ZOSANO PHARMA CORP

FORM 10-K
(Annual Report)

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Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

or

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

Commission File Number 001-36570

ZOSANO PHARMA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**45-4488360**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

34790 Ardentech Court
Fremont, CA 94555
(Address of principal executive offices) (Zip Code)

(510) 745-1200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common stock, par value $0.0001 per share	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

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

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

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2016 (the last business day of the registrant's most recently completed second quarter) was approximately $7,331,084.

As of February 20, 2017, the registrant had a total of 19,450,274 shares of its common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for its 2017 Annual Meeting of Stockholders, which Definitive Proxy will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2016, are incorporated by reference into Part III of this Form 10-K.

Zosano Pharma Corporation
Annual Report on Form 10-K
For the Fiscal Year ended December 31, 2016

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Cautionary Note Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "intend," "seek," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential," or the negative of those terms, and similar expressions and comparable terminology intended to reference future periods. Forward-looking statements include, but are not limited to, statements about:

- the anticipated timing, costs and conduct of our planned clinical trials and preclinical studies, as applicable, for our candidate M207 (previously known as ZP-Triptan);
- our expectations regarding the clinical effectiveness and safety of our product candidates;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- our manufacturing capabilities and strategy;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- our intellectual property position and our ability to obtain and maintain intellectual property protection for our product candidates;
- our expectations regarding competition;
- the anticipated trends and challenges in our business and the markets in which we operate;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to establish and maintain development partnerships;
- our ability to attract or retain key personnel;
- our expectations regarding federal, state and foreign regulatory requirements; and
- regulatory developments in the United States and foreign countries.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth below in Item 1A, "Risk Factors," and in our other reports filed with the U.S. Securities Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K.

Unless the context otherwise indicates, references in this Annual Report to the terms “Zosano”, the “Company”, “we”, “our” and “us” refer to Zosano Pharma Corporation and its subsidiary.

PART I

Item 1. BUSINESS.

Overview

Zosano Pharma Corporation and its subsidiary (“Company”) is a clinical stage pharmaceutical company that has developed a proprietary intracutaneous delivery system. It can offer rapid absorption of drug, consistent drug delivery, improved ease of use and room-temperature stability, benefits that we believe differentiate our delivery platform from other non-oral formulations or injections. 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 intracutaneous patch consists of an array of titanium microneedles that is coated with our proprietary formulation of a previously approved drug that is attached to an adhesive patch. When the patch is applied with our hand-held applicator, the microneedles penetrate the skin resulting in dissolution and absorption of the drug through the capillary bed. We believe our system enables rapid and consistent delivery of the drug that is easy and convenient to administer. We focus on developing our microneedle patch system for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, for markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, M207. M207 is our proprietary formulation of zolmitriptan coated onto our patented intracutaneous microneedle patch, which is then applied with our proprietary applicator to ensure uniform, and consistent application. Zolmitriptan is, one of a class of serotonin receptor agonists known as triptans, used for the treatment of migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. The objective of M207 is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding the GI tract. In July 2016, we announced the dosing of the first subject in the M207 pivotal efficacy trial, known as ZOTRIP trial. In February 2017, we announced the completion and results of the ZOTRIP trial, in which M207 achieved both co-primary endpoints of pain freedom and most bothersome symptom freedom at 2 hours.

ZOTRIP Trial Primary Endpoint Results for 3.8mg

Primary endpoint	Placebo	3.8mg M207	p-value
Pain freedom	14.3%	41.5%	0.0001
Most bothersome symptom free	42.9%	68.3%	0.0009

We received encouraging data on key secondary endpoints, such as pain freedom at one hour ($p<0.01$), while also demonstrating a mild safety profile, with no Serious Adverse Events (“SAEs”) reported in the trial.

We received feedback from the United States Food and Drug Administration (“FDA”) on M207’s regulatory path prior to initiating the ZOTRIP trial. The agency has indicated that, under Section 505(b)(2) of the Food, Drug and Cosmetic act, one positive pivotal efficacy trial, in addition to the required safety trial, would be sufficient to file a New Drug Application (“NDA”) for M207 as an acute treatment of migraine.

We made the decision in early 2016 to prioritize the clinical development of M207 and to suspend further development of our other product candidates, Daily B104, Weekly B206 and D107 (previously known as Daily

ZP-PTH, Weekly ZP-PTH, and ZP-Glucagon, respectively). While we intend to continue the clinical development of M207 through commercialization in the United States ourselves, we remain open to opportunities with potential strategic partners to ensure our product candidate will receive the best chance of commercial success.

Our Strategy

Our goal is to make intracutaneous drug delivery a preferred delivery modality for indications where fast absorption of drug provides a therapeutic benefit to patients. Our near term focus is the continued development of our lead product candidate, M207, as well as other drugs that treat CNS conditions and disorders. The key elements of our strategy are to:

- ***Develop and commercialize M207 .*** We believe that M207, if approved, will offer significant therapeutic and practical advantages compared to existing migraine therapeutics. In our pivotal trial, M207 proved to be highly efficacious demonstrating rapid absorption of drug, and sustained freedom of migraine symptoms while avoiding the gastrointestinal tract ("GI tract"). Based on published literature of non-injectable methods of delivery, the 3.8mg dose of M207 demonstrated an improved profile in pain freedom at one hour, two hours, 24 hours and 48 hours, and approached that of injections. Our next step in the development of M207 includes initiating the required long-term safety study, which will commence after a meeting with the FDA to review the pivotal trial data and existing development plans. We have retained world-wide commercial rights to M207 and we intend to develop M207 through FDA approval and subsequent commercialization. However, we remain open to opportunities with potential strategic partners to ensure our product candidates will receive the best chance of commercial success.
- ***P ursue indications with high unmet medical need and greater probability of clinical , regulatory and commercial success*** . We focus on indications in which a high therapeutic index, rapid absorption of drug, with sustained effect and ease of product use offer particularly important therapeutic, practical and commercial advantages over existing therapies and drug delivery modalities. We intend to leverage our expertise in CNS to explore other product opportunities that would be complementary to our lead product, M207.
- ***Pursue indications with high unmet medical need and greater probability of clinical regulatory and commercial success*** . We focus on indications in which rapid absorption can enhance efficacy and sustainability of effect. That coupled with ease of use might offer particularly important therapeutic, practical, and commercial advantages over existing therapies and drug delivery modalities. We intend to leverage our expertise in CNS to explore other product opportunities that would be complementary to our lead product, M207.

M207 for Migraine

The focus of our development efforts is on our product candidate M207, our proprietary formulation of zolmitriptan, one of a class of serotonin receptor agonists known as triptans, used for the treatment of migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. Our M207 intracutaneous delivery system is applied to an individual's upper arm to deliver zolmitriptan to the circulation, with the objective of providing rapid absorption of drug and sustained freedom of migraine symptoms while avoiding the GI tract.

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

We believe that each of the currently available methods of non-oral administration, including nasal spray, subcutaneous injection and iontophorectic patch (which is a device that delivers medicine through the skin by a

low electrical current), have significant disadvantages. Nasal sprays have been associated with taste disturbances. Patients are hesitant to self-administer injections and thus primarily seek an injectable triptan at an urgent care setting or at the physicians' office. The iontophoretic patch has been discontinued due to reported cases of serious application site reactions. There are other delivery technologies in development, such as pulmonary delivery. However, none have been approved to date. M207 demonstrated statistical significance in both co-primary endpoints of pain freedom at two hours and most bothersome symptom freedom at 2 hours post dose. There were no SAEs reported in the trial, and application site reactions were generally mild and resolved without sequelae.

