Zosano Pharma Corp
Form S-1/A
January 26, 2015
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As filed with the Securities and Exchange Commission on January 26, 2015.

Registration No. 333-196983

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 8

to

FORM S-1

REGISTRATION STATEMENT

under

THE SECURITIES ACT OF 1933

ZOSANO PHARMA CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware	2834	45-4488360
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code No.)	(I.R.S. Employer Identification No.)

34790 Ardentech Court

Fremont, California 94555

(510) 745-1200

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Vikram Lamba

President and Chief Executive Officer

34790 Ardentech Court

Fremont, California 94555

(510) 745-1200

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the Securities Act) please check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)(2)	Amount of Registration Fee(3)
Common Stock, par value $0.0001 per share	$59,340,000	$6,896

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the additional shares that the underwriters have the option to purchase from the registrant solely to cover over-allotments, if any.
(3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 26, 2015

PROSPECTUS

4,300,000 Shares

Common Stock

This is the initial public offering of the common stock of Zosano Pharma Corporation. No public market currently exists for our common stock. Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol ZSAN. We expect that the initial public offering price will be between $10.00 and $12.00 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 13 of this prospectus.

	Per Share	*Total*
Initial public offering price	$	$
Underwriting discounts and commissions(1)(2)	$	$
Proceeds to us (before expenses)	$	$

(1) We refer you to Underwriting beginning on page 158 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 645,000 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 up to $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. Eli Lilly and Company may elect to not purchase any shares that would cause Eli Lilly and Company to own in excess of 18% of our outstanding common stock after this offering and the concurrent private placement (which could result in Eli Lilly and Company investing less than $15 million). 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 indicated an interest in purchasing an aggregate amount of up to $5 million worth of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these potential investors, or any of these potential investors may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these potential investors as they will on any 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 , 2015.

Joint Book-Running Managers

Ladenburg Thalmann **Roth Capital Partners**

Prospectus dated , 2015.

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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.

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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 13 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

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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 up to $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

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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.

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Our microneedle patch system consists of a 3 to 6 cm^2 array of titanium microneedles approximately 200-350 microns long, coated with a hydrophilic formulation of the relevant drug, and attached to an adhesive patch. The 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:

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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 13 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

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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 up to $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. Lilly may elect to not purchase any shares that would cause Lilly to own in excess of 18% of our outstanding common stock after this offering and the concurrent private placement (which could result in Lilly investing less than $15 million). 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

We were incorporated under the laws of the State of Delaware as ZP Holdings, Inc. in January 2012, and changed our name to Zosano Pharma Corporation in June 2014. Our business was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006. We were originally incorporated under the name The Macroflux Corporation, and changed our name to Zosano Pharma, Inc. in 2007 following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of ZP Holdings was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of ZP Holdings. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc. Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. Our telephone number is (510) 745-1200. Our website address is www.zosanopharma.com. The information contained on our website is 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.

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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.

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The Offering

Common stock offered by us	4,300,000 shares
Common stock to be sold in the concurrent private placement to Eli Lilly and Company	1,363,636 shares (assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, resulting in Lilly purchasing a total of $15 million worth of our common stock and owning less than 18% of our outstanding common stock after this offering and the concurrent private placement). Lilly may elect to not purchase any shares that would cause Lilly to own in excess of 18% of our outstanding common stock after this offering and the concurrent private placement (which could result in Lilly investing less than $15 million).
Common stock to be outstanding after this offering and the concurrent private placement	11,616,112 shares (12,261,112 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 $42.3 million, or approximately $48.9 million if the underwriters exercise in full their over-allotment option, based on the initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated 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, assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, 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 48 for additional information.

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Risk factors	You should read the Risk Factors section beginning on page 13 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 indicated an interest in purchasing an aggregate amount of up to $5 million worth of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these potential investors, or any of these potential investors may determine to purchase more, less or no shares in this offering. Any shares purchased by these potential 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, assuming an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. By their terms, if the closing of this offering occurs on or before March 31, 2015 and we raise gross proceeds of at least $25 million (including the gross proceeds of the concurrent private placement with Lilly), the principal and all unpaid and accrued interest on each note will automatically convert into our common stock at a conversion price equal to 85% of our initial public offering price.

