for the foreseeable future. However, if we do make distributions of cash or property on our common stock, those payments generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock."



Subject to the discussion below on backup withholding and FATCA, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty generally will be required to provide a properly executed IRS Form W-8BEN (or other appropriate version of IRS Form W-8 or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements by providing a properly executed IRS Form W-8ECI (or successor form). However, such U.S. effectively

---

**Table of Contents**

**Index to Financial Statements**

connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons. In addition, any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

**Gain on Sale, Exchange or Other Disposition of Our Common Stock**

Subject to the discussion below on backup withholding and FATCA, a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons and, if the non-U.S. holder is a foreign corporation for U.S. federal income tax purposes, it also may be subject to a branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain;

the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any; or

we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a U.S. real property holding corporation. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. Even if we are or were to become a U.S. real property holding corporation, gains realized by a non-U.S. holder on a disposition of our common stock will not be subject to U.S. federal income tax if our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. No assurance can be provided that our common stock will continue to be regularly traded on an established securities market for purposes of the rules described above.

**Federal Estate Tax**

Common stock owned (or treated as owned) by an individual who is not a citizen or a resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes, and therefore may be subject to U.S. federal estate tax, unless an applicable estate or other tax treaty provides otherwise.

**Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder payments of dividends on our common stock to such holder and the tax withheld, if any, with respect to such dividends, along with certain other

## **Table of Contents**

### **Index to Financial Statements**

information. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person in order to avoid backup withholding with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in *Distributions on Our Common Stock*, generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or other agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

### **FATCA Withholding and Information Reporting**

The Foreign Account Tax Compliance Act of 2010, commonly referred to as FATCA, generally will impose a U.S. federal withholding tax at a rate of 30% on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to certain foreign entities (including foreign financial institutions and non-financial foreign entities, each as defined in the Code), unless (1) in the case of a foreign financial institution, such foreign entity undertakes certain information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with the entity), (2) in the case of a non-financial foreign entity, such entity either certifies that it does not have any substantial United States owners, as defined in the Code, or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules.

If a non-U.S. holder is a foreign financial institution and is subject to the information reporting and due diligence requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain specified United States persons or United States-owned foreign entities, each as defined in the Code, annually report certain information about such accounts, and withhold 30% on payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

The FATCA withholding tax rules generally will be applicable to dividends on our common stock that are paid after June 30, 2014, and to gross proceeds from a sale or other disposition of our common stock that occurs after December 31, 2016.

Non-U.S. holders may be required to provide us with certifications of their respective classifications for FATCA purposes, and, in the case of non-U.S. holders that are not individuals, also may be required to provide us with information about their beneficial owners. Prospective investors should consult their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**Table of Contents****Index to Financial Statements****UNDERWRITING**

Ladenburg Thalmann & Co. Inc. and Roth Capital Partners, LLC are acting as joint book-running managers of the offering and as representatives of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

| <b>Underwriters</b>           | <b>Number of Shares</b> |
|-------------------------------|-------------------------|
| Ladenburg Thalmann & Co. Inc. | 2,250,000               |
| Roth Capital Partners, LLC    | 2,250,000               |
| <b>Total</b>                  | <b>4,500,000</b>        |

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

Certain of our existing investors have agreed to purchase an aggregate amount of \$550,000 worth of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discounts and commissions on the shares purchased by these investors as they will on the other shares sold to the public in this offering. The shares purchased by these investors will be subject to lock-up restrictions described in Shares Eligible for Future Sale.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Commissions and Discounts**

The following table shows the per share and total underwriting discount to be paid to the underwriters by us at the initial public offering price set forth on the cover page of this prospectus. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

|           | <b>No Exercise of<br/>Over-Allotment<br/>Option</b> | <b>Full Exercise<br/>of<br/>Over-Allotment<br/>Option</b> |
|-----------|---|---|
| Per Share | \$ 0.77   | \$ 0.77   |

Total \$ 3,465,000 \$ 3,984,750

The representatives have advised us that the underwriters propose to offer directly to the public the shares purchased pursuant to the underwriting agreement at the initial public offering price set forth on the cover page of this prospectus and to certain securities dealers at the initial public offering price less a concession not in excess of \$0.462 per share. After the offering, the representatives may change the offering price and other selling terms.

**Private Placement Fee**

The representatives are entitled to a private placement fee in an amount equal to 3.5% of the gross proceeds we receive in the concurrent private placement with Lilly, or \$525,000, payable by us in cash upon the closing of the concurrent private placement.

## **Table of Contents**

### **Index to Financial Statements**

The expenses of the offering, not including the underwriting discount, are estimated at approximately \$1.7 million and are payable by us.

We have also agreed to reimburse the representatives for certain of their expenses relating to this offering in an amount of up to \$45,000, of which \$20,000 is considered by the Financial Industry Regulatory Authority, Inc. to be underwriter compensation.

### **Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 675,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

### **Lock-Up Agreements**

We, all of our directors and executive officers, and holders of substantially all of our outstanding stock have agreed that, for a period of 180 days, or the lock-up period, after the date of this prospectus subject to certain limited exceptions described below, we and they will not directly or indirectly, without the prior written consent of the representatives of the underwriters, (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of common stock (including, without limitation, shares of common stock that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for common stock, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (3) make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any of our other securities, or (4) publicly disclose the intention to do any of the foregoing.

These lock-up restrictions will not apply to: (1) bona fide gifts, sales or other dispositions made exclusively by the holder to the holder's family, partners, members, stockholders or affiliates (as applicable), and transfers or other dispositions by will, other testamentary documents or intestate succession, *provided* that such transferee agrees to be bound by the terms of the lock-up agreement, the parties agree to not make any filing or public announcement regarding such transfer or disposition prior to the expiration of the lock-up period and the holder notifies the representatives of the underwriters at least two business days prior to the proposed transfer or disposition; (2) the exercise of warrants or stock options granted pursuant to the Company's stock option/incentive plans or otherwise, or the conversion of securities, in each case outstanding on the date of this prospectus, *provided* that the restrictions shall apply to the shares of common stock issued upon such exercise or conversion; (3) the establishment of any trading plan established pursuant to Rule 10b5-1 under the Exchange Act, *provided* that no sales or securities convertible into common stock shall be made pursuant to such plan prior to the expiration of the lock-up period, and the Company does not, and is not required to, report the establishment of such plan in any public report or filing with the SEC under the Exchange Act prior to the expiration of the lock-up period; (4) any forfeiture, sale or other transfer to the company in connection with the termination of the holder's employment with or services to the company; and (5) the transfer of



shares to the company to satisfy withholding taxes for any equity award granted prior to the date of this prospectus.

The representatives of the underwriters may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release

**Table of Contents**

**Index to Financial Statements**

common stock and other securities from lock-up agreements, the representatives of the underwriters will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

At least three business days before the effectiveness of any release or waiver of any of the restrictions described above with respect to an officer or director of the Company, the representatives of the underwriters will notify us of the impending release or waiver and we have agreed to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver.

**Offering Price Determination**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was negotiated between the representative and us. In determining the initial public offering price of our common stock, the representative considered:

the history and prospects for the industry in which we compete;

our financial information;

the ability of our management and our business potential and earning prospects;

the prevailing securities markets at the time of this offering; and

the recent market prices of, and the demand for, publicly traded shares of generally comparable companies. An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

**Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

**Stabilization, Short Positions and Penalty Bids**

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for

## **Table of Contents**

### **Index to Financial Statements**

purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ Capital Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

### **Listing on The NASDAQ Capital Market**

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol ZSAN.

### **Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

### **Other Relationships**

Some of the underwriters and their affiliates have provided in the past to us and our affiliates, and may provide from time to time in the future, certain financial advisory, investment banking and other services in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, the underwriters and their affiliates may effect transactions for their own account or the accounts of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

### **Conflicts of Interest**

Theodore D. Roth, the President and an associated person of Roth Capital Partners, LLC, or Roth, one of the underwriters in this offering, is also a director of BMR and, therefore, a conflict of interest may be deemed to exist

with respect to Roth because Mr. Roth is deemed to control BMR (as a director of BMR) and BMR is deemed to control us (as an affiliate of a beneficial owner of in excess of 10% of our outstanding capital stock). Mr. Roth has agreed not to vote on any matter relating to us while serving as a director of BMR. In addition, a portion, constituting less than 5%, of the net proceeds of this offering may be used to make required payments of interest and principal as they become due under our note payable to our largest stockholder, which is an affiliate of BMR. See Use of Proceeds.

**Table of Contents**

**Index to Financial Statements**

**NOTICE TO INVESTORS**

**Notice to Investors in the United Kingdom**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State ) an offer to the public of any securities which are the subject of the offering contemplated by this prospectus supplement and the related prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any such securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;
- (c) by the underwriter to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of these securities shall result in a requirement for the publication by the issuer or the underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any such securities to be offered so as to enable an investor to decide to purchase any such securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented, warranted and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any of the securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and
- (b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

**European Economic Area**

In particular, this document does not constitute an approved prospectus in accordance with European Commission's Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with

this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance

**Table of Contents**

**Index to Financial Statements**

with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000; and (3) an annual net turnover of more than 50,000,000, as shown in the last annual or consolidated accounts; or

in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of securities to the public in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the shares offered hereby are securities.



**Table of Contents**

**Index to Financial Statements**

**LEGAL MATTERS**

The validity of the common stock being offered will be passed upon for us by Foley Hoag LLP, Boston, Massachusetts. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York, has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

**EXPERTS**

The balance sheets as of December 31, 2013 and 2012 and the related statements of operations, statements of stockholders' (deficit) equity and statements of cash flows for the years then ended, appearing in this prospectus have been audited by Marcum LLP, an independent registered public accounting firm, as stated in their report appearing elsewhere herein, and are included in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933 with respect to the shares of common stock to be sold in this offering. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. Some items are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement filed as part of the registration statement. Statements contained in this prospectus about the contents of any contract or any other document filed as an exhibit are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other documents filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website.

Upon the closing of this offering, we will become subject to the full informational and periodic reporting requirements of the Exchange Act. We will fulfill our obligations with respect to such requirements by filing periodic reports and other information with the SEC. We intend to furnish our stockholders with annual reports containing financial statements certified by an independent registered public accounting firm. We also maintain a website at [www.zosanopharma.com](http://www.zosanopharma.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Our website is not a part of this prospectus.