ZOTRIP Phase 2/3 Trial achieved statistical significance on co-primary endpoints with the 3.8mg dose

On February 13, 2017 the Company announced the results of our ZOTRIP pivotal efficacy trial for M207. Our ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of M207 (1.0mg, 1.9mg, and 3.8mg) to placebo for the treatment of a single migraine attack. Subjects were enrolled in the ZOTRIP trial at 36 centers across the United States. Those recruited into the trial had a history of at least one year of migraine episodes with or without aura. Upon recruitment, the subjects entered a one-month run-in period that ensured they met the key eligibility criteria of two to eight migraine attacks per month, which was documented using an electronic diary or an app on their cell phone. Subjects also identified the most bothersome symptoms and indicated the presence or absence of nausea, phonophobia or photophobia, during the episodes in the run-in period. Successfully screened subjects were then randomized into the treatment/dosing period in which they had 8 weeks to confirm and receive blinded treatment for a single migraine attack, termed "qualifying migraine," in which the subject's most bothersome symptom had to be present. During a qualifying migraine, subjects scored the severity of pain on a 4-point scale, the presence or absence of migraine-associated symptoms (phonophobia, photophobia, or nausea), starting pre-dose and then at several intervals over 48 hours post-dose. The co-primary endpoints for the trial were those defined in the October 2014 FDA Draft Guidance—"Migraine: Developing Drugs for Acute Treatment" as pain freedom and most bothersome symptom freedom at two hours. Safety was assessed by adverse events reported and other standard safety measures.

Five hundred and eighty nine subjects were enrolled in the ZOTRIP trial, of which 365 were randomized. Of those randomized, 333 subjects were treated and are included in the safety analysis, and 321 qualified for the modified intent-to-treat (mITT) population. With the multiple doses and multiple endpoints in the trial, a sequential testing procedure was used beginning with the highest dose and the co-primary endpoints. Since statistical significance was not achieved for most bothersome symptom in the 1.9 mg group, p-values for secondary endpoints should be considered nominal p-values.

As illustrated in the tables and figure below, the ZOTRIP trial results demonstrated that the 3.8 mg M207 dose achieved statistically significant pain freedom and most bothersome symptom freedom at two hours. The 3.8mg dose also achieved statistical significance in the secondary endpoints of pain freedom at 45 minutes and 60 minutes and showed durability of effect on pain freedom at 24 and 48 hours. Additionally, M207 was not associated with any SAEs. While the 1.0mg and 1.9mg doses of M207 demonstrated statistical significance in pain freedom at two hours, they did not achieve statistical significance in freedom from most bothersome symptom at two hours. Statistical significance is an indicator of the likelihood of an observed effect being due to the study drug rather than due to chance. The "p" value is the probability of an event occurring by chance alone. When the p value is less than 5% (0.05) the results are considered to be statistically significant.

ZOTRIP Trial Primary Endpoint Results

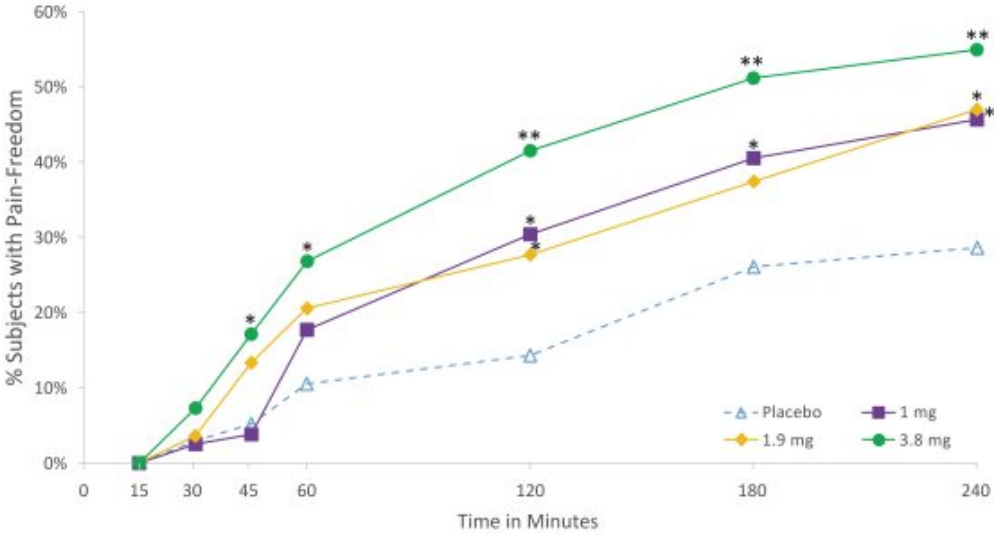
Primary endpoint	Placebo	3.8mg M207	p-value
Pain freedom	14.3%	41.5%	0.0001
Most bothersome symptom free	42.9%	68.3%	0.0009

ZOTRIP Trial Secondary Endpoints Results

Pain Freedom	Placebo	3.8mg M207	p-value
Pain freedom at 45 minutes	5.2%	17.1%	0.0175
Pain freedom at 60 minutes	10.4%	26.8%	0.0084
Pain freedom at 24 hours	39.0%	69.5%	0.0001
Pain freedom at 48 hours	39.0%	64.6%	0.0013

M207 was well-tolerated with no SAEs reported in the ZOTRIP trial. The most frequently reported adverse event was redness at the application site (18.3% of subjects) and all cases of redness resolved. Thirteen subjects (3.9%) reported pain at the application site; with application site pain reported as mild in all but three subjects. Additionally, five (1.5%) subjects across M207-treated groups reported dizziness versus zero subjects in the placebo group, and four (1.2%), subjects across M207-treated groups reported nausea whereas zero subjects in the placebo group reported this event.

The ZOTRIP trial results demonstrating pain freedom after treating with M207 are illustrated below:



* p-value < 0.05; ** p-value < 0.001; CMH test controlling for Baseline Most Bothersome Symptom

We have performed the following sub group analysis:

Pain Freedom at 2 Hours	Placebo	3.8mg M207	p-value
All Subjects	14.3%	41.5%	0.0001
Morning Migraine	15.9%	44.4%	0.0056

Sustained Pain Freedom	Placebo	3.8mg M207	p-value
2 – 24 Hours	10.4%	31.7%	0.001
2 – 48 Hours	9.1%	26.8%	0.0035

Pain Relief	Placebo	3.8mg M207	p-value
1 Hour	53.2%	68.3%	< 0.05
2 Hours	57.1%	80.5%	< 0.05

Sustained Pain Relief	Placebo	3.8mg M207	p-value
2 – 24 Hours	37.7%	68.3%	< 0.0001
2 – 48 Hours	32.5%	63.4%	< 0.0001

Nausea Freedom	Placebo	3.8mg M207	p-value
2 Hours	63.6%	81.7%	< 0.05

Most Frequent Adverse Events (≥ 4% for any treatment group)

	Placebo	ZP-Zolmitriptan 1 mg	ZP-Zolmitriptan 1.9 mg	ZP-Zolmitriptan 3.8 mg
General disorders and administration site conditions				
Application site erythema	10.8%	16.3%	19.5%	26.5%
Application site bruise	3.6%	6.3%	13.8%	14.5%
Application site pain	1.2%	2.5%	2.3%	9.6%
Application site bleeding	0.0%	3.8%	5.7%	4.8%
Dizziness	0.0%	1.3%	0.0%	4.8%

Our Research Programs

Our internal research and development programs use molecules with demonstrated safety and efficacy that are formulated to enable delivery through our intracutaneous delivery system. We intend to pursue product development opportunities that utilize the Section 505(b)(2) regulatory pathway, which may reduce clinical development and regulatory timelines relative to new chemical entity development. In selecting our development candidates, we consider the therapeutic advantage of rapid onset, the size of the market, the level of competition and the potential selling price.