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 (assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus);

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.

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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.

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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 assumed 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 $42.3 million from this offering, based on the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated 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.

	Nine Months Ended September 30,		Year Ended December 31,	
	2014	2013	2013	2012
	(unaudited)			
	(in thousands except per share data)			
Statements of Operations Data:				
Revenue:				
License fees revenue	$ 1,819	$ 3,688	$ 4,250	$ 9,250
Collaborative development support services	662			2,374
Total revenue	2,481	3,688	4,250	11,624
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

Total operating expenses	11,538	7,452	12,219	8,476
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) [1]	$ (1.68)		$ (1.06)	
Weighted-average pro forma shares used in computing pro forma net loss per common share basic and diluted (unaudited)[1]	5,696		5,211	

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	As of September 30, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted[2]
	(unaudited; in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 2,303	2,303	59,117
Working capital (deficit)	$ (7,853)	(1,944)	56,313
Total assets	$ 15,165	15,165	70,536
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)	53,501

(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 assumed 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 proposed 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.

(2) A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) by approximately $4.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, and the number of shares we issue and sell to Lilly in the concurrent private placement remain the same, after deducting estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) by $10.2 million, assuming the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us.

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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.

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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 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

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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.

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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.

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

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including Daily ZP-PTH, ZP-Glucagon, ZP-Triptan or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we expect that we will have to submit to the FDA 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.

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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

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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.

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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

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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 Teribone™ 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

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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.

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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.

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

If approved for marketing, the commercial success of 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

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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.

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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.

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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

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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.

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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

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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,

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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.

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

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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

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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

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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

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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

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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 reign 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.

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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.

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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.

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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.

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

We expect the initial public offering price of our common stock to be 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 an assumed initial public offering price of $11.00 per share, which is the midpoint of the price range on the cover of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, you will experience immediate dilution of $6.32 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 assumed 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 4,300,000 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 64.5% of our outstanding common stock, assuming that certain of our existing investors purchase all $5 million of the shares they have indicated an interest in purchasing in this offering, assuming

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 11.7% of our common stock. Additionally, funds controlled by one investor, New Enterprise Associates, or NEA, will beneficially own approximately 20.2% of our common stock, and funds controlled by a

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second investor, BMR, will beneficially own approximately 22.9% of our common stock. As a result, NEA and BMR, acting together, with or 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

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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.

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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.

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.

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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.

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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 tha 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.

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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.

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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 $42.3 million, or approximately $48.9 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated 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, assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, after payment by us of the private placement fee due to the representatives of the underwriters.

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) the net proceeds from this offering by approximately $4.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, and the number of shares we sell to Lilly in the concurrent private placement remain the same, after deducting estimated underwriting discounts, commissions and the private placement fee.

Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us by $10.2 million, assuming the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts, commissions and the private placement fee.

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

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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.

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

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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 assumed initial public offering price, upon the closing of this offering, 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 4,300,000 shares of our common stock offered in this offering, assuming an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated 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 (assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share), 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.

The pro forma information below is illustrative only and our capitalization following the closing of this offering and the concurrent private placement will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. 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.

	As of September 30, 2014		
	Actual	Pro Forma	Pro Forma as Adjusted
	(in thousands, except par value)		
Cash and cash equivalents	$ 2,303	2,303	59,117
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	1	1	2

adjusted; 5,140 shares, 5,772 shares, and 11,435 shares issued and outstanding, actual, pro forma, and pro forma as adjusted, respectively.			
Additional paid-in capital	124,964	130,873	187,686
Accumulated deficit	(134,187)	(134,187)	(134,187)
Total stockholders equity (deficit)	(9,222)	(3,313)	53,501
Total capitalization	$ 11,155	11,155	67,969

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents and total stockholders (deficit) equity by approximately $4.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, and the net proceeds of the concurrent private placement remain the same, after deducting

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estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us, and giving effect to the terms of the notes which provide that the principal and all unpaid and accrued interest on each note automatically converts into our common stock at a conversion price equal to 85% of our initial public offering price if the closing of this offering occurs on or before March 31, 2015. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents and total stockholders equity (deficit) and total capitalization by $10.2 million, assuming the assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and the net proceeds of the concurrent private placement remain the same, after deducting estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us.