**Table of Contents**

**Index to Financial Statements**

**Zosano Pharma Corporation and Subsidiaries**

**Financial Statements**

**December 31, 2013 and 2012**

**Contents**

|  |     |
|--|-----|
| <u>Report of Independent Registered Public Accounting Firm</u>   | F-2 |
| Audited Consolidated Financial Statements:                       |     |
| <u>Consolidated Balance Sheets</u>                               | F-3 |
| <u>Consolidated Statements of Operations</u>                     | F-4 |
| <u>Consolidated Statements of Stockholders' Equity (Deficit)</u> | F-5 |
| <u>Consolidated Statements of Cash Flows</u>                     | F-6 |
| <u>Notes to Consolidated Financial Statements</u>                | F-7 |

F-1

Table of Contents

Index to Financial Statements

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 (formerly known as ZP Holdings, Inc. and subsidiaries) (the Company) as of December 31, 2013 and 2012, 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, 2013 and 2012, 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.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements Going Concern and Management's Plans, the Company's recurring losses from operations and the need for additional capital raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 Going Concern and Management's Plans. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Marcum LLP

Marcum LLP

San Francisco, CA

May 13, 2014, except for the Reverse Stock Split paragraph of Note 2, as to which the date is July 16, 2014



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

|  | <b>December 31,</b> |             |
|--|---------------------|-------------|
|  | <b>2013</b>         | <b>2012</b> |
| <b><u>ASSETS</u></b>   |                     |             |
| Current assets:  |                     |             |
| Cash and cash equivalents  | \$ 5,913            | \$ 4,973    |
| Accounts receivable  |                     | 130         |
| Accounts receivable from joint venture partner   | 3,426               | 730         |
| Short-term investment  | 361                 |             |
| Prepaid expenses and other current assets  | 465                 | 73          |
| Total current assets   | 10,165              | 5,906       |
| Restricted cash  | 65                  | 35          |
| Property and equipment, net  | 11,714              | 1,389       |
| Investment in joint venture  |                     | 12,298      |
| Other long-term assets   | 140                 |             |
| Total assets   | \$ 22,084           | \$ 19,628   |
| <b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>   |                     |             |
| Current liabilities:   |                     |             |
| Accounts payable   | \$ 3,412            | \$ 383      |
| Accrued compensation   | 2,676               | 124         |
| Revolving line of credit   | 496                 |             |
| Deferred revenue   | 1,125               | 3,375       |
| Related parties notes payable, current   | 3,108               |             |
| Other accrued liabilities  | 716                 | 99          |
| Total current liabilities  | 11,533              | 3,981       |
| Deferred rent  | 363                 | 601         |
| Related party secured promissory note  | 9,711               | 9,026       |
| Commitments and contingencies  |                     |             |
| Stockholders' equity:  |                     |             |
| Common stock, \$0.0001 par value: 30,000 shares authorized; 5,107 shares issued and outstanding as of December 31, 2013 and 2012 | 1                   | 1           |
| Additional paid-in capital   | 124,699             | 124,634     |
| Accumulated deficit  | (124,223)           | (118,615)   |
| Stockholders' equity   | 477                 | 6,020       |

|   |           |           |
|---|-----------|-----------|
| Total liabilities and stockholders equity | \$ 22,084 | \$ 19,628 |
|---|-----------|-----------|

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

F-3

Table of ContentsIndex 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>2013</b>                    | <b>2012</b>     |
| License fees revenue  | \$ 4,250                       | \$ 9,250        |
| Collaborative development support services  |                                | 2,374           |
| <b>Total revenue</b>  | <b>4,250</b>                   | <b>11,624</b>   |
| Operating expenses:   |                                |                 |
| Research and development  | 7,637                          | 5,399           |
| General and administrative  | 4,582                          | 3,077           |
| <b>Total operating expenses</b>   | <b>12,219</b>                  | <b>8,476</b>    |
| (Loss) income from operations   | (7,969)                        | 3,148           |
| Other income (expense):   |                                |                 |
| Interest expense, net   | (760)                          | (663)           |
| Warrant revaluation income  |                                | 71              |
| (Loss) income before equity in loss of joint venture and gain on termination of joint venture | (8,729)                        | 2,556           |
| Equity in loss of joint venture   | (366)                          | (738)           |
| Gain on termination of joint venture  | 3,487                          |                 |
| <b>Net (loss) income</b>  | <b>\$ (5,608)</b>              | <b>\$ 1,818</b> |
| Net (loss) income per common share:   |                                |                 |
| Basic   | \$ (1.10)                      | \$ 0.47         |
| Diluted   | \$ (1.10)                      | \$ 0.47         |
| Weighted-average shares used in computing net (loss) income per common share:                 |                                |                 |
| Basic   | 5,107                          | 3,908           |
| Diluted   | 5,107                          | 3,908           |
| Pro forma net loss per common share basic and diluted (unaudited)                             | \$ (1.06)                      |                 |
|   | 5,211                          |                 |

Weighted-average shares used in computing pro forma net loss per common share basic and diluted (unaudited)

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

F-4



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

(in thousands)

|   | Common Stock |        | Additional      | Accumulated  | Total                         |
|---|--------------|--------|-----------------|--------------|-------------------------------|
|   | Shares       | Amount | Paid-In Capital | Deficit      | Stockholders (Deficit) Equity |
| <b>Balance at January 1, 2012</b>   | 595          |        | 114,907         | (120,433)    | (5,526)                       |
| Issuance of common stock at date of merger in January 2012  | 938          |        |                 |              |                               |
| Conversion of convertible promissory notes to common stock in April 2012                                | 2,217        | 1      | 7,089           |              | 7,090                         |
| Exchange of ZP Opco, Inc. common stock options for Zosano Pharma Corporation common stock in April 2012 |              |        |                 |              |                               |
| Conversion of BMR loans to common stock in April 2012   | 1,344        |        | 2,575           |              | 2,575                         |
| Stock-based compensation expense  |              |        | 45              |              | 45                            |
| Issuance of restricted stock awards in lieu of cash bonus in December 2012                              | 13           |        | 18              |              | 18                            |
| Net income  |              |        |                 | 1,818        | 1,818                         |
| <b>Balance at December 31, 2012</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                        |

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

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

|  | <b>Year Ended December 31,</b> |                |
|--|--------------------------------|----------------|
|  | <b>2013</b>                    | <b>2012</b>    |
| <b>Cash flows from operating activities:</b>   |                                |                |
| Net (loss) income  | \$ (5,608)                     | \$ 1,818       |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: |                                |                |
| Depreciation   | 428                            | 1,069          |
| Stock-based compensation   | 65                             | 63             |
| Equity in loss of joint venture  | 366                            | 738            |
| Gain on termination of joint venture   | (3,487)                        |                |
| Accretion of interest payment  | 765                            | 830            |
| Revaluation of warrants to fair value  |                                | (71)           |
| Deferred rent  | (239)                          | (489)          |
| Change in operating assets and liabilities:  |                                |                |
| Accounts receivable  | 130                            | 1,082          |
| Accounts receivable from joint venture partner   | 3,204                          | (730)          |
| Prepaid expenses and other assets  | (532)                          | 116            |
| Accounts payable   | 265                            | (100)          |
| Accrued compensation and other liabilities   | 3,169                          | (985)          |
| Deferred revenue   | (2,250)                        | (2,840)        |
| <b>Net cash flow (used in) provided by operating activities</b>                                    | <b>(3,724)</b>                 | <b>501</b>     |
| <b>Cash flow from investing activities:</b>  |                                |                |
| Distribution from joint venture  | 2,431                          | 1,539          |
| Purchase of property and equipment   | (897)                          | (21)           |
| Proceeds from sale of property and equipment   |                                | 16             |
| (Increase) decrease in restricted cash   | (30)                           | 35             |
| Sales of short-term investments  |                                | 415            |
| Purchase of short-term investment  | (365)                          |                |
| <b>Net cash flow provided by investing activities</b>  | <b>1,139</b>                   | <b>1,984</b>   |
| <b>Cash flow from financing activities:</b>  |                                |                |
| Proceeds from borrowings under bridge financing and line of credit                                 | 3,525                          |                |
| Repayment of equipment loan  |                                | (1,112)        |
| <b>Net cash flow provided by (used in) financing activities</b>                                    | <b>3,525</b>                   | <b>(1,112)</b> |

|  |                 |                 |
|--|-----------------|-----------------|
| <b>Net increase in cash and cash equivalents</b> | <b>940</b>      | <b>1,373</b>    |
| Cash and cash equivalents at beginning of year   | 4,973           | 3,600           |
| <b>Cash and cash equivalents at end of year</b>  | <b>\$ 5,913</b> | <b>\$ 4,973</b> |

**Supplemental cash flow information:**

|  |          |    |
|--|----------|----|
| 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 | \$ |

**Non-cash investing and financing activities:**

|  |          |          |
|--|----------|----------|
| Conversion of debt to common stock                                   | \$       | \$ 9,665 |
| Transfer of property and equipment upon termination of joint venture | \$ 9,856 | \$       |

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

**Table of Contents****Index to Financial Statements****Zosano Pharma Corporation and Subsidiaries****Notes to Consolidated Financial Statements****For the Years Ended December 31, 2013 and 2012****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 also believes that by focusing its internal development efforts on proprietary formulations of generic molecules with known safety and efficacy, it can reduce its clinical and regulatory risk and development costs and accelerate its time to commercialization.

The Company's wholly owned subsidiary, ZP Opco, Inc. (formerly named Zosano Pharma, Inc.), was incorporated in the State of Delaware on February 6, 2006. The Company's headquarters and operations are located in Fremont, California. The Company has two wholly owned subsidiaries as of December 31, 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.

In April 2012, the Company commenced its planned principal operations, established its manufacturing facility and received revenues from its microneedle patch system technology including payment for its collaboration support services and therefore, exited the development stage.

***Reverse Merger and Recapitalization***

The Company was incorporated on January 26, 2012 under the laws of the State of Delaware. In April 2012, the Company entered into a reverse merger and recapitalization transaction with Opco. The reverse merger, which resulted in a recapitalization, was achieved through an agreement and plan of merger between the Company and Opco. The Company was the acquiring legal entity in the transaction while Opco was the surviving reporting entity for accounting purposes because its former stockholders emerged from the transaction with a controlling interest. The acquisition is treated as a recapitalization of Opco as, prior to the transaction, the Company had no significant assets, liabilities or operations. The recapitalization was achieved by converting common stock and Series A, B, and C Preferred Stock of Opco into 595,258 shares of the Company's common stock as follows:

| Type | ZP Opco, Inc.<br>Number of shares | Conversion Rate | The Company's Common Stock |
|------|-----------------------------------|-----------------|----------------------------|
|------|-----------------------------------|-----------------|----------------------------|

|                          |            |                      | <b>Pre-Reverse Split</b> | <b>Post-Reverse Split</b> |
|--------------------------|------------|----------------------|--------------------------|---------------------------|
|                          |            |                      | <b>(# of shares)</b>     | <b>(# of shares)</b>      |
| Series A Preferred Stock | 4,140,000  | 0.001703397851193810 | 7,052                    | 1,763                     |
| Series B Preferred Stock | 14,000,000 | 0.004132587086262290 | 57,856                   | 14,464                    |
| Series C Preferred Stock | 4,666,667  | 0.495747988320586000 | 2,313,491                | 578,373                   |
| Common Stock             | 5,362,829  | 0.000490963849667203 | 2,633                    | 658                       |
|                          |            |                      | 2,381,032                | 595,258                   |

In addition, convertible unsecured promissory notes originally issued by Opco to certain of its stockholders prior to the recapitalization in the aggregate principal amount of approximately \$6.2 million, plus accrued interest of approximately \$0.9 million, were converted into 2,217,027 shares of common stock of the Company.