Our microneedle patch system consists of a 3 cm^2 to 6 cm^2 array of titanium microneedles approximately 200-350 microns in length, coated with a hydrophilic formulation of drug, and attached to an adhesive patch. The maximum amount of drug that can be coated on a patch's microneedle array depends on the active molecule of the drug formulation, the weight of the excipients in the drug formulation, and the coatable surface area of the microneedle array. For example, we use patches with 2 cm^2 , 3 cm^2 and 6 cm^2 microneedle arrays. In the pivotal trial for M207 we used two 3 cm^2 patches to deliver the appropriate dose. Based on our testing, we believe 3.8mg of zolmitriptan could also be coated on a single patch with a 6 cm^2 microneedle array while maintaining acceptable tolerability. The patch is applied with a hand-held applicator that presses the microneedles into the skin to a uniform depth in each application, close to the capillary bed, allowing for dissolution and absorption of the drug, but not deep enough to contact the nerve endings in the skin. The typical patch wear time is generally thirty to sixty minutes.

We have tested our microneedle patch system in preclinical and clinical proof of concept studies that demonstrated its technical feasibility with multiple compounds, ranging from small molecules to proteins. Based on this research, we believe that our microneedle patch system can be used to deliver treatments for a wide variety of indications in which rapid absorption can enhance onset of efficacy and sustainability of effect.

That coupled with ease of use might offer particularly important therapeutic, practical, and commercial advantages over existing options.

Competition

Competition for our product candidates

The development and commercialization of new products to treat migraine is highly competitive. We expect to have considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have substantially greater financial, technical and other resources than we do. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization.

Companies marketing products that treat migraine that may compete with our M207 product candidate include Teva Pharmaceutical Industries, Inc., Zogenix, Inc., GlaxoSmithKline plc, Eli Lilly & Company, AstraZeneca plc and Allergan, Inc.

Competition in drug delivery platforms

In addition to competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies that develop and market products that compete against those that we develop, we face additional competition from companies that may develop and license drug delivery platforms similar to ours, and from alternative formulations and methods of delivery of the drugs on which we have focused, including oral formulations, nasal sprays, intracutaneous patches, intramuscular and subcutaneous injection and infusion. Such companies include, but are not limited to, 3M Company, Endo Pharmaceuticals, Corium International, Inc. and Pantec Biosolutions AG.

Research and Development

As of December 31, 2016 , our research and development group consisted of 26 employees, located in our headquarters in Fremont, California. Our research and development staff have broad knowledge and skills in a range of disciplines applicable to formulation of drugs and the design and manufacture of our microneedle patch system. Our research and development group has particular expertise in two areas critical to our success: developing drug formulations that can be delivered using our intracutaneous delivery and optimizing the system to deliver those drugs.

The goals of our research and development efforts are to identify and develop drugs that can be delivered using our intracutaneous delivery system. In the years ended December 31, 2016 and 2015, we incurred $20.5 million and $20.4 million, respectively, of research and development expense. See Part II–Item 7–“Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report for additional detail regarding our research and development activities.

Manufacturing

We operate a current good manufacturing practices (“cGMP”) compliant manufacturing facility in Fremont, California, and believe we have adequate manufacturing capabilities and capacity to produce our intracutaneous delivery system for preclinical and Phase 1 and Phase 2 clinical trials of all of our product candidates, and pivotal Phase 3 trials of most of our product candidates. In order to expand our manufacturing capabilities for large scale production, we are exploring both internal and outsourced manufacturing and supply alternatives. We purchase various components or intermediates of our intracutaneous delivery system from third-party vendors, including the titanium foil and formed micro-arrays, active pharmaceutical ingredients and excipients, inner ring, adhesive backing, ring and backing assembly, outer ring and primary and secondary packing components. The majority of these components and intermediaries are available from multiple sources. We also outsource the manufacturing of our applicators.

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

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, and includes a co-molded polymer desiccant which is proprietary to one of our suppliers. We then insert the patch assembly into the primary packaging, which is purged with nitrogen for longer shelf life. Product testing is performed using both in-house and contract labs.

We intend to explore alliances with contract manufacturing organizations ("CMOs") to expand our manufacturing capacity as we believe this will be critical to support the late-stage development, launch and commercial production of our product candidates, including M207.

Intellectual Property

Our strategy is to rely on a combination of patent, trade secret and trademark laws in the United States and other jurisdictions, and to rely on license and confidentiality agreements to protect our proprietary technology and brand. The laws of some countries in which our products are licensed may not protect our intellectual property rights to the same extent as the laws of the United States.

As of December 31, 2016, we held exclusive licenses to or owned 27 United States patents and four United States patent applications, as well as numerous foreign counterpart patents and patent applications (including one Patent Cooperation Treaty patent applications), covering key features of our intracutaneous delivery system, such as formulation, methods of treatment, coating, array design, patch anchoring, patch application, delivery, manufacturing and packaging.

We license all of these patents and patent applications, other than an issued US patent and pending US and international applications for D107 and M207 formulation and a new applicator design described below, from ALZA Corporation, or ALZA, on an exclusive basis for all countries. These patents and patent applications are foundational and apply generally to each of our product candidates and their related applicators. Under the terms of the license agreement with ALZA, we are responsible for all development and development costs related to our intracutaneous delivery system. We are also responsible for commercializing our intracutaenous delivery system, including preparing and paying for all related regulatory filings. We are obligated to pay ALZA royalties in the low to mid-single digits on sales by us of products that would otherwise infringe one of the licensed patents or that is developed by us based on certain ALZA know-how or inventions, and to pay ALZA amounts equal to the greater of royalties in the low to mid- single digits on sales by our sublicensees of such products or a percentage in the mid-tens to low twenties of royalties received by us on sales by our sublicensees of such products. We are also obligated to pay ALZA a percentage of non-royalty revenue that we receive from our sublicensees based on sales of such products. The license agreement will terminate upon the expiration of our obligations to make the royalty and other payments described above to ALZA. Additionally, we may terminate the agreement at any time for convenience upon prior written notice to ALZA, and either party may terminate the agreement upon a material breach of the agreement by the other party.

We have filed three pending United States patent applications, two pending European applications, a pending Patent Cooperation Treaty application covering our single-use applicator and formulations of D107 and zolmitriptan. The D107 patent was issued in November 2015 with an expiration date of 2034.