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.

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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 assumed initial public offering price set forth in the next paragraph and a conversion price for the principal and all unpaid and accrued interest on each convertible promissory note equal to 85% of such assumed initial public offering price.

After giving effect to the sale of 4,300,000 shares of common stock in this offering at an assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated 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 $53.5 million, or $4.68 per share. This represents an immediate increase in adjusted net tangible book value to existing stockholders of $3.12 per share and an immediate dilution of $6.32 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:

Assumed 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	$ 3.12	
Pro forma as adjusted net tangible book value per share after this offering		$ 4.68
Pro forma as adjusted dilution per share to investors participating in this offering		$ 6.32

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value (deficit) will increase to $4.98 per share, representing an immediate increase in adjusted net tangible book value

(deficit) to existing stockholders of $3.42 per share and an immediate dilution of $6.02 per share to new investors.

Each $1.00 increase in the assumed initial public offering price of $11.00 per share would increase the pro forma as adjusted net tangible book value (deficit) by $4.0 million, the pro forma as adjusted net tangible book value (deficit) per share by $0.42 per share (giving effect to the changes in the number of shares of common stock issuable in the concurrent private placement and the conversion price at which our convertible promissory notes would convert to common stock) and the dilution in pro forma net tangible book value (deficit) per share to investors in this offering by $0.58 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts, commissions

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and the private placement fee and estimated offering expenses payable by us. Each $1.00 decrease in the assumed initial public offering price of $11.00 per share would decrease the pro forma as adjusted net tangible book value (deficit) by $4.0 million, the pro forma as adjusted net tangible book value (deficit) per share by $0.43 per share (giving effect to the changes in the number of shares of common stock issuable in the concurrent private placement and the conversion price at which our convertible promissory notes would convert to common stock) and the dilution in pro forma net tangible book value (deficit) per share to investors in this offering by $0.57 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us.

A one million share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value (deficit) by $10.2 million, increase the pro forma as adjusted net tangible book value (deficit) per share by approximately $0.45 and decrease the dilution per share to investors participating in this offering by approximately $0.45, assuming the assumed initial public offering price of $11.00 per share remains the same, after deducting the estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us. A one million share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value (deficit) by $10.2 million, decrease the pro forma as adjusted net tangible book value (deficit) per share by approximately $0.53 and increase the dilution per share to investors participating in this offering by approximately $0.53, assuming the assumed initial public offering price of $11.00 per share remains the same, after deducting the estimated underwriting discounts, commissions and the private placement fee and estimated offering expenses payable by us.

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, assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, 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, assuming an 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;

- 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.

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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 assumed initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before the deduction of the estimated 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	62.4%	$ 145,349,000	75.4%	$ 20.37
New investors	4,300,000	37.6	47,300,000	24.6	$ 11.00
Total	11,435,213	100.0%	$ 192,649,000	100.0%	

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) total consideration paid by new investors by $4.3 million and increase (decrease) the percent of total consideration paid by new investors by 1.6%, assuming the number of shares we are offering, as set forth on the cover page of this prospectus, remains the same, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering.

If the underwriters overallotment option is exercised in full, the number of shares held by new investors will increase to 4,945,000, or 41.0% 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 59.0% 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, assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, 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, assuming an 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;

- 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 indicated an interest in purchasing an aggregate amount of up to $5 million worth of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these potential investors, or any of these potential investors may determine to purchase more, less or no shares in this offering. The foregoing discussion and tables do not reflect any potential purchases by these potential investors in the number of shares purchased by existing stockholders.

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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.