**Table of Contents**

**Index to Financial Statements**

All outstanding and unexercised stock options granted under Opco's 2007 Equity Incentive Plan were cancelled and in exchange, the holders received 213 shares of common stock of the Company.

All outstanding warrants to purchase securities of Opco were terminated as a result of the reverse merger and recapitalization.

All shares and per share amounts have been retroactively restated for the effect of this reverse merger and recapitalization for all periods presented.

**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.

***Going Concern and Management's Plans***

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has a history of incurring operating losses and negative cash flows from operating activities. The Company had an accumulated deficit of approximately \$124.2 million as of December 31, 2013. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Through December 31, 2013, the Company has relied primarily on the proceeds from private equity offerings and loan proceeds to finance its operations. Management expects to incur additional losses in the future to conduct product research and development and to conduct pre-commercialization activities. Additional capital will be required to undertake these activities and to meet the operating requirements of the Company through 2014 and beyond. The Company intends to raise such capital through the issuance of additional equity through public or private offerings, borrowings, and strategic alliances with partner companies. However, if such financing is not available at adequate levels or on acceptable terms, the Company could be required to significantly reduce operating expenses and delay or reduce the scope of or eliminate some of its development programs or its commercialization efforts, enter into a collaboration or other similar arrangement with respect to commercialization rights to any of its product candidates, out-license intellectual property rights to its transdermal delivery technology and sell unsecured assets, or a combination of the above, which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all.

***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 - Joint Venture). Intercompany balances and transactions have been eliminated in consolidation.

***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.

***Short-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

**Table of Contents**

**Index to Financial Statements**

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 planned to raise new investment capital through the sale of the Company's common stock or other securities to institutional investors in a private placement (the PIPE Financing). The Company had anticipated that in connection with the PIPE Financing it would enter into a registration rights agreement pursuant to which the Company would agree to file a registration statement with the SEC to register for resale the securities it planned to issue through the PIPE Financing. As of December 31, 2013, the Company has decided not to undertake the PIPE Financing as planned and it is actively pursuing the sale of the Shell Corporation. Accordingly, the Company accounts for its investment in the Shell Corporation using the cost method of accounting and classifies it as a short-term investment in its consolidated balance sheet.

***Equity Investments and Joint Venture***

The Company's equity investments include investment in entities over which the Company has significant influence but not control, generally representing an ownership of between 20% and 50% of the voting rights or membership interest. The Company's equity investments are accounted for using the equity method of accounting and are initially recognized at cost. The Company's share of the equity investments' profits or losses is recognized in the consolidated statements of operations. When the Company's share of losses in an equity investment equals or exceeds the Company's interest in the equity method investment, the Company will not recognize further losses unless the Company has incurred obligations or made payments on behalf of the equity investment.

Unrealized gains on transactions between the Company and entities accounted for as equity investments are eliminated to the extent of its interest in the equity investment. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred.

The entire carrying amount of the investments is tested for impairment by comparing its recoverable amount with its carrying amount, whenever there is an indication that the investment may be impaired.

***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 \$65,000 and \$35,000 was restricted for use as security for its corporate purchasing cards and is classified as restricted cash as of December 31, 2013 and 2012, respectively.

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

The Company records a receivable from Asahi Kasei Pharma Corporation (Asahi) and its affiliate AKP USA, Inc. (AKPUS) for payment due the Company pursuant to the terms of the joint venture operating agreement. Such receivable includes 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. (See Note 6 Joint Venture.)

***Fair Value Measurements***

The Company records its financial assets and liabilities at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most

## **Table of Contents**

### **Index to Financial Statements**

advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance for fair value establishes a three-level hierarchy for disclosure of fair value measurements, as follows:

Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 Inputs (other than quoted market prices included in Level 1) that are either directly or indirectly observable, 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 instrument's anticipated life.

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 financial assets and liabilities of the Company, such as cash and cash equivalents, accounts receivable from joint venture partner, short-term investment, 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 related parties 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 debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms and maturities.

### ***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.

### ***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 has not experienced any impairment of its long-lived assets for the years ended December 31, 2013 and 2012.

***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.

F-10

---

**Table of Contents****Index to Financial Statements*****Related Parties Promissory Notes***

The Company accounts for its unsecured and secured promissory notes issued to certain 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.

***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,

F-11

---

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

(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 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, 2013, the Company incurred research and development costs of approximately \$6.5 million in connection with the Company's research and development efforts and approximately \$1.1 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, 2012, the Company incurred research and development costs of approximately \$1.9 million in support of the Company's collaborative development services to Asahi, approximately \$2.8 million in connection with the Company's research and development efforts, and approximately \$0.7 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates.

***Clinical Trial Accruals***

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 grant is estimated on the date of grant using the Black-Scholes option pricing model, and is recognized as expense on a straight-line basis over the employee's requisite service period (generally the vesting period), net of estimated forfeitures. Forfeitures are estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from the prior estimates.

F-12

**Table of Contents**

**Index to Financial Statements**

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 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 Income (Loss) per Common Share***

Basic net income (loss) per common share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for potential dilutive common stock equivalents. Diluted net income (loss) per common share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, convertible promissory notes and options to purchase common stock are considered potential dilutive common stock equivalents.

The Company follows guidance under ASC 260-10-45-48 for the calculation of diluted net income per common share for contingently convertible debt. The guidance provides that if convertible debt is convertible only upon a contingency that is not based on the issuer's stock price or the price of the convertible instrument, the if-converted method generally should be applied only if the necessary conditions have been satisfied by the end of the period by using the number of shares, if any, that would be issuable if the end of the reporting period were the end of the contingency period.

For the year ended December 31, 2013, diluted net loss per common share was the same as basic net loss per common share since the effect of inclusion of potentially dilutive common stock equivalents would have an antidilutive impact



due to the loss reported. For the year ended December 31, 2012, the effect of inclusion of common stock options in the computation of diluted net income per common share would have been anti-dilutive under the treasury stock method because the average fair value of the Company's common stock for the period, as determined by the Board of Directors with input from management, did not exceed the exercise prices of the stock options.

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

A total of 469,776 shares and 314,935 shares of common stock options were excluded from the computations of diluted net income (loss) per common share for the year ended December 31, 2013 and 2012, respectively.

***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. All common shares and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

***Unaudited Pro Forma Presentation***

The Company is pursuing a public offering to raise the additional capital needed to continue its planned operations. The unaudited pro forma net loss per common share for the year ended December 31, 2013 is computed using the weighted-average number of common shares outstanding, reflecting the pro forma effects of the automatic conversion of the Company's related parties convertible notes, including principal and interest, into shares of common stock upon completion of this offering at a price equal to 85% of the assumed initial public offering price.

The following unaudited pro forma basic and diluted net loss per common share calculation for the year ended December 31, 2013 assumes the conversion of all outstanding related parties convertible notes into shares of common stock as if the conversion had occurred at the beginning of the period or, if later, the original issue date, using the if-converted method:

|   | <b>Year Ended<br/>December 31, 2013<br/>(unaudited;<br/><br/>in thousands,<br/>except per share<br/>amount)</b> |
|---|---|
| <i>Numerator:</i>   |   |
| Net loss per common share   | \$ (5,608)  |
| Add:  |   |
| Interest expense on related parties convertible notes   | 75  |
| Pro forma net loss  | \$ (5,533)  |
| <i>Denominator:</i>   |   |
| Weighted average shares used in computing net loss per common share   | 5,107   |
| Add:  |   |
| Pro forma adjustments to reflect the weighted average assumed conversion of related parties convertible notes | 104   |
|   | 5,211   |

Weighted average shares used in computing pro forma net loss per common share basic and diluted

|   |    |        |
|---|----|--------|
| Pro forma net loss per common share basic and diluted | \$ | (1.06) |
|---|----|--------|

***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

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

In July 2013, the FASB issued Accounting Standards Update (ASU) 2013-11, *Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures and are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company is currently assessing the impact of this ASU on its consolidated financial statements.

In February 2013, the FASB issued guidance which addresses the presentation of amounts reclassified from accumulated other comprehensive income. This guidance does not change current financial reporting requirements, instead an entity is required to cross-reference to other required disclosures that provide additional detail about amounts reclassified out of accumulated other comprehensive income. In addition, the guidance requires an entity to present significant amounts reclassified out of accumulated other comprehensive income by line item of net income if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. Adoption of this standard is required for periods beginning after December 15, 2012 for public companies. The amended guidance became effective for the Company in the first quarter of fiscal year 2013. The election to adopt this guidance did not have a material impact on the Company's consolidated financial statements.

**3. Fair Value of Financial Instruments**

The Company records its financial assets and liabilities at fair value. The carrying values of certain financial assets and liabilities of the Company, such as cash and cash equivalents, accounts receivable from joint venture partner, short-term investment, 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 related parties 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 related party secured promissory note approximates its fair value because the interest rate approximates 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, 2013 and 2012:

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

**December 31, 2012**

|   | <b>Level I</b>        | <b>Level II</b> | <b>Level III</b> | <b>Total</b> |
|---|-----------------------|-----------------|------------------|--------------|
|   | <b>(in thousands)</b> |                 |                  |              |
| <b>Financial Assets:</b>                  |                       |                 |                  |              |
| Certificates of deposit (restricted cash) | \$ 35                 | \$              | \$               | \$ 35        |

F-15

**Table of Contents****Index to Financial Statements****4. Property and Equipment**

The following table is a summary of property and equipment:

|                                 | <b>December 31,</b>   |             |
|---------------------------------|-----------------------|-------------|
|                                 | <b>2013</b>           | <b>2012</b> |
|                                 | <b>(in thousands)</b> |             |
| Laboratory and office equipment | \$ 1,108              | \$ 1,049    |
| Manufacturing equipment         | 10,769                | 1,196       |
| Computer equipment and software | 230                   | 186         |
| Leasehold improvements          | 15,534                | 1,084       |
| Construction in progress        | 738                   | 91          |
|                                 | 28,379                | 3,606       |
| Less: Accumulated depreciation  | (16,665)              | (2,217)     |
| Property and equipment, net     | \$ 11,714             | \$ 1,389    |

Property and equipment depreciation and amortization expense was approximately \$0.4 million and \$1.1 million for the years ended December 31, 2013 and 2012, respectively.