The last of our issued technology platform patents will expire in 2027. We believe that the long life of our patent portfolio may make collaborating with us particularly attractive for third parties seeking to extend the lifecycle of profitable drugs nearing the expiration of their patent protection.

We rely on trade secrets to protect substantial portions of our technology. We generally seek to protect these trade secrets by entering into non-disclosure agreements and other contractual provisions with our employees, consultants and customers, and have restricted access to our manufacturing facilities and other technology.

We have one registered trademark to Zosano, "ZOSANO PHARMA," Reg. No. 3705884.

Government Regulation and Product Approval

United States—FDA Process

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications ("NDAs") warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. We expect each of our product candidates will be subject to review by the FDA as a drug/device combination product under NDA standards. Medical products containing a combination of new drugs, biological products or medical devices are regulated as "combination products" in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. We have discussed our development strategy with the FDA on our M207 program.

Drug Approval Process

None of our product candidates may be marketed in the United States until the product has received FDA approval. The steps to be completed before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an investigational new drug application ("IND") for human clinical testing, which must become effective before human clinical trials in the U.S. may begin and must be updated annually;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication to the FDA's satisfaction;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials in the U.S. may begin. An IND will automatically become effective thirty days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We submitted an IND to the FDA in connection with our Phase 2 trial of Daily B104 in

2008, but we have not submitted an IND to the FDA for D107. We submitted an IND on M207 in the second fiscal quarter of 2016 in connection with our completed Phase 2/3 efficacy trial.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials necessary for product approval are typically conducted in three sequential phases, but the phases may overlap. The trial protocol and informed consent information for trial subjects in clinical trials must also be approved by an Institutional Review Board ("IRB") for each institution where the trials will be conducted, and each IRB must monitor the trial until completion. Trial subjects must sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy extensive good clinical practice ("GCP") regulations and regulations for informed consent and privacy of individually identifiable information.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA reviews any NDA submitted to ensure that it is sufficiently complete for substantive review before the FDA accepts the NDA for filing. The FDA may request additional information rather than accept the NDA for filing. Even if the NDA is filed, companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of an NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized. Further, the FDA may place conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy (REMS) to assure the safe use of the drug. If the FDA requires a REMS, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless the manufacturing is in compliance with cGMP regulations. If the NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose

other conditions. Approval may also be contingent on an approved REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical trials be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements

Oftentimes, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical trials. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities. This latter effort includes assessment of ongoing compliance with cGMP regulations. We have used and intend to continue to use third- party manufacturers to produce active pharmaceutical ingredients, ("API"), for our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, including withdrawal of the product from the market.

Hatch-Waxman Act

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, Section 505(b)(2) of the FDCA was enacted, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Amendments permit the applicant to rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, which is referred to as the Reference Listed Drug, the applicant is required to certify to the FDA concerning any listed patents in the FDA's Orange Book publication that relate to the Reference Listed Drug. Specifically, the applicant must certify for all listed patents one of the following certifications: (i) the required patent information has not been filed by the original applicant; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the 505(b)(2) application. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Referenced Listed Drug has expired.

A certification that the new product will not infringe the Reference Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the Reference Listed Drug once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA by imposing a 30-month automatic statutory injunction, which may be shortened by the court in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30 month stay terminates if a court issues a final order determining that the patent is invalid, unenforceable or not infringed. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

The Hatch-Waxman Act provides five years of data exclusivity for new chemical entities which prevents the FDA from accepting Abbreviated New Drug Applications and 505(b)(2) applications containing the protected active ingredient. The Hatch-Waxman Act also provides three years of exclusivity for applications containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new uses of approved products such as new indications, delivery mechanisms, dosage forms, strengths, or conditions of use.

Pricing and Reimbursement

Sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of reimbursement from third-party payers such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and also the out-of-pocket obligations of member patients for such products. In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. We have consciously selected compounds for development that offer therapeutic benefit based on fast onset of action. If our products are approved by the FDA, we intend to work with payers to demonstrate the clinical benefits of our products over other delivery modalities to secure adequate and commercially favorable pricing and reimbursement levels.

Other Governmental Regulations, Healthcare Laws and Environmental Matters

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

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA has indicated that our product candidate M207 is covered by the PREA, but the FDA may, on its own initiative or at the request of an applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Although we currently do not have any products on the market, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations, many of which may become more applicable to us if our product candidates are approved and we begin commercialization. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

If we establish international operations, we will be subject to compliance with the Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA for activities by our partners, collaborators, contract research organizations, vendors or other agents.

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

Employees

As of December 31, 2016, we had 38 employees, all of whom are full time and 5 of whom held doctorate degrees in their respective scientific and pharmaceutical fields. We make extensive use of third party contractors, consultants and advisors to perform many of our present activities.

Corporate Information

We were incorporated under the laws of the State of Delaware as ZP Holdings, Inc. in January 2012, and changed our name to Zosano Pharma Corporation in June 2014. Our business was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006. We were originally incorporated under the name The Macroflux Corporation, and changed our name to Zosano Pharma, Inc. in 2007 following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of ZP Holdings was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of ZP Holdings. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc. ZP Group LLC, a former subsidiary that was originally formed as a joint venture with Asahi Kasei Pharmaceuticals USA (Asahi) ceased operations in December 2013 and was later dissolved in December 2016.

Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. Our telephone number is (510) 745-1200. Our website address is www.zosanopharma.com. The information contained on our website is neither incorporated by reference into nor a part of this Annual Report on Form 10-K.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, as well as general economic and business risks, and all of the other information contained in this Annual Report on Form 10-K and other documents that we file with the U.S. Securities and Exchange Commission, or the SEC. Any of the following risks could have a material adverse effect on our business, operating results, financial condition and prospects and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. You should also refer to the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and the related notes thereto.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have a history of operating losses. We expect to continue to incur losses over the next several years and may never become profitable.

Since inception, we have incurred significant operating losses. For the year ended December 31, 2016 we incurred a net loss of $29.8 million. As of December 31, 2016, we had an accumulated deficit of $196.8 million. We expect to continue to incur additional significant operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue the development of our product candidate, M207. These expenditures will be incurred for development, clinical trials, regulatory compliance, infrastructure, and manufacturing. Even if we succeed in developing, obtaining regulatory approval for and commercializing M207 or one of our other product candidates, because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict that we will ever be able to manufacture, distribute and sell any of our products profitably, and we may never generate revenue that is significant enough to achieve or maintain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

Since inception, we have generated no revenues from product sales. We are not approved to make and have not made any commercial sales of products. We expect that our product development activities will require additional significant operating and capital expenditures resulting in negative cash flow for the foreseeable future.

We expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. 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, like in our August 2016 private placement in which we sold 4.8 million shares of our common stock and warrants to purchase up to 9.6 million shares of our common stock for an aggregate purchase price of $7.5 million, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends on our common stock.

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

If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our development or future commercialization efforts or partner with third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

In June 2014, we entered into a loan and security agreement with Hercules Capital, Inc. which provided us $4.0 million in debt financing. In June 2015, we entered into a first amendment to the loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million ("Hercules Term Loan"). The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance would be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. As of July 1, 2016, we are required to make month installment payments on the principal and interest of the Hercules Term Loan and, if we cannot meet the principal payment requirements under the first amendment to the loan and security agreement, we could be in default. In addition, we will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date we prepay the Hercules Term Loan and a $351,135 end of term charge on the earlier of loan maturity or at the date we prepay the Hercules Term Loan. We may prepay all, but not less than all, of the Hercules Term Loan subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties.