	Nine Months Ended September 30,		Year ended December 31,	
	2014	2013	2013	2012
	(unaudited)			
	(in thousands, except per share amounts)			
Statements of Operations Data:				
License fees revenue	$ 1,819	$ 3,688	$ 4,250	$ 9,250
Collaborative development support services	662			2,374
Total revenue	2,481	3,688	4,250	11,624
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
Total operating expenses	11,538	7,452	12,219	8,476
Income (loss) from operations	(9,057)	(3,764)	(7,969)	3,148
Other income (expense):				
Interest expense, net	(1,261)	(526)	(760)	(663)
Other expense	(143)	(20)		
Warrant revaluation income				71
Income (loss) before equity in 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 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[1]	$ (1.68)		$ (1.06)	
Weighted-average shares used in computing pro forma net loss per common share basic and diluted[1]	5,696		5,211	

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	As of September 30, 2014 (unaudited)	As of December 31, 2013	2012
		(in thousands)	
Balance Sheet Data:			
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.

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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

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

In 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

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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,

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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 56 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

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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.

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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 up to $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. Lilly may elect to not purchase any shares that would cause Lilly to own in excess of 18% of our outstanding common stock after this offering and the concurrent private placement (which could result in Lilly investing less than $15 million).

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.

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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;

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fees paid to conduct nonclinical studies, drug formulation, and cost of consumables for 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 Ended September 30,		Year Ended December 31,		From Inception in October 2006 to
	2014	2013	2013	2012	September 30, 2014
			(in thousands)		
Product candidate:					
ZP-PTH [1]	$ 528	$ 756	$ 1,757	$	$ 38,663
ZP-Glucagon [2]	959	1,667	2,886	139	3,985
ZP-Triptan [3]	865	33	142		1,007
Collaborative development support [4]	392			1,882	2,274
Other research projects [5]	1,245	926	972	1,881	9,286
Unallocated research and development expenses [6]	4,241	1,379	1,879	1,497	63,087
Total research and development expenses	$ 8,230	$ 4,761	$ 7,636	$ 5,399	$ 118,302

(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

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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.

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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

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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.

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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:

	Nine Months Ended September 30,		Year Ended December 31,	
For valuation of employees and joint venture employees grants:	**2014**	**2013**	**2013**	**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,

For valuation of non-employee grants:	Nine Months Ended September 30, 2014	2013	2013	2012
Assumptions:				
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%

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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.

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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 Per Common Share at Grant Date (in $)	Grant Date Fair Value Per Award Share (in $)	Total Stock-Based Compensation Expense ($ in thousands)
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[1]	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**				

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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 Underlying Grants	Exercise Price of Shares (in $)	Fair Value Per Common Share at Grant Date (in $)	Grant Date Fair Value Per Award Share (in $)	Total Stock-Based Compensation Expense ($ in thousands)
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

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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

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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.

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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.

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Initial public offering price

In January 2015, in consultation with the underwriters, we estimated that the initial public offering price for the shares of common stock offered by this prospectus would be between $10.00 and $12.00 per share. Among the factors that were considered in making the estimate of our 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 estimated initial public offering price 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 estimated 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 up to $15 million worth of our common stock in a separate private placement concurrent with the closing of this offering.
- The fact that whereas the estimated 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 estimated initial public offering

price range 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 estimating 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.

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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

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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

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

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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

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

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

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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

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

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

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

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

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Comparison of the years ended December 31, 2012 and 2013

Revenue

	Year Ended December 31,		Change	
	2013	2012	Amount	%
	(in thousands)			
Revenue:				
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

	Year Ended December 31,		Change	
	2013	2012	Amount	%
	(in thousands)			
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.

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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.

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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 $42.3 million, assuming an initial public offering price of $11.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated 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, assuming that 4,300,000 shares are sold by us in this offering at an initial public offering price of $11.00 per share, after payment by us of the private placement fee due to the representatives of the underwriters. If this offering and the concurrent private placement are successful, we anticipate that these

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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 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:

	Nine Months Ended September 30,		Year Ended December 31,	
	2014	2013	2013	2012
	(unaudited)			
	(in thousands)			
Cash generated from (used in):				
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)
Total cash (used) generated	$ (3,610)	$ (683)	$ 940	$ 1,373

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

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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:

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

(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

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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

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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.