**5. 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, 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.

Under the collaboration and license agreement, the Company was obligated to deliver, using its best efforts, multiple services over an extended period of time. Such deliverables included granting of perpetual licenses of its proprietary technology and research and development services (i.e., development of intended product, designing of manufacturing equipment for volume commercialization, transferring of its know-how to Asahi, among others). In exchange for these deliverables, during 2011 the Company received an 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 are recorded in operating expenses in the consolidated statements of operations.

The Company applied the guidance under ASC 605-25, *Multiple Element 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 \$2.3 million for each of the year ended December 31, 2013 and 2012, and was recorded as license fees

revenue in the consolidated statements of operations.

Also under the collaboration agreement, the Company was eligible to receive payments based upon the achievement of certain contractually specified events. Revenue recognized for the fulfillment of these contractually specified events of \$2.0 million and \$7.0 million was recorded as license fees revenue in the consolidated statements of operations for the years ended December 31, 2013 and 2012, respectively.

Reimbursement of research and development and out-of-pocket expenses becomes due as the related services are performed under the collaboration agreement and were recognized as revenue on a time and material

---

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

basis and recorded as collaborative research and development services revenue, with the corresponding cost of service revenue recorded as research and development and manufacturing services expense in the consolidated statements of operations.

In January 2014, Asahi terminated the collaboration and license agreement with the Company and as a result, commercialization rights for the Company's proprietary transdermal delivery technology in Japan, China, Taiwan and South Korea were returned to the Company. (See Note 13 Subsequent Events.)

**6. Joint Venture**

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 approximately \$14.6 million (net book value) of certain 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.

Pursuant to ZP Group LLC's operating agreement, the Company was entitled to distributions from the joint venture entity (ZP Group LLC). Distributions received by the Company from ZP Group LLC are accounted for as a reduction of the carrying amount of the Company's investment in joint venture when the payment is received. For the years ended December 31, 2013 and 2012, the Company recorded approximately \$2.3 million and \$1.5 million, respectively, as a reduction to the carrying amount of its investment in joint venture.

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 was to receive:

- (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 accounts 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 from joint venture partner for the net amount due



the Company on its consolidated balance sheet as of December 31, 2013.

The joint venture termination agreement also provides for a period of reconciliation and true-up for costs and expenses in connection with the wind-down of ZP Group LLC's operations and settlement for outstanding liabilities and commitments. The Company subsequently entered into a settlement agreement on March 25, 2014 to settle all costs and expenses as stipulated in the joint venture termination agreement. (See Note 13 Subsequent Events.)

F-17

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

The following summarizes the Company's investment in the joint venture as of December 31, 2013 and 2012:

|   | <b>Carrying Value<br/>(in<br/>thousands)</b> |
|---|--|
| Balance as of January 1, 2012           | \$   |
| Investment in ZP Group LLC              | 14,575                                       |
| Share of loss from equity investment    | (738)  |
| Distribution                            | (1,539)                                      |
| <br>                                    |  |
| 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)                                      |
| <br>                                    |  |
| Balance as of December 31, 2013         | \$   |

The financial positions and results of operations of the investment accounted for under the equity method are as follows:

| <b>Joint Venture in ZP Group LLC</b> | <b>December 20,<br/>2013</b>              | <b>December 31,<br/>2012</b> |
|--------------------------------------|---|------------------------------|
|                                      | <b>(in thousands, except percentages)</b> |                              |
| Current assets                       | \$ 5,289                                  | \$ 7,391                     |
| Non-current assets                   | 9,856                                     | 12,488                       |
| Current liabilities                  | 5,785                                     | 7,447                        |
| Non-current liabilities              |   | 300                          |
| Revenue                              | 17,143                                    | 13,004                       |
| Operating expenses                   | 17,563                                    | 13,932                       |
| Net loss                             | (423)                                     | (929)                        |
| Interest held (%)                    | 50%                                       | 50%                          |

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

| <b>For the Period<br/>December 20, 2013</b> |  | <b>For the Year Ended<br/>December 31, 2012</b> |  |
|---|--|---|--|
| <b>(in thousands)</b>                       |  |   |  |
| <b>ZP<br/>Group<br/>LLC</b>                 | <b>Company's<br/>Equity in<br/>Loss of</b> | <b>ZP<br/>Group<br/>LLC</b>                     | <b>Company's<br/>Equity in<br/>Loss of</b> |
|   |  |   |  |

|   |          | <b>Joint<br/>Venture<br/>Computation</b> |       | <b>Joint<br/>Venture<br/>Computation</b> |          |
|---|----------|--|-------|--|----------|
| Reported net loss of joint venture  | \$ (423) |  |       | \$ (929)                                 |          |
| Contractual adjustment for special items solely allocated to the Company* | 308      | \$                                       | (308) | 548                                      | \$ (548) |
| Adjusted net loss of joint venture to be allocated to members             | (115)    |  |       | (381)                                    |          |
| The Company's share of allocated net loss                                 |          |  | (58)  |  | (190)    |
| Equity in loss of joint venture   |          | \$                                       | (366) | \$                                       | (738)    |

\* 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.

---

**Table of Contents****Index to Financial Statements****7. Debt Financing*****Bridge Financing Related Parties 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 bears 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 Company may 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.

Upon the closing of a qualified financing, which is 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. 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 contains customary conditions related to events of default and certain general covenants. The note purchase agreement does not require that the Company to comply with any affirmative covenants.

***Secured Financing with BMR Holdings***

In July 2011, the Company issued a convertible, unsecured promissory note (the 2011 Note) to its landlord, BioMed Realty Holdings, Inc. and affiliates (BMR Holdings), for unpaid rent with interest at a rate of 10% per annum, compounded annually, due January 31, 2012. In connection with the recapitalization of the Company in April 2012, the Company entered into and completed a stock purchase and loan restructuring agreement with BMR Holdings in which the outstanding balance of the 2011 Note of approximately \$2.6 million and then outstanding warrants were cancelled. In exchange, the Company issued to BMR Holdings 1,344,314 shares of common stock, making BMR Holdings a 23.75% shareholder of the Company at time of the recapitalization.

Also in April 2012, the Company renegotiated a new lease agreement with BMR Holdings to include reduced rent obligations. In connection with the rent reduction, the Company issued a new secured promissory note (the 2012 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 2012 Note or eliminated. The 2012 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 2012 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 BMR Holdings 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 2012 Note. The Company may prepay the 2012 Note, in whole or in part, at any time without prepayment penalty or premium. Further, the Company is required to prepay the 2012 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.

The 2012 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

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

collateralized assets, undergo a change of jurisdiction or relocation of its business, incur debt or incur liens, subject to certain exceptions. The 2012 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.

***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 provides 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 (See Note 13 Subsequent Events).

***Security Priority***

BMR Holdings has a first priority security interest and lien in and to all of the Company's tangible and intangible properties and assets, including intellectual properties.

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

***Short-term related parties notes payable:***

| Lender                             | Description     | Maturity Date     | Outstanding      |                  | Interest Rate Per Annum | Security/Covenant                |
|------------------------------------|-----------------|-------------------|------------------|------------------|-------------------------|----------------------------------|
|                                    |                 |                   | Principal Amount | Accrued Interest |                         |                                  |
| 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 |

Edgar Filing: Zosano Pharma Corp - Form 424B4

|               |                |                |          |       |       |           |
|---------------|----------------|----------------|----------|-------|-------|-----------|
| AKP USA, Inc. | Line of credit | March 14, 2014 | 491      | 5     | 1.15% | Unsecured |
|               |                |                | \$ 3,524 | \$ 80 | 7.05% |           |

F-20

**Table of Contents****Index to Financial Statements***Long-term related party debt:*

| <b>Lender</b>         | <b>Description</b> | <b>Maturity Date</b> | <b>Outstanding Principal Amount</b> | <b>Accrued Interest</b> | <b>Interest Rate Per Annum</b> | <b>Security/Covenant</b>  |
|-----------------------|--------------------|----------------------|-------------------------------------|-------------------------|--------------------------------|---|
| <b>(in thousands)</b> |                    |                      |                                     |                         |                                |   |
| 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 |
|                       |                    |                      | \$ 8,557                            | \$ 1,154                |                                |   |

The following table summarizes the Company's outstanding long-term debt as of December 31, 2012:

| <b>Lender</b>         | <b>Description</b> | <b>Maturity Date</b> | <b>Outstanding Principal Amount</b> | <b>Accrued Interest</b> | <b>Interest Rate Per Annum</b> | <b>Security/Covenant</b>  |
|-----------------------|--------------------|----------------------|-------------------------------------|-------------------------|--------------------------------|---|
| <b>(in thousands)</b> |                    |                      |                                     |                         |                                |   |
| BMV Direct SOTRS LP   | Recapitalization   | April 26, 2016       | \$8,557                             | \$469                   | 8.00%                          | First security interest in all properties and assets, including certain intellectual properties |
|                       |                    |                      | \$ 8,557                            | \$ 469                  |                                |   |

For the years ended December 31, 2013 and 2012, total interest expense on the Company's short-term bridge financing was approximately \$80,000 and none, respectively, and interest expense on the Company's long-term related party debt was approximately \$0.7 million and \$0.5 million, respectively.

**8. 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.



## Edgar Filing: Zosano Pharma Corp - Form 424B4

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.

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 \$6.3 million and \$7.4 million as of December 31, 2013 and 2012, 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

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

prepaid rent which is being expensed on a straight-line basis over the term of the lease. As of December 31, 2013, the prepaid rent of approximately \$5.9 million is offset against the deferred rent liability of approximately \$6.3 million, resulting in a net deferred rent liability of approximately \$0.4 million. As of December 31, 2012, the net deferred rent liability was approximately \$0.6 million.

Also in April 2012, the Company entered into a sub-lease agreement with ZP Group LLC, an equity investment of the Company. 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 and \$0.5 million for the year ended December 31, 2013 and 2012, respectively, were recorded as reduction of rental expense.

For the years ended December 31, 2013 and 2012, rental expense under operating leases before rental income was \$0.6 million and \$0.9 million, respectively.

Future minimum payments under non-cancelable operating leases as of December 31, 2013, are as follows (in thousands):

|                                      |                 |
|--------------------------------------|-----------------|
| 2014                                 | \$ 885          |
| 2015                                 | 673             |
| 2016                                 | 614             |
| 2017                                 | 632             |
| 2018                                 | 651             |
| Thereafter                           | 164             |
| <b>Total future minimum payments</b> | <b>\$ 3,619</b> |

***Indemnification***

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, 2013.