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

- incur indebtedness;
- create liens on our property;
- make payments on any subordinated debt, while the Hercules loan remains outstanding;
- make investments in or loans to others;
- acquire assets other than in the ordinary course;
- dispose of the collateral that secures the Hercules loan;
- transfer or sell any assets;
- engage in any transaction that would constitute a change of control; and
- change our corporate name, legal form or jurisdiction.

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

We have pledged substantially all of our assets, including our intellectual property, to secure our obligations to Hercules under the loan facility under the promissory note. If we default on our obligations prior

to repaying this indebtedness, and are unable to obtain a waiver for such default, Hercules would have a right to accelerate our payments under the loan facility or the note, as applicable, and possibly foreclose on the collateral, which would potentially include our intellectual property. Any such action on the part of Hercules would significantly harm our business and our ability to operate.

We have limited operating history and capabilities.

Although our business was formed in 2006, we have had limited operations since that time. We do not currently have the ability to perform the sales, marketing and manufacturing functions necessary for the production and sale of M207 or our other product candidates on a commercial scale. The successful commercialization of any of our product candidates will require us to perform a variety of functions, including:

- continuing to conduct clinical development of our product candidates;
- obtaining required regulatory approvals;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations continue to be focused on acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to transition at some point from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

The audit report contained in our Annual Report on Form 10-K for the year ended December 31, 2016 contains an explanatory paragraph to the effect that there is doubt about our ability to continue as a going concern.

As of December 31, 2016, we had an accumulated deficit of $196.8 million as well as negative cash flows from operating activities. We will continue to require substantial funds to continue research and development, including clinical trials of our lead product candidate, M207. As noted above, we expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. There is no assurance that such additional funds will be obtained for our ongoing operations and that the Company will succeed in it future operations. Substantial doubt exists about the Company's ability to continue as a going concern. Our audited consolidated financial statements include a "going concern" disclosure that may discourage some third parties from contracting with us and some investors from purchasing our stock or providing alternative capital financing, which could adversely affect our business, financial condition, results of operations and prospects.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

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

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

development of M207. Also, even though we have discussed our development strategy with the FDA on our M207 program and received feedback from the FDA about the size and the length of the safety study, the FDA may decide to expand on the requirements that have already been provided to us, which would further delay the regulatory approval process.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we have decided to focus on developing our product candidate M207 for treatment of migraine. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

We have focused our clinical development efforts on our product candidate, M207. The development and commercialization of our product candidate 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 product candidates, require the establishment of a risk evaluation and mitigation strategy, or REMS, or cause an approved product candidate to be taken off the market;
- the FDA may identify deficiencies in our manufacturing processes or facilities or those of our third- party manufacturers;
- the FDA may change its approval policies or adopt new regulations;
- we may need to depend on third-party manufacturers to supply or manufacture our products;
- we depend on contract research organizations to conduct our clinical trials;
- we may experience delays in the commencement of, enrollment of patients in and timing of our clinical trials;

- we may not be able to demonstrate that any of our product candidates are safe and effective as a treatment for their respective indications to the satisfaction of the United States Food and Drug Administration, or FDA, or other similar regulatory bodies;
- we may be unable to establish or maintain collaborations, licensing or other arrangements;
- the market may not accept our product candidates;
- we may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- we may experience competition from existing products or new products that may emerge; and
- we and our licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our products.

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

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this Annual Report on Form 10-K. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act ("FDCA"). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidates, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market each of our product candidates. The time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. The conduct of later-stage clinical trials and the submission of a successful NDA is a complicated process. To date, we have conducted only one Phase 2/3 clinical trial, we have limited experience in preparing and submitting regulatory filings, and we 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 M207 product candidate. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission of other product candidate we are developing.

Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite approvals for commercialization of such product candidate.

In addition, our competitors may file petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

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

Human clinical trials are very expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Furthermore, failure of a product candidate can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- changes in government regulation, administrative action or changes in FDA policy with respect to clinical trials that change the requirements for approval;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these clinical trials or tests are not positive or are only modestly positive and/or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have our product candidate(s) removed from the market after obtaining marketing approval.

Our development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring product candidates to market before we do, and thereby impair our ability to successfully commercialize our product candidates.

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

Even if our clinical trials are completed as planned, we cannot be certain that the results will support the intended use of our products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our

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

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

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical testing, early clinical trials and even later state clinical trials, like our phase 2/3 ZOTRIP trial, does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While members of our management team have experience in designing clinical trials, we have limited experience in designing clinical trials and we may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

We may in the future conduct clinical trials for product candidates in sites around the world, and government regulators, including the FDA in the United States, may choose to not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States.

There is no guarantee that data from these clinical trials will be accepted by regulators approving our product candidates for commercial sale. In the case of the United States, although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the United States population, and the data must be applicable to the United States population and United States medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials, it would likely result in the need for additional clinical trials, which would be both costly and time-consuming and likely to delay or permanently halt our development of a product candidate. Similar regulations and risks apply to other jurisdictions as well.

In addition, the conduct of clinical trials outside the United States could have a significant negative impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;

- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

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

We cannot assure you that we will receive the approvals necessary to commercialize M207, our other product candidates or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States. In order to obtain FDA approval of any product candidate, we expect that we will have to submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended indication and indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our product candidates will ultimately be considered safe for humans and effective for indicated uses by the FDA. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our products;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

We may never obtain regulatory approval for any of our product candidates. Failure to obtain approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, unless other products can be developed. There is no guarantee that we will ever be able to develop or acquire another product.

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

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS,") as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing authorization to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/ educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws and similar requirements in other countries.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our products, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

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

- restrictions on such product candidate, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

We or any of our future partners may choose not to continue developing or commercialize a product or product candidate at any time during development or after approval, which would reduce or eliminate our potential return on investment for that product or product candidate.

We currently do not have any products approved for sale and currently are focusing our clinical development efforts solely on M207. Currently, we do not have any collaborations with any partners for any of our products. In April 2016, we suspended further development related to our other candidates, Daily B104, Weekly B206 and D107.

At any time, we or any partners with whom we collaborate in the future may decide to discontinue the development of a marketed product or product candidate or not to continue commercializing a marketed product or a product candidate for a variety of reasons, including the appearance of new technologies that make our product obsolete, the position of our partner in the market, competition from another product, or changes in or failure to comply with applicable regulatory requirements. If we or our partners terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have lost the opportunity to allocate those resources to potentially more productive uses. If one of our future partners terminates a development program or ceases to market an approved or commercial product, we will not receive any future milestone payments or royalties relating to that program or product under a partnership agreement with that party.

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

We may not be able to complete the clinical trials required for our product candidates in a timely manner, or at all, and ultimately obtain regulatory approval for any of our product candidates. If we are unable to complete clinical trials of and obtain regulatory approval for our product candidates, our business will be significantly affected.

Our long-term growth will be limited unless we successfully develop a pipeline of additional product candidates.