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(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.

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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 £-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.

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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®, 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 up to $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.

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

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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.

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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^2 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^2 patch with a single-use applicator. While we have developed prototypes for both the 6 cm^2 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

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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.

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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

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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^2 array of titanium microneedles approximately 200-350 microns long, coated with a hydrophilic formulation of the relevant drug, and attached to an adhesive patch. The maximum amount of active drug that can be coated on a patch s microneedle array depends on the active molecule of the drug formulation, the weight of the excipients in the drug formulation, and the coatable surface area of the microneedle array. For example, we use patches with 2 cm^2, 3 cm^2 and 6 cm^2 microneedle arrays, and, based on our testing, we believe that the maximum amount of zolmitriptan that can be coated on a patch with a 6 cm^2 microneedle array is approximately 3.5 mg. The patch is applied with a hand-held applicator that 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

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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® 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®.

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.

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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.

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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.

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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 48. 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

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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 up to $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 £-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

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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.

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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.® T_{MAX} is a measure of the time after administration of a drug when it reaches the highest serum concentration. C_{MAX} is a measure of the peak serum concentration achieved after the drug has been administered; and

- comparable efficacy compared to Forteo® as measured by both six-month spine BMD and six-month hip BMD, even with lower bioavailability versus Forteo®.

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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® 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®.

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® 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®).

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®, 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®.

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.

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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® 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.

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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^2 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^2 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 bioavailabilty 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^2 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

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below. The table below the two graphs shows the data points in the first of the two graphs, and the CV, or coefficient of variation, which represents the variability of the specified data points.

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

Note: AUC measured in ng*hr/mL

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;

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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^2 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.

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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 iontophorectic 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:

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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 .

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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^2 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.

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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.

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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.

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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:

Manufacturer	Product	Method of Treatment
Amgen	Romosozumab (1)	Injection (monthly)
Lilly	Forteo®	Injection in thigh or abdomen (daily)
Lilly	Blosozumab (1)	Injection (twice monthly)
Radius	BA058 (1)	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:

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

(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:

Manufacturer	Product	Method of Treatment
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.

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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.

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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.

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

United States Patent Number (Expiration Date)	Europe Patent Number (Expiration Date)	Japan Patent Number (Expiration Date)	China Patent Number (Expiration Date)	Pat (Exp
4/466,461***; US14/52326***;				
,556,821 (18-Mar-2025); ,361,022 (18-Mar-2025); ,633,159 (15-Feb-2027); 008/0039775**; 010/0119568** ;	EP 1 744 683**; EP 2 001 453**;	JP 5007427 (18-Mar-2025); JP 5309203 (18-Mar-2025);		
,537,795 (31-May-2023); ,579,013 (29-Jun-2024); ,963,935 (23-May-2027); ,663,155 (24-Jun-2023); 010/0221305**; 014/0260096**;	EP 1 333 880 (26-Oct-2021); EP 1 392 389 (20-Apr-2022); EP 1 638 523 (29-Jun-2024);	JP 4659336 (26-Oct-2021); JP 5388415 (21-Oct-2024); JP 5456234 (29-Jun-2024);	CN 100548228 (21-Oct-2024); CN 1842320 (29-Jun-2024); CN 100566669 (18-Mar-2025); CN 1239212 (26-Oct-2021); CN 100349632 (20-Apr-2022); CN 100421653 (6-Sep-2021);	KR 10081209
,050,988 (9-Dec-2018); ,083,196 (9-Dec-2018); ,322,808 (9-Dec-2018); ,184,826 (17-Jun-2017);	EP 1 037 686 (9-Dec-2018); EP 1 037 687 (9-Dec-2018);	JP 4012252 (17-Jun-2017); JP 4061022 (9-Dec-2018);	CN 1170603 (9-Dec-2018); CN 1161164 (9-Dec-2018);	
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* Patents are for the benefit of all formulations
** Publication Number (pending)
*** Application Number (pending)

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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

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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 wi