**9. Stockholders' Equity*****Common Stock***

The Company's certificate of incorporation authorizes the Company to issue 30.0 million 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. As of December 31, 2013 and 2012, 5,106,800 shares of the Company's common stock were issued and outstanding.

**10. Stock Incentive Plan**

The Company adopted the 2012 Stock Incentive Plan (the 2012 Plan) which provides for the granting of stock options and restricted stock awards to employees, directors and consultants of the Company. Options

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

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, 2013, the Company has 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 are 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. In 2012, 12,500 shares of fully vested restricted stock awards were granted to certain officers of the Company.

The following table summarizes options and restricted stock awards activity under the 2012 Plan and related information:

|  | Shares Available for Grant | Outstanding Number of Awards (in shares) | Weighted-Average Exercise Price per Share | Weighted-Average Remaining Contractual Term (In Years) | Aggregate Intrinsic Value |
|--|----------------------------|--|---|--|---------------------------|
| Shares reserved under the 2012 Plan              | 566,027                    |  |   |  |                           |
| Granted  | (327,435)                  | 327,435                                  | \$ 1.41                                   |  |                           |
| Exercised/vested and released                    |                            | (12,500)                                 |   |  |                           |
| Cancelled/forfeited                              |                            |  |   |  |                           |
| Balance at December 31, 2012                     | 238,592                    | 314,935                                  | \$ 1.46                                   | 9.53   |                           |
| Granted  | (203,943)                  | 203,943                                  | \$ 1.40                                   |  |                           |
| Exercised/vested and released                    |                            |  |   |  |                           |
| Cancelled/forfeited                              | 49,102                     | (49,102)                                 | \$ 1.40                                   |  |                           |
| Balance at December 31, 2013                     | 83,751                     | 469,776                                  | \$ 1.44                                   | 8.88   |                           |
| Exercisable at December 31, 2013                 |                            | 107,813                                  | \$ 1.47                                   | 8.26   | \$                        |
| Vested and expected to vest at December 31, 2013 |                            | 409,826                                  | \$ 1.43                                   | 8.69   | \$                        |

The aggregate intrinsic values of options outstanding and exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock as determined by the Board of Directors with input from management as of December 31, 2013. The estimated fair value of the common stock underlying the stock options was determined at each grant date by the board of directors and was supported by periodic independent third-party valuations.

The following summarizes the composition of stock options outstanding and exercisable as of December 31, 2013:

| <b>Exercise Price</b> | <b>Options Outstanding and Exercisable</b> |   |
|-----------------------|--|---|
|                       | <b>Number of Shares</b>                    | <b>Weighted-Average Remaining Contractual Life (in years)</b> |
| \$1.40                | 54,748                                     | 8.39  |
| \$1.54                | 53,065                                     | 8.13  |

F-23

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

The weighted-average grant-date fair value of options and awards granted during the years ended December 31, 2013 and 2012 were \$0.97 per share and \$1.04 per share, respectively. The total fair value of options and awards that vested during the years ended December 31, 2013 and 2012 were approximately \$0.1 million and \$52,000, respectively. No option was exercised in the year ended December 31, 2013 and 2012. 12,500 shares of fully vested restricted stock awards were released in 2012.

***Stock-Based Compensation Expense***

Total stock-based compensation expense included in the Company's consolidated statements of operations is as follows:

|                            | <b>Year Ended December 31,</b> |              |
|----------------------------|--------------------------------|--------------|
|                            | <b>2013</b>                    | <b>2012</b>  |
|                            | <b>(in thousands)</b>          |              |
| Research and development   | \$ 16                          | \$ 26        |
| General and administrative | 49                             | 37           |
|                            | <b>\$ 65</b>                   | <b>\$ 63</b> |

The total unrecognized stock-based compensation expense related to stock-based compensation arrangements at December 31, 2013, was approximately \$0.2 million, and is expected to be recognized over a weighted-average period of approximately 2.88 years.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option valuation model. Since the Company is private and does not have any trading history for its common stock, the expected stock price volatility was calculated based on the average historical volatility for comparable publicly traded pharmaceutical companies. The Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the Company's stock-based awards. The expected term of the options is based on the average period the stock options are expected to remain outstanding. As the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term is calculated as the midpoint between the weighted-average vesting term and the contractual expiration period, also known as the simplified method. The risk-free interest rate is based on U.S. Treasury zero coupon issues with remaining terms consistent with the expected terms of the stock options, as determined at the time of grant. To date, the Company has not declared or paid any cash dividends and does not have any plans to do so in the future. Therefore, the Company used an expected divided yield of zero.

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>2013</b>                    | <b>2012</b> |

Edgar Filing: Zosano Pharma Corp - Form 424B4

|                          |        |        |
|--------------------------|--------|--------|
| Dividend yield           |        |        |
| Risk-free interest rate  | 1.74%  | 0.97%  |
| Expected volatility      | 89.00% | 89.00% |
| Expected term (in years) | 6.08   | 6.08   |

In the years ended December 31, 2013 and 2012, the Company granted 2,500 shares and 4,836 shares of common stock options, respectively, with an exercise price of \$1.40 per share, in exchange for services from consultants. Stock-based compensation expense related to stock options granted to nonemployees is measured and recognized as 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 these options is measured using

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

the Black-Scholes option pricing model reflecting an expected life that is assumed to be the remaining contractual life of the option. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned. For the years ended December 31, 2013 and 2012, the Company recorded an immaterial amount of stock-based compensation expense related to the stock options granted to non-employees.

The fair value of the stock options granted to nonemployees was calculated using the Black-Scholes option pricing model with the following assumptions:

|                          | <b>Year Ended December 31,</b> |             |
|--------------------------|--------------------------------|-------------|
|                          | <b>2013</b>                    | <b>2012</b> |
| Dividend yield           |                                |             |
| Risk-free interest rate  | 3.01%                          | 1.78%       |
| Expected volatility      | 89.00%                         | 89.00%      |
| Expected term (in years) | 10.00                          | 10.00       |

**11. 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, 2013 and 2012 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>2013</b>                    | <b>2012</b> |
| Federal statutory tax rate | (34.00)%                       | 34.00%      |
| State statutory tax rate   | (5.85)%                        | 5.85%       |
| Warrant revaluation        | 1.16%                          | (3.32)%     |
| Other                      | 0.37%                          | 5.87%       |
| Valuation allowance        | 38.32%                         | (42.40)%    |
| Provision for income taxes | %                              | %           |

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, 2013 and 2012, the Company had net deferred tax assets of \$56.5 million and \$53.9 million, respectively. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain.

Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately \$2.6 million during the year ended December 31, 2013, and decreased by approximately \$0.8 million during the year ended December 31, 2012.





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

Significant components of the Company's net deferred tax assets and liabilities at December 31, 2013 and 2012 are as follows:

|  | <b>Year Ended December 31,</b> |             |
|--|--------------------------------|-------------|
|  | <b>2013</b>                    | <b>2012</b> |
|  | <b>(in thousands)</b>          |             |
| Net operating loss carryforwards         | \$ 52,823                      | \$ 48,690   |
| Deferred revenue                         | 448                            | 1,344       |
| Accruals                                 | 300                            | 46          |
| Deferred rent                            | 601                            | 792         |
| Research and development credits         | 5,850                          | 5,376       |
| AMT credit                               | 20                             | 20          |
| Other                                    | 294                            | 691         |
| Depreciation and amortization            | (2,498)                        | (144)       |
| Investments                              |                                | (1,645)     |
| Research and development credit reserves | (1,359)                        | (1,249)     |
| Net deferred tax assets                  | 56,479                         | 53,921      |
| Valuation allowance                      | (56,479)                       | (53,921)    |
|  | \$                             | \$          |

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 since its formation and, accordingly, some or all of its net operating loss carryforwards may not be available to offset future taxable income.

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 since its formation 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, 2012 through December 31, 2013. 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 2013 and

extended 50% bonus depreciation. The Act does not have any impact on the Company's federal tax credits carryforward as of December 31, 2013.

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.

**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 and \$1.2 million of unrecognized tax benefits as of December 31, 2013 and 2012, respectively. 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>2013</b>                    | <b>2012</b> |
|  | <b>(in thousands)</b>          |             |
| Balance at the beginning of year               | \$ 1,249                       | \$ 1,167    |
| Increase related to prior year tax positions   |                                |             |
| Increase related to current year tax positions | 110                            | 82          |
| Balance at the end of year                     | \$ 1,359                       | \$ 1,249    |

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, 2013 and 2012, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

**12. 401(k) Plan**

The Company's employees, upon meeting certain requirements, are eligible to participate in a 401(k) plan. The 401(k) plan provides that each participant may contribute a portion of his or her pre-tax compensation, up to a statutory limit. Participants that are 50 years or older can also make "catch-up" contributions up to certain additional amount above the statutory limit. Employee contributions are held and invested by the plan's trustee. The 401(k) plan also permits the Company to make discretionary matching contributions. The Company did not make any matching contribution for the years ended December 31, 2013 and 2012.

**13. Subsequent Events*****Termination of License Agreement and Return of Asian Marketing Rights***

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. In connection with the collaboration and license agreement with Asahi, Company had previously received a \$7.5 million nonrefundable upfront license fee. The \$7.5 million payment was recorded in the Company's consolidated balance sheet as deferred revenue upon receipt and recognized in its

consolidated statements of operations as revenue on a straight-line basis over the performance and service period. 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 will recognize as revenue the remaining \$1.1 million of the nonrefundable upfront license fee as of March 31, 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. Pursuant to the terms of the collaboration and license agreement and upon its termination, commercialization rights in Japan, China, Taiwan and South Korea were returned to the Company.

F-27

**Table of Contents**

**Index to Financial Statements**

***Collaboration with Novo Nordisk***

In January 2014, the Company entered into an agreement with Novo Nordisk A/S (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. Initially, the Company and Novo Nordisk will engage in collaborative efforts to carry out preclinical experiments to verify delivery of semaglutide using the microneedle patch system.

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. As of the date of this report, the Company has received an upfront payment. The Company is also eligible to receive milestones and royalties on sales of products and will receive development support, as well as reimbursement of all development and manufacturing costs.

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

In February 2014, the Company further 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, remain the same as the promissory notes issued to the same parties in September 2013.

***Final Settlement of Joint Venture Affairs***

In March 2014, the Company entered into a settlement agreement with Asahi, 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. All outstanding liabilities, materials, drug supplies and equipment are settled through provisions under the settlement agreement.