Our long-term growth will be limited unless we successfully develop a pipeline of additional product candidates. We do not have internal new drug discovery capabilities, and our primary focus is on developing improved intracutaneous drug delivery systems by reformulating drugs previously approved by the FDA using our proprietary technologies.

If we are unable to expand our product candidate pipeline and obtain regulatory approval for our product candidates on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would harm our long-term business, results of operations, financial condition and prospects.

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

All of our product candidates are still in preclinical or clinical development. Our product candidates may have undesirable side effects, or have characteristics that are unexpected.

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

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product candidate;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product candidate is administered, conduct additional clinical trials or change the labeling of the product;

- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product candidate;
- we may be required to limit the patients who can receive the product candidate;
- we may be subject to limitations on how we promote the product candidate;
- sales of the product candidate may decrease significantly;
- regulatory authorities may require us to take our approved product candidate off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our product candidates.

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

Any failure in our internal manufacturing operations could cause us to be unable to meet the demand for product candidates for our clinical trials and delay the development or regulatory approval of our product candidates. Our internal manufacturing operations may encounter difficulties involving, among other things, material supplies, production yields, regulatory compliance, quality control and quality assurance, and shortages of qualified personnel. Regulatory approval of our product candidates could be impeded, delayed, limited or denied if the FDA does not maintain the approval of our manufacturing processes and facilities.

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

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

We have limited experience manufacturing our product candidates, including M207, and to date have only manufactured our product candidates for our clinical trials. If any of our product candidates are approved, we will need to scale up our own capabilities or contract with third parties to support the production of commercial level quantities of our product candidates, which may require expensive process improvements. If we decide to manufacture commercial quantities of our product candidates ourselves, we will be required to devote substantial resources to the construction or purchase of a commercial scale manufacturing facility, the purchase of manufacturing equipment and hiring additional personnel. Significant scale up of manufacturing may also require process improvements as well as additional technologies and validation studies, which are costly, may not be successful and which the FDA must review and approve. If we are unable to establish a new manufacturing facility or expand our existing manufacturing facilities, purchase equipment, hire adequate personnel to support our manufacturing efforts or implement necessary process improvements, we may be unable to produce commercial materials or meet demand, if any should develop, for our product candidates. Any such failure would have a material adverse effect on our business, financial condition and results of operations.

If we instead decide to contract with third parties to support commercial scale manufacture of our product candidates and we are unable to arrange for such a third-party manufacturing source for any of our product candidates, or fail to do so on commercially reasonable terms, we may not be able to successfully produce, develop and market one or more of our product candidates, or we may be delayed in doing so. Reliance on third-party manufacturers also entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with

our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Contract manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If our third-party manufacturers are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects. Our reliance on contract manufacturers will further expose us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

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 product candidates will depend upon their acceptance by the medical community, including physicians, patients and health care payers. The degree of market acceptance of any product candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of our products generally;
- relative convenience and ease of administration;
- prevalence and severity of any adverse effects;
- willingness of physicians to prescribe our product and of the target patient population to try new therapies and routes of administration;
- efficacy and safety of our products compared to competing products;
- introduction of any new products, including generics, that may in the future become available to treat indications for which our products may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our products may show utility;
- pricing and cost-effectiveness;
- effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling; and
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payers.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payers and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources and may never be successful.

Even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or

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

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We use customized equipment to coat and package our microneedle patch system; any production or equipment performance failures could negatively impact our clinical trials of our product candidates or sales of our product candidates, if approved.

We presently use customized equipment to coat and package our microneedle patch system. We also rely on third parties to manufacture our equipment. If we experience equipment malfunctions and we do not have adequate inventory of spare parts or qualified personnel to repair the equipment, we may encounter delays in the manufacture of our microneedle patch system and may not have sufficient inventory to meet the demands of our clinical development programs or, if any of our product candidates is approved, our customers' demands, each of which could adversely affect our business, financial condition and results of operations.

We rely on third party manufacturers for various components of our microneedle patch system, and our business could be harmed if those third parties fail to provide us with sufficient quantities of those components at acceptable quality levels and prices.

We rely on third-party manufacturers for various components of our microneedle patch system, including API raw materials used in manufacturing, and capital equipment. Reliance on third party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance. In addition, third party manufacturers may not be able to comply with cGMP, or similar regulatory requirements outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates that we may develop.

Any failure or refusal to supply the components for our product candidates or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to fail to fill our purchase orders, the development or commercialization of the affected product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

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 there is any dispute or disruption in our relationship with our CROs or if we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities, but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely affected. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CRO fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or if the quality of the clinical data they obtain is compromised due to the failure to conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If we are not able to establish collaborations, we may have to alter our development plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund our expenses. We may seek to collaborate with third parties for certain of our development programs, and potentially for the commercialization of our lead product candidate, M207.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time- consuming to negotiate and document. We may also be restricted under collaboration agreements from entering into agreements with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail, reduce or delay the development of a particular product candidate, or one or more of our other development programs, delay its or their potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate revenue.

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

We may seek strategic partnerships, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex.

The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategy, or a merger, acquisition, sale or downsizing;
- a collaboration partner may not devote sufficient resources towards, or cease development in, therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;
- a collaboration partner could develop a product candidate that competes, either directly or indirectly, with our product candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a dispute may arise between us and a collaboration partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- a collaboration partner may use our products or technology in such a way as to invite litigation from a third party; and
- a collaboration partner may exercise a contractual right to terminate a strategic alliance, making us ineligible to receive milestone or royalty payments under such agreement.

RISKS RELATED TO MARKETING AND SALE OF OUR PRODUCTS

We have no experience selling, marketing or distributing approved product candidates and have no internal capabilities to do so.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to developing adequate sales and marketing support for any of our product candidates, if approved by the FDA. Although we may develop a targeted commercial infrastructure to market and distribute our proprietary product candidates, our future success may depend, in part, on our ability to enter into and maintain collaborative relationships to provide such capabilities, on the collaborators'

strategic interest in the product candidates under development and on such collaborators' ability to successfully market and sell any such product candidates. There can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our product candidates, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with the needed technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

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

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

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial and other resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our product candidates will have to compete with existing therapies, new formulations of existing drugs and new therapies that may be developed in the future. We face competition from pharmaceutical, biotechnology and medical device companies, including intracutaneous delivery companies, in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business.

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

Our ability to commercialize any product candidate for which we receive regulatory approval, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the product candidate will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover the product candidate. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our product candidates, once approved, market acceptance of the product could be reduced.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and may have to limit development of a product candidate or commercialization of an approved product.

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product candidate. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for an approved product and loss of revenue;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize an approved product candidate.

Insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any product candidates approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or a series of claims brought against us, particularly if judgments exceed our insurance coverage, could cause our stock price to decline and could adversely affect our results of operations and business.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

Business disruptions could seriously harm our future revenues, results of operations and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

We are a party to an Intellectual Property License Agreement dated October 5, 2006, as amended, with ALZA Corporation and we may enter into additional license agreements in the future. Our existing license agreement imposes, and we expect that any future license agreements will impose, various diligence, product payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could have a material adverse effect on our business, financial condition and results of operations.

Our failure to obtain and maintain patent protection for our technology and our product candidates could permit our competitors to develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected.