**Table of Contents**

**Index to Financial Statements**

**Zosano Pharma Corporation and Subsidiaries**

**Index to Unaudited Interim Condensed Consolidated Financial Statements**

**September 30, 2014**

Unaudited Interim Condensed Consolidated Financial Statements:

|   |      |
|---|------|
| <u>Condensed Consolidated Balance Sheets</u>                                  | F-30 |
| <u>Condensed Consolidated Statements of Operations</u>                        | F-31 |
| <u>Condensed Consolidated Statements of Cash Flows</u>                        | F-32 |
| <u>Notes to Unaudited Interim Condensed Consolidated Financial Statements</u> | F-33 |

F-29

Table of ContentsIndex to Financial Statements**ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except par value)

|  | September 30,<br>2014 | Pro Forma<br>September 30,<br>2014<br>(unaudited) | December 31,<br>2013 |
|--|-----------------------|---|----------------------|
| <b><u>ASSETS</u></b>   |                       |   |                      |
| Current assets:  |                       |   |                      |
| Cash and cash equivalents  | \$ 2,303              | \$ 2,303  | \$ 5,913             |
| Accounts receivable  | 173                   | 173   |                      |
| Accounts receivable from joint venture partner   |                       |   | 3,426                |
| Short-term investment  | 343                   | 343   | 361                  |
| Prepaid expenses and other current assets  | 213                   | 213   | 465                  |
| Total current assets   | 3,032                 | 3,032   | 10,165               |
| Restricted cash  | 35                    | 35  | 65                   |
| Property and equipment, net  | 10,515                | 10,515  | 11,714               |
| Other long-term assets   | 1,583                 | 1,583   | 140                  |
| Total assets   | \$ 15,165             | 15,165  | \$ 22,084            |
| <b><u>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</u></b>                                |                       |   |                      |
| Current liabilities:   |                       |   |                      |
| Accounts payable   | \$ 1,409              | \$ 1,409  | \$ 3,412             |
| Accrued compensation   | 1,399                 | 1,399   | 2,676                |
| Revolving line of credit   |                       |   | 496                  |
| Deferred revenue   | 306                   | 306   | 1,125                |
| Secured promissory note, current portion (net of issuance cost and incl. accrued interest) | 1,018                 | 1,018   |                      |
| Related parties convertible notes (incl. accrued interest)                                 | 5,909                 |   | 3,108                |
| Freestanding warrant liability   | 114                   | 114   |                      |
| Other accrued liabilities  | 730                   | 730   | 716                  |
| Total current liabilities  | 10,885                | 4,976   | 11,533               |
| Deferred rent  | 166                   | 166   | 363                  |
| Secured promissory note, net of issuance cost (incl. accrued interest)                     | 2,878                 | 2,878   |                      |
| Related party note payable (incl. accrued interest)  | 10,458                | 10,458  | 9,711                |
| Commitments and contingencies  |                       |   |                      |
| Stockholders' equity (deficit):  |                       |   |                      |



Edgar Filing: Zosano Pharma Corp - Form 424B4

|   |           |           |           |
|---|-----------|-----------|-----------|
| Common stock, \$0.0001 par value: 30,000 shares authorized as of September 30, 2014, pro forma, and as of December 31, 2013, respectively; 5,140 shares issued and outstanding as of September 30, 2014, 5,772 shares issued and outstanding pro forma, and 5,107 shares issued and outstanding as of December 31, 2013 | 1         | 1         | 1         |
| Additional paid-in capital  | 124,964   | 130,873   | 124,699   |
| Accumulated deficit   | (134,187) | (134,187) | (124,223) |
| Stockholders' equity (deficit)  | (9,222)   | (3,313)   | 477       |
| Total liabilities and stockholders' equity (deficit)  | \$ 15,165 | \$ 15,165 | \$ 22,084 |

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

F-30

Table of ContentsIndex to Financial Statements

**ZOSANO PHARMA CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)

|   | <b>Nine Months<br/>Ended September 30,<br/>2014                  2013<br/>(unaudited)</b> |            |
|---|---|------------|
| Revenue:  |   |            |
| License fees revenue  | \$ 1,819  | \$ 3,688   |
| Collaborative development support services  | 662   |            |
| Total revenue   | 2,481   | 3,688      |
| Operating expenses:   |   |            |
| Cost of license fees revenue  | 100   |            |
| Research and development  | 8,230   | 4,760      |
| General and administrative  | 3,208   | 2,692      |
| Total operating expenses  | 11,538  | 7,452      |
| Loss from operations  | (9,057)   | (3,764)    |
| Other expense:  |   |            |
| Interest expense, net   | (1,261)   | (526)      |
| Other expense   | (143)   | (20)       |
| Loss before equity in gain of joint venture and gain on debt forgiveness                                    | (10,461)  | (4,310)    |
| Equity in gain of joint venture   |   | 45         |
| Gain on debt forgiveness  | 497   |            |
| Net loss  | \$ (9,964)  | \$ (4,265) |
| Net loss per common share basic and diluted   | \$ (1.95)   | \$ (0.84)  |
| Weighted-average shares used in computing net loss per common share basic and diluted                       | 5,121   | 5,107      |
| Pro forma net loss per common share basic and diluted (unaudited)   | \$ (1.68)   |            |
| Weighted-average shares used in computing pro forma net loss per common share basic and diluted (unaudited) | 5,696   |            |

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

F-31

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

**ZOSANO PHARMA CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED CASH FLOW STATEMENTS**  
(in thousands)

|   | <b>Nine Months Ended September 30,</b> |             |
|---|--|-------------|
|   | <b>2014</b>                            | <b>2013</b> |
|   | <b>(unaudited)</b>                     |             |
| <b>Cash flows from operating activities:</b>                                  |  |             |
| Net loss  | \$ (9,964)                             | \$ (4,265)  |
| Adjustments to reconcile net loss to net cash (used in) operating activities: |  |             |
| Depreciation  | 2,278                                  | 260         |
| Stock-based compensation  | 122                                    | 55          |
| Equity in gain of joint venture   |  | (45)        |
| Gain on debt forgiveness  | (497)                                  |             |
| Amortization of debt issuance cost  | 34                                     |             |
| Accretion of interest payment   | 1,106                                  | 526         |
| Cost of debt subordination  | 141                                    |             |
| Revaluation of warrant liability to fair value                                | (2)                                    |             |
| Deferred rent   | (197)                                  | (178)       |
| Change in operating assets and liabilities:                                   |  |             |
| Accounts receivable   | (173)                                  | 101         |
| Accounts receivable from joint venture partner                                | 3,426                                  | 115         |
| Prepaid expenses and other assets   | (1,191)                                | (399)       |
| Accounts payable  | (2,003)                                | 485         |
| Accrued compensation and other liabilities                                    | (1,262)                                | 609         |
| Deferred revenue  | (819)                                  | (1,688)     |
| Net cash flow used in operating activities                                    | (9,001)                                | (4,424)     |
| <b>Cash flow from investing activities:</b>                                   |  |             |
| Distribution from joint venture   |  | 1,213       |
| Purchase of property and equipment  | (1,079)                                | (506)       |
| Decrease in restricted cash   | 30                                     |             |
| Decrease in short-term investment   | 18                                     |             |
| Net cash flow (used in) provided by investing activities                      | (1,031)                                | 707         |
| <b>Cash flow from financing activities:</b>                                   |  |             |
| Proceeds from exercise of stock options and issuance of common stock          | 2                                      |             |
| Proceeds from borrowings under related parties bridge notes                   | 2,500                                  | 3,034       |
| Proceeds from debt financing, net of issuance cost                            | 3,920                                  |             |

|  |          |          |
|--|----------|----------|
| Net cash flow provided by financing activities             | 6,422    | 3,034    |
| Net decrease in cash and cash equivalents                  | (3,610)  | (683)    |
| Cash and cash equivalents at beginning of period           | 5,913    | 4,973    |
| Cash and cash equivalents at end of period                 | \$ 2,303 | \$ 4,290 |
| <b>Non-cash financing activities:</b>                      |          |          |
| Issuance of common stock in connection with debt financing | \$ 141   |          |
| Accrued deferred offering costs                            | \$ 1,068 |          |

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

F-32

**Table of Contents**

**Index to Financial Statements**

**Zosano Pharma Corporation and Subsidiaries**

**Notes to Unaudited Interim Condensed Consolidated Financial Statements**

**September 30, 2014**

**1. Summary of Significant Accounting Policies**

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

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial reporting and as required by Regulation S-X, Rule 10-01. The preparation of the accompanying condensed 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 condensed consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

***Going Concern and Management's Plans***

The accompanying condensed consolidated financial statements have been prepared assuming Zosano Pharma Corporation and subsidiaries (the Company) will continue as a going concern. The Company has a history of incurring operating losses and negative cash flows from operating activities. The Company had an accumulated deficit of approximately \$134.2 million as of September 30, 2014. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Through September 30, 2014, the Company has relied primarily on the proceeds from private equity offerings and loan proceeds to finance its operations. Management expects to incur additional losses in the future to conduct product research and development and to conduct pre-commercialization activities. Additional capital will be required to undertake these activities and to meet the operating requirements of the Company in the next twelve months and beyond. The Company intends to raise such capital through the issuance of additional equity through public or private offerings, borrowings, and strategic alliances with partner companies. However, if such financing is not available at adequate levels or on acceptable terms, the Company could be required to significantly reduce operating expenses and delay or reduce the scope of or eliminate some of its development programs or its commercialization efforts, enter into a collaboration or other similar arrangement with respect to commercialization rights to any of its product candidates, out-license intellectual property rights to its transdermal delivery technology and sell unsecured assets, or a combination of the above, which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all.

***Unaudited Interim Financial Information***

The condensed consolidated balance sheet as of September 30, 2014, condensed consolidated statements of operations and statements of cash flows for the nine months ended September 30, 2014 and 2013 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company's financial position as of September 30, 2014, and

the results of operations and cash flows for the nine months ended September 30, 2014 and 2013. The financial data and other information disclosed in these notes to the interim condensed consolidated financial statements as of September 30, 2014 and for the nine month periods ended September 30, 2014 and 2013 are also unaudited. The results for the nine months ended September 30, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014 or for any other interim period or for any future year. These financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2013.

**Table of Contents****Index to Financial Statements*****Initial Public Offering Related Events***

On June 20, 2014, the Company's board of directors approved a change of name of the Company from ZP Holdings, Inc. to Zosano Pharma Corporation.

On June 24, 2014, the Company filed a registration statement with the Securities and Exchange Commission related to a planned initial public offering of its common stock.

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 and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

On July 11, 2014, the Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation, effective upon the closing of the Company's planned initial public offering of shares of its common stock, pursuant to which the Company will be authorized to issue up to 100.0 million shares of common stock and up to 5.0 million shares of preferred stock.

On July 11, 2014, the Company's board of directors approved the 2014 Equity and Incentive Plan, which will become effective in connection with the closing of the Company's planned initial public offering.