Our commercial success is significantly dependent on intellectual property related to our product candidate portfolio. We are either the licensee or assignee of numerous issued and pending patent applications that cover various aspects of our assets, including, most importantly, our microneedle patch system and our product candidates.

Our success depends in large part on our and our licensor's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the

issuance, scope, validity, enforceability and commercial value of our and our licensor's patent rights are highly uncertain. Our and our licensor's pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidates without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ legal help and related professionals as needed to comply with those requirements. Failure to meet a required fee payment, document production or procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances the defect can be cured through late compliance but there are situations where the failure to meet the required deadline cannot be cured. Such an occurrence could compromise the intellectual property protection around a preclinical or clinical product candidate and possibly weaken or eliminate our ability to protect our eventual market share for that product candidate.

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

In addition to our patented technology and product candidates, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our corporate collaborators, outside scientific collaborators,

sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. In addition, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We could be prevented from selling product candidates, if approved, and could be forced to pay damages and defend against litigation, if we infringe the rights of third parties.

We conduct freedom-to-operate studies to guide our early-stage research and development away from areas where we are likely to encounter obstacles in the form of third party intellectual property conflicts, and to assess the advisability of licensing third party intellectual property or taking other appropriate steps to address any freedom-to-operate or development issues. However, with respect to third party intellectual property, it is impossible to establish with certainty that any of our product candidates will be free of claims by third party intellectual property holders or whether we will require licenses from such third parties. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications.

If our product candidates, methods, processes or other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product;
- redesign our product candidates or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose and which could result in a substantial diversion of our financial and management resources.

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

We intend to pursue regulatory approval of certain of our product candidates, including M207, pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or the FDCA. A Section 505(b)(2) application is a type of NDA that enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of a previously approved product for which the applicant has no right of reference, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Such applications involve significant costs, including filing fees.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved product or the FDA's prior findings of safety and effectiveness for a previously approved product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies and that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the

required patent information has not been filed by the original applicant; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product candidate have expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest to occur of 30 months beginning on the date the patent holder receives notice, expiration of the patent, settlement of the lawsuit, or until a court deems the patent unenforceable, invalid or not infringed.

If we rely in our Section 505(b)(2) regulatory filings on clinical trials conducted, or the FDA's prior findings of safety and effectiveness, for a previously approved product that involves patents referenced in the Orange Book, then we will need to make the patent certifications or the Paragraph IV certification described above. If we make a Paragraph IV certification and the holder of the previously approved product that we referenced in our application initiates patent litigation within the time periods described above, then any FDA approval of our Section 505(b)(2) application would be delayed until the earlier of 30 months, resolution of the lawsuit, or the other events described above. Accordingly, our anticipated dates of commercial introduction of our product candidates would be delayed. In addition, we would incur the expenses, which could be material, involved with any such patent litigation. As a result, we may invest a significant amount of time and expense in the development of our product candidates only to be subject to significant delay and patent litigation before our product candidates may be commercialized, if at all.

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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we may be reliant on them to do so.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

There is a great deal of litigation concerning intellectual property in our industry, and we could become involved in litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business, financial condition, results of operations and ability to compete in the marketplace.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office ("USPTO") and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, results of operations, financial condition and cash flows and future prospects.

Intellectual property rights do not necessarily address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our product candidates, which are aimed initially at the generic market and are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

RISKS RELATED TO LEGISLATION AND ADMINISTRATIVE ACTIONS

Our relationships with customers and third-party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to 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 ("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 payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

State and non-U.S. laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

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

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

The final rule implementing the Physician Payments Sunshine Act is complex, ambiguous, and broad in scope. When and if our product candidates, including M207, become approved, we will within a defined time period become subject to the reporting and disclosure provisions of the Physician Payments Sunshine Act. Accordingly, we will be required to collect and report detailed information regarding certain financial relationships we have with physicians, dentists and teaching hospitals. It is difficult to predict how the new requirements may impact existing relationships among manufacturers, distributors, physicians, dentists and teaching hospitals. The Physician Payments Sunshine Act preempts similar state reporting laws, although we may also be required to continue to report under certain provisions of such state laws. While we expect to have

substantially compliant programs and controls in place to comply with the Physician Payments Sunshine Act requirements, our compliance with the new final rule will impose additional costs on us. Additionally, failure to comply with the Physician Payment Sunshine Act may subject the Company to civil monetary penalties.

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

From time to time, legislation is implemented to rein in rising healthcare expenditures. In March 2010, President Obama signed into law the ACA, as amended by the Health Care and Education Reconciliation Act. The ACA included a number of provisions affecting the pharmaceutical industry, including annual, non- deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition, among other things, the ACA also established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. Congress has also proposed a number of legislative initiatives, including possible repeal of the ACA. At this time, it remains unclear whether there will be any changes made to certain provisions of the ACA or its entirety. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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.

More recently, President Trump has suggested that he plans to seek repeal of all or portions of the ACA, and he has indicated that he wants Congress to replace the ACA with new legislation. 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 product candidates become subject to recall it could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our product candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our product candidates in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those actions as recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Governments outside the United States may impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement for our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

RISKS RELATED TO EMPLOYEE MATTERS, OUR OPERATIONS AND MANAGING GROWTH

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

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

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- potential unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

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

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

We are highly dependent on our chief executive officer and our chief business officer. We do not have “key person” life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development and diversion of management resources, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always

possible to identify and deter employee misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions, including civil, criminal or administrative.

We may not successfully manage our growth.

Our success will depend upon the effective management of our growth, which will place a significant strain on our management and on administrative, operational and financial resources. To manage this growth, we may be required to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. Our inability to manage this growth could have a material adverse effect on our business, financial condition and results of operations.

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

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

RISKS RELATING TO AN INVESTMENT IN OUR COMMON STOCK

If we are unable to maintain listing of our securities on the NASDAQ Capital Market or another reputable stock exchange, it may be more difficult for the Company's stockholders to sell their securities.

NASDAQ requires listing issuers to comply with certain standards in order to remain listed on its exchange. On October 12, 2016, the Company received a letter from The NASDAQ Stock Market, LLC (the "Letter") stating that the Company had failed to maintain at least a $1.00 minimum bid price for its common stock (the "Minimum Bid Requirement") as required for continued listing of the Company's common stock on the NASDAQ Capital Market. Subsequently, on January 24, 2017, the Company received a notice from the Director of NASDAQ Listing Qualifications indicating that the Company had regained compliance with the Minimum Bid Requirement under NASDAQ Listing Rule 5550(a)(2).

If, for any reason, NASDAQ should delist the Company's securities from trading on its exchange (including, if the Company fails to comply with the Minimum Bid Requirement in the future) and the Company is unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

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 product candidates or those of our competitors;
- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- disputes concerning our intellectual property or other proprietary rights;
- recruitment or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

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

Substantial future sales of shares by existing stockholders, or the perception that such sales may occur, could cause our stock price to decline.