***Unaudited Pro Forma Presentation***

The unaudited pro forma balance sheet as of September 30, 2014 gives effect to the automatic conversion of the Company's related parties convertible notes of \$5.9 million of principal and interest into an aggregate of 631,947 shares of common stock upon completion of a planned initial public offering at a price equal to 85% of the assumed initial public offering price, resulting in the reclassification of the related liabilities to additional paid-in capital.

The following unaudited pro forma basic and diluted net loss per common share calculation for the nine months ended September 30, 2014 assumes the conversion of all outstanding related parties convertible notes into 631,947 shares of common stock as if the conversion had occurred at the beginning of the period or, if later, the original issue date, using the if-converted method:

|                           | <b>Nine Months Ended<br/>September 30,<br/>2014<br/>(unaudited;<br/><br/>in thousands,<br/>except per share<br/>amount)</b> |
|---------------------------|---|
| <i>Numerator:</i>         |   |
| Net loss per common share | \$ (9,964)  |



Edgar Filing: Zosano Pharma Corp - Form 424B4

|   |    |         |
|---|----|---------|
| Add:  |    |         |
| Interest expense on related parties convertible notes   |    | 375     |
| Pro forma net loss  | \$ | (9,589) |
| <i>Denominator:</i>   |    |         |
| Weighted average shares used in computing net loss per common share   |    | 5,121   |
| Add:  |    |         |
| Pro forma adjustments to reflect the weighted average assumed conversion of related parties convertible notes |    | 575     |
| Weighted average shares used in computing pro forma net loss per common share basic and diluted               |    | 5,696   |
| Pro forma net loss per common share basic and diluted   | \$ | (1.68)  |

F-34

**Table of Contents**

**Index to Financial Statements**

***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. Intercompany balances and transactions have been eliminated in consolidation.

***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.

***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 September 30, 2014 and December 31, 2013, respectively.

***Short-Term Investment***

The Company accounts for its investment in Zosano, Inc., the public shell corporation it acquired in October 2013, using the cost method of accounting and classifies this investment as a short-term investment in its consolidated balance sheet. The Company continues to actively pursue selling this investment.

***Deferred Offering Costs***

Deferred offering costs, consisting of legal, accounting, printing and filing fees related to the initial public offering are capitalized and will be offset against proceeds from the initial public offering upon the closing of the offering. In the event the offering is terminated, all capitalized deferred offering costs will be expensed. As of September 30, 2014, approximately \$1.4 million of expenses related to the initial public offering had been deferred as other long-term assets in the Company's consolidated balance sheet. No offering costs were deferred as of December 31, 2013.

***Revenue Recognition***

The Company generates revenue from collaboration arrangements for the development and commercialization of its microneedle patch system and product candidates. 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 license and collaboration agreements may contain multiple elements, including grants of licenses to the Company's proprietary technology and know-how related 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. 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. If the Company determines that the license does not have standalone value separate from the research and

**Table of Contents**

**Index to Financial Statements**

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. The Company periodically reviews the estimated period of performance based on the progress made under each arrangement.

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 an event that can only be achieved based on the Company'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 the milestone method guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company's performance to achieve the milestone after commencement of the agreement. Other contingent payments received for which payment is contingent solely on the results of a collaborative partner's performance or the achievement of certain pre-defined corporate objectives are not accounted for using the milestone method. Such payments will be recognized as revenue when the objective is met and collectability is reasonably assured.

Amounts related to research and development funding are recognized as the related services or activities are performed, in accordance with the contractual 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.

***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.

For the nine months ended September 30, 2014, the Company incurred research and development costs of approximately \$0.4 million in support of the Company's collaborative development services to Novo Nordisk A/S, approximately \$3.5 million in connection with the Company's research and development efforts, and approximately \$4.3 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates. For the nine months ended September 30, 2013, the Company incurred research and development costs of approximately \$3.5 million in connection with the Company's research and development efforts and approximately \$1.3 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates.

***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 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 Income (Loss) per Common Share***

Basic net income (loss) per common share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for potential dilutive common stock equivalents. Diluted net income (loss) per common share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, convertible promissory notes, warrants and options to purchase common stock are considered potential dilutive common stock equivalents.

F-36

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

For the nine months ended September 30, 2014 and 2013, diluted net loss per common share was the same as basic net loss per common share since the effect of inclusion of potentially dilutive common stock equivalents would have an antidilutive effect due to the loss reported.

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:

|   | <b>September 30,</b> |                |
|---|----------------------|----------------|
|   | <b>2014</b>          | <b>2013</b>    |
|   | <b>(unaudited)</b>   |                |
| Warrant to purchase common stock as exercised             | 31,674               |                |
| Outstanding options to purchase common stock as exercised | 527,619              | 499,525        |
|   | <b>559,293</b>       | <b>499,525</b> |

**2. 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, short-term investment, 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.

Edgar Filing: Zosano Pharma Corp - Form 424B4

The following tables set forth the fair value of the Company's financial instruments as of September 30, 2014 and December 31, 2013:

|   | <b>September 30, 2014</b> |                 |                  | <b>Total</b> |
|---|---------------------------|-----------------|------------------|--------------|
|   | <b>Level I</b>            | <b>Level II</b> | <b>Level III</b> |              |
| <b>(unaudited; in thousands)</b>          |                           |                 |                  |              |
| <b>Financial assets:</b>                  |                           |                 |                  |              |
| Certificates of deposit (restricted cash) | \$ 35                     | \$              | \$               | \$ 35        |
| <b>Financial liabilities:</b>             |                           |                 |                  |              |
| Freestanding warrant liability            |                           |                 | 114              | 114          |

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

F-37

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

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 Freestanding Warrant Liability for significant unobservable inputs used to determine the fair value of the freestanding warrant liability.) There were no transfers between levels within the fair value hierarchy during the periods presented.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs:

|   | <b>September 30, 2014</b><br><b>(unaudited;</b> |     |
|---|---|-----|
| <b>Financial liabilities:</b>   | <b>in thousands)</b>                            |     |
| Balance at January 1, 2014  | \$  |     |
| Issuance of freestanding warrant                                      |   | 116 |
| Transfer from (to) Level 1 and 2                                      |   |     |
| Change in fair value of freestanding warrant liability <sup>(1)</sup> |   | (2) |
| Balance at September 30, 2014   | \$  | 114 |

- (1) Change in fair value of the freestanding warrant is recorded as other income (expense) in the Company's condensed statement of operations. For the nine months ended September 30, 2014, the Company recorded approximately \$2,000 related to the change in fair value of its freestanding warrant liability.

**3. Property and Equipment**

The following table is a summary of property and equipment:

|                                 | <b>September 30, 2014</b><br><b>(unaudited)</b> | <b>December 31, 2013</b> |
|---------------------------------|---|--------------------------|
|                                 | <b>(in thousands)</b>                           |                          |
| Laboratory and office equipment | \$ 1,108  | \$ 1,108                 |
| Manufacturing equipment         | 10,851  | 10,769                   |
| Computer equipment and software | 230   | 230                      |
| Leasehold improvements          | 15,534  | 15,534                   |
| Construction in progress        | 1,736   | 738                      |
|                                 | 29,459  | 28,379                   |
| Less: Accumulated depreciation  | (18,944)  | (16,665)                 |



|                             |           |    |        |
|-----------------------------|-----------|----|--------|
| Property and equipment, net | \$ 10,515 | \$ | 11,714 |
|-----------------------------|-----------|----|--------|

Property and equipment depreciation and amortization expense was approximately \$2.3 million and \$0.3 million for the nine months ended September 30, 2014 and 2013, respectively.

#### **4. Termination of Collaboration with Asahi Kasei Pharma Corporation**

The Company's collaboration and license agreement with Asahi Kasei Pharma Corporation (Asahi) was terminated on January 27, 2014, at which time the performance and service period effectively ended. In connection with the collaboration and license agreement with Asahi, the Company had previously received a \$7.5 million nonrefundable upfront license fee. The \$7.5 million payment was recorded in the Company's consolidated balance sheet as deferred revenue upon receipt and recognized in its consolidated statements of operations as revenue on a straight-line basis over the performance and service period. 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

---

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

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.

**5. Settlement of Joint Venture Affairs**

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. The joint venture termination agreement 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 September 30, 2014 financial statements was limited to the collection of the Company's receivables from Asahi of approximately \$3.4 million as final settlement.

**6. Collaboration with Novo Nordisk**

In January 2014, the Company entered into an agreement with Novo Nordisk A/S (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 September 30, 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.

**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

F-39

---

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

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 condensed consolidated statement of operations for the nine months ended September 30, 2014.

**8. Debt Financing*****Bridge Financing Related Parties Convertible 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, remain the same as the promissory notes issued to the same parties in September 2013.

In June 2014, the Company amended the convertible bridge notes to provide that any failure by the Company to pay any amount under the convertible bridge notes during the period from maturity of the convertible bridge notes through the date that the loan with Hercules Technology Growth Capital, Inc. (Hercules) is repaid in full will not constitute a default under the convertible bridge notes. In September 2014, the Company further amended the convertible bridge notes to extend the date by which a qualified financing must occur in order for the convertible bridge notes to convert into equity securities to March 31, 2015. Upon the closing of a qualified financing, which is defined in the convertible bridge notes as an equity financing on or prior to December 31, 2014 in which the Company raises at least \$25 million (which, for purposes of this definition as it relates to the Company's planned initial public offering of its common stock, will include the gross proceeds of the concurrent private placement with Eli Lilly and Company described under Note 11 Subsequent Events), the convertible bridge notes convert into the equity security sold in the qualified financing, at price equal to 85% of the lowest per share price at which the equity security is sold in the qualified financing.

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

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 approximately \$0.5 million on its consolidated statement of operations for the nine months ended September 30, 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 (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

F-40

**Table of Contents**

**Index to Financial Statements**

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 is 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 is 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. In July 2014, Hercules waived its participation and conversion rights in respect of the Company's planned initial public offering.

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, an affiliate of BioMed Realty Holdings, Inc. (BMR Holdings) agreed to subordinate its existing secured financing 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 the BMR Holdings affiliate that is the holder of the BMR secured promissory note. The Company recorded the fair value of the common stock issued to the BMR Holdings affiliate of approximately \$141,000 as a cost of debt subordination and included this amount as other expense in its condensed statement of operations for the nine months ended September 30, 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 financing that have been capitalized as debt issuance costs and are being amortized to interest expense using the effective interest method over the term of the loan. For the nine month periods ended September 30, 2014, the Company recorded interest expense related to the Hercules Term Loan of approximately \$177,000.

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

The following tables summarize the Company's outstanding short-term financing and long-term debt as of September 30, 2014:

*Short-term related parties convertible notes and current portion of long-term debt:*

| Lender                                   | Description     | Maturity Date     | Outstanding      |               | Accrued Interest | Interest Rate Per Annum | Security/Covenant   |
|--|-----------------|-------------------|------------------|---------------|------------------|-------------------------|---|
|  |                 |                   | Principal Amount | Debt Discount |                  |                         |   |
| BMV Direct SO LP                         | Working capital | September 9, 2014 | \$ 552           | \$            | \$ 37            | 8.00%                   | Unsecured, convertible to common  |
| BMV Direct SOTRS LP                      | Working capital | September 9, 2014 | 2,061            |               | 135              | 8.00%                   | Unsecured, convertible to common  |
| New Enterprise Associates 12, L.P.       | Working capital | September 9, 2014 | 2,341            |               | 154              | 8.00%                   | Unsecured, convertible to common  |
| ProQuest Investments IV, L.P.            | Working capital | September 9, 2014 | 580              |               | 49               | 8.00%                   | Unsecured, convertible to common  |
| Hercules Technology Growth Capital, Inc. | Working capital | June 3, 2017      | 1,072            | (94)          | 40               | 12.05%                  | First security interest in all properties and assets, including intellectual properties |
|  |                 |                   | \$ 6,606         | \$ (94)       | \$ 415           | 8.66%                   |   |

*Long-term debt:*

| Lender              | Description      | Maturity Date  | Outstanding      |               | Accrued Interest | Interest Rate Per Annum | Security/Covenant  |
|---------------------|------------------|----------------|------------------|---------------|------------------|-------------------------|--|
|                     |                  |                | Principal Amount | Debt Discount |                  |                         |  |
| BMV Direct SOTRS LP | Recapitalization | April 26, 2016 | \$ 8,557         | \$            | \$ 1,901         | 8% - 12.05%*            | Second security interest in all properties and assets, including intellectual properties |
| Hercules Technology | Working capital  | June 3, 2017   | 2,928            | (67)          | 17               | 12.05%                  | First security interest in all properties and  |

Growth  
Capital, Inc.

assets, including  
intellectual properties

\$ 11,485 \$ (67) \$ 1,918

\* In June 2014, the Company amended the BMR 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. The change to the terms of the BMR note did not result in debt modification accounting in accordance with ASC 470-50.

F-42



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

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

*Short-term related parties convertible notes:*

| <b>Lender</b>                      | <b>Description</b> | <b>Maturity Date</b> | <b>Outstanding Principal Amount (in thousands)</b> | <b>Accrued Interest</b> | <b>Interest Rate/ Weighted-Average Interest Rate Per Annum</b> | <b>Security/Covenant</b>         |
|------------------------------------|--------------------|----------------------|--|-------------------------|--|----------------------------------|
| 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 |
| AKP USA, Inc.                      | Line of credit     | March 14, 2014       | 491  | 5                       | 1.15%  | Unsecured                        |
|                                    |                    |                      | \$ 3,524   | \$ 80                   | 7.05%  |                                  |

*Long-term related party debt:*

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

For the nine months ended September 30, 2014 and 2013, total interest expense on the Company's short-term debt was approximately \$0.5 million and \$14,000, respectively, and interest expense on the Company's long-term debt was approximately \$0.8 million and \$0.5 million, respectively.

**9. Freestanding Warrant Liability**

In connection with the Hercules Term Loan (see Note 8, Senior Secured Term Loan with Hercules), the Company issued a warrant to Hercules to purchase shares of the Company's stock having a purchase price of up to \$280,000 at an exercise price per share equaling the lesser of (1) 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 (2) \$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 initial public offering.

In accordance with ASC 480, Distinguishing Liabilities from Equity, the Company accounts for the warrant to purchase shares of the Company's common stock in connection with the Hercules Term Loan as a liability in its condensed consolidated balance sheet. The warrant is recorded on the Company's balance sheet at fair value on the date of issuance as a debt discount and 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

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

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 other income (expense) in the accompanying condensed consolidated statements of operations. For the nine months ended September 30, 2014, the Company recorded an income of approximately \$2,000 related to the changes in fair value of the warrant. The Company determined the fair value of the warrant as of September 30, 2014 using a Black-Scholes option valuation model with the following assumptions: expected term equals to the remaining life of the warrant of approximately 9.67 years; volatility equals 89%; risk free interest rate of 2.63%; and no dividend yield.

**10. Stock Incentive Plan**

As of September 30, 2014, the Company has reserved 566,027 shares of common stock for issuance under the 2012 Plan.

The following table summarizes options and restricted stock awards activity under the 2012 Plan and related information:

|  | <b>Shares Available for Grant (in shares)</b> | <b>Outstanding Number of Awards (in shares)</b> | <b>Weighted-Average Exercise Price per Share</b> | <b>Weighted-Average Remaining Contractual Term (in years)</b> | <b>Aggregate Intrinsic Value (in thousands)</b> |
|--|---|---|--|---|---|
| Balance at December 31, 2013   | 83,751  | 469,776   | \$ 1.44  | 7.39  |   |
| Granted (unaudited)  | (130,784)                                     | 130,784   | \$ 1.98  |   |   |
| Exercised (unaudited)  |   | (1,580)   | \$ 1.40  |   |   |
| Cancelled/forfeited (unaudited)                                      | 71,361  | (71,361)  | \$ 1.40  |   |   |
| <b>Balance at September 30, 2014 (unaudited)</b>                     | <b>24,328</b>                                 | <b>527,619</b>                                  | <b>\$ 1.58</b>                                   | <b>7.12</b>   |   |
| <b>Exercisable at September 30, 2014 (unaudited)</b>                 |   | <b>207,956</b>                                  | <b>\$ 1.48</b>                                   | <b>6.24</b>   | <b>\$ 633</b>                                   |
| <b>Vested and expected to vest at September 30, 2014 (unaudited)</b> |   | <b>501,931</b>                                  | <b>\$ 1.59</b>                                   | <b>7.02</b>   | <b>\$ 1,468</b>                                 |

The aggregate intrinsic values of options outstanding and exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock of \$4.52 per common share as determined by the Board of Directors with input from management as of September 30, 2014. The estimated fair value of the common stock underlying the stock options was determined at each grant date by the board of directors and was supported by periodic independent third-party valuations.

The following summarizes the composition of stock options outstanding and exercisable as of September 30, 2014:

| Exercise Price | Options Outstanding and Exercisable |  |
|----------------|-------------------------------------|--|
|                | Number of Shares                    | Weighted-Average Remaining Contractual Life (in years) |
|                | (unaudited)                         |  |
| \$1.28         |                                     |  |
| \$1.40         | 129,538                             | 8.25   |
| \$1.54         | 76,649                              | 2.75   |
| \$4.52         | 1,769                               | 9.78   |
| \$1.28 \$4.52  | 207,956                             | 6.24   |

F-44

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

The weighted-average grant-date fair value of options and awards granted during the nine months ended September 30, 2014 and 2013 were \$1.47 per share and \$0.97 per share, respectively. The total fair value of options and awards that vested during the nine months ended September 30, 2014 and 2013 were approximately \$96,000 and \$67,000, respectively.

***Stock-Based Compensation Expense***

Total stock-based compensation expense included in the Company's consolidated statements of operations is as follows:

|   | <b>Nine Months Ended September 30,</b> |              |
|---|--|--------------|
|   | <b>2014</b>                            | <b>2013</b>  |
|   | <b>(unaudited; in thousands)</b>       |              |
| Research and development                      | \$ 58                                  | \$ 16        |
| General and administrative                    | 64                                     | 39           |
| <b>Total stock-based compensation expense</b> | <b>\$ 122</b>                          | <b>\$ 55</b> |

In February 2014, the Company's board of directors, based on recommendation by management, adopted a resolution to extend the stock option exercise period to certain former ZP Group LLC employees whose employment was terminated as a result of the termination of the joint venture with Asahi from 60 days to 120 days post-termination. As a result, a total of 19,354 options were modified. In accordance with the provisions of ASC 718, the Company accounted for the modification as an exchange of the original award for a new award and accordingly, approximately \$3,000 of incremental compensation cost related to these options was recognized during the nine month period ended September 30, 2014.

In June 2014 and pursuant to an employment agreement between the Company and one of its former officers, the vesting of an additional 7,075 shares of stock options was accelerated upon the termination of the officer's employment. As a result, the Company recognized \$7,000 as compensation expense for the nine month period ended September 30, 2014.

The total unrecognized stock-based compensation expense related to stock-based compensation arrangements as of September 30, 2014 was approximately \$0.4 million, and is expected to be recognized over a weighted-average period of approximately 2.74 years.

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

|                         | <b>Nine Months Ended September 30,</b> |             |
|-------------------------|--|-------------|
|                         | <b>2014</b>                            | <b>2013</b> |
| Dividend yield          | 0%                                     | 0%          |
| Risk-free interest rate | 2.02%                                  | 1.74%       |

Edgar Filing: Zosano Pharma Corp - Form 424B4

|                       |        |        |
|-----------------------|--------|--------|
| Expected volatility   | 89.00% | 89.00% |
| Expected term (years) | 6.08   | 6.08   |

Stock-based compensation expense related to stock options granted to nonemployees is measured and recognized as earned. The fair value of these options is measured using the Black-Scholes option pricing model reflecting an expected life that is assumed to be the remaining contractual life of the option. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned. No options were granted to nonemployees in the nine months ended September 30, 2014, and 2,500 options were granted to a nonemployee in the nine months ended September 30, 2013. For the nine months ended September 30, 2014 and 2013, the Company recorded stock-based compensation expense related to stock options granted to non-employees of approximately \$12,000 and an immaterial amount, respectively.

F-45

---

**Table of Contents****Index to Financial Statements****11. Subsequent Events*****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. The Company also entered into a stock purchase agreement with Lilly pursuant to which Lilly will purchase up to \$15 million worth of the Company's common stock in a private placement concurrent 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.

***Bridge Financing Related Parties Convertible Notes***

In December 2014, the Company entered into a note purchase agreement with certain of the purchasers of the February 2014 convertible bridge notes pursuant to which the Company issued convertible bridge notes, raising an aggregate amount of approximately \$1.3 million in debt financing. These convertible bridge notes bear 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. Upon the closing of a qualified financing, which is defined in the convertible bridge notes as an equity financing on or before March 31, 2015 in which the Company raises at least \$25 million (which, for purposes of this definition as it relates to the Company's planned initial public offering of its common stock, will include the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest shall automatically convert into the equity security sold in the qualified financing, at price equal to 85% of the lowest per share price at which the equity security is sold in the qualified financing.

Table of Contents

Index to Financial Statements

**4,500,000 Shares**

**Common Stock**

**PROSPECTUS**

*Joint Book-Running Managers*

**Ladenburg Thalmann**

**January 26, 2015**

**Roth Capital Partners**

Until February 20, 2015, 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.