If our existing stockholders, particularly our directors and executive officers and the venture capital funds affiliated with two of our current directors, sell substantial amounts of our common stock in the public market, or are perceived by the public market as intending to sell substantial amounts of our common stock, the trading price of our common stock could decline significantly. As of February 20, 2017, we had 19,450,274 shares of common stock outstanding. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, certain holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended ("Securities Act"). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act,

except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by existing stockholders could have a material adverse effect on the market price of our common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities and industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes unfavorable research about our business, or if our clinical trials or operating results fail to meet the analysts' expectations, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Requirements associated with being a public reporting company will continue to increase our costs significantly, as well as divert significant company resources and management attention.

We have only been subject to the reporting requirements of the Securities Exchange Act of 1934, as amended ("Exchange Act") and the other rules and regulations of the SEC since January 2015. We are working with our legal, independent accounting, and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public reporting company. These areas include corporate governance, corporate control, disclosure controls and procedures, and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. Compliance with the various reporting and other requirements applicable to public reporting companies will require considerable time, attention of management, and financial resources.

Further, the listing requirements of The NASDAQ Capital Market require that we satisfy certain corporate governance requirements relating to director independence, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time and financial resources to ensure that we comply with all of these requirements. These reporting and corporate governance requirements, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

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

We have never declared or paid any cash dividends on our common stock, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. Additionally, our existing debt agreements contain covenants that restrict our ability to pay dividends. Therefore, we do not expect to declare or pay any dividends on our common stock for the foreseeable future. As a result, your ability to receive a return on an investment in our common stock will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which you purchased it.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our directors, executive officers, and the holders of more than 10% of our common stock together with their affiliates beneficially own a significant number of shares of our common stock. These stockholders, acting together, may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited

acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, certain provisions of the Sarbanes-Oxley Act and the rules and regulations of The NASDAQ Capital Market. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities.

Our disclosure controls and procedures may not be effective to ensure that we make all required disclosures.

As a public reporting company, we are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

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

- providing for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors;
- limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board and stockholder meetings;
- limiting the determination of the number of directors on our board and the filling of vacancies or newly created seats on the board to our board of directors then in office; and
- providing that directors may be removed by stockholders only for cause.

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

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

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

We are an "emerging growth company," and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

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

We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenue of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement filed under the Securities Act.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

It em 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555, and are leased under a seven-year property rental agreement that commenced in 2012. We do not own any real property. We believe our present facilities are sufficient for our current and planned near-term operations.

Item 3. LEGAL PROCEEDINGS

We are not party to any material pending legal proceedings. However, we may from time to time become involved in litigation relating to claims arising in the ordinary course of our business.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock has been publicly traded and listed on The NASDAQ Capital Market under the symbol "ZSAN" since our initial public offering, or IPO, of our common stock on January 27, 2015. Prior to that time, there was no public market for our common stock. The following table sets forth on a per share basis, for the periods indicated, the low and high sale prices of our common stock as reported by the NASDAQ Global Select Market.

	High	Low
2016		
First Quarter	$ 2.71	$ 1.97
Second Quarter	$ 2.38	$ 1.11
Third Quarter	$ 1.97	$ 0.72
Fourth Quarter	$ 1.08	$ 0.45

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

Holders of Common Stock

As of February 20, 2017, there were 41 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends in the foreseeable future. Additionally, our secured term loan facility with Hercules contains covenants that restrict our ability to pay dividends.

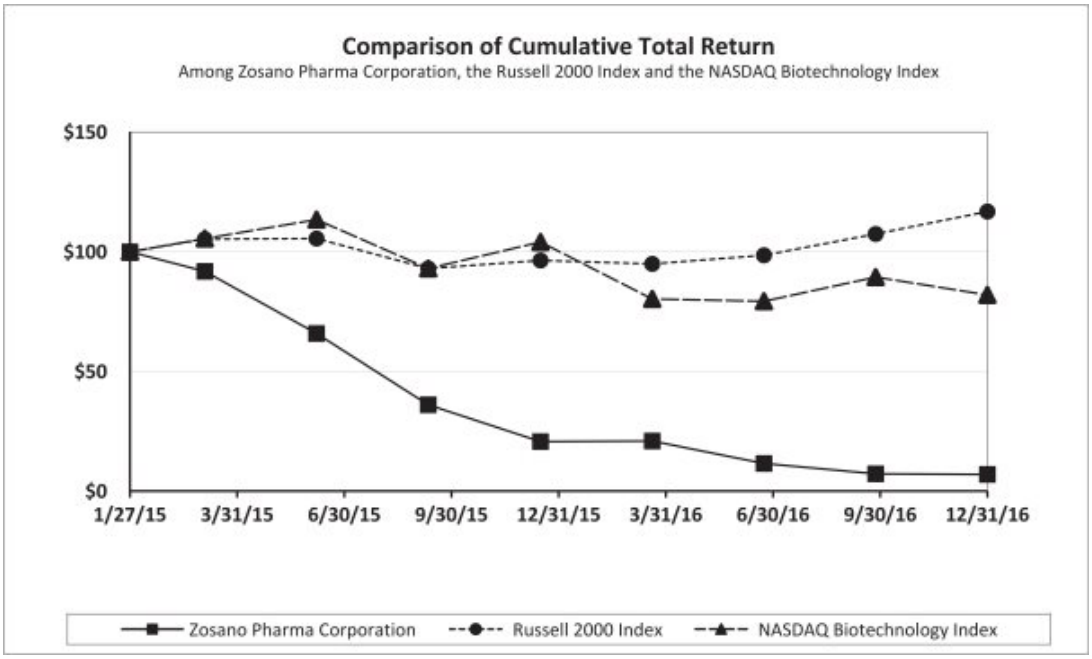
Securities Authorized for Issuance under Equity Compensation Plans

See Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information with respect to our compensation plans under which equity securities are authorized for issuance.

Performance Graph

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

The following graph shows the cumulative total stockholder return of an investment of $100 in cash on January 27, 2015 (the first day of trading of our common stock), through December 31, 2016 for (i) our common stock, (ii) the Russell 2000 Index (U.S.) and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Recent Sale of Unregistered Securities

We did not sell any unregistered equity securities during the period covered by this Annual Report on Form 10-K that have not already been reported in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. SELECTED FINANCIAL DATA

The selected financial data in the tables below should be read together with our financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report on Form 10-K. The selected financial data in this section is not intended to replace our financial statements and the accompanying notes. Our historical results are not necessarily indicative of our expected future results. The statements of operations data for 2016 and 2015 and the balance sheet data as of December 31, 2016 and 2015 were derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,	
	2016	2015
	(in thousands, except per share data)	
Consolidated Statements of Operations Data:		
Revenue:		
License fees	$ -	$ 170
Collaboration revenue	-	143
Total revenue	-	313
Operating expenses:		
Research and development	20,457	20,366
General and administrative	8,176	6,315
Total operating expenses	28,633	26,681
Loss from operations	(28,633)	(26,368)
Other income (expense):		
Interest expense, net	(1,192)	(1,564)
Other expense, net	(7)	(97)
Warrant revaluation income	-	48
Loss on debt extinguishment	-	(446)
Net loss	(29,832)	(28,427)
Unrealized loss on marketable securities, net of tax effect	-	(46)
Comprehensive loss	$ (29,832)	$ (28,473)
Net loss per common share — basic and diluted	$ (2.17)	$ (2.49)
Weighted-average shares used in computing net loss per common share — basic and diluted	13,773	11,414

	December 31,	
	2016	2015
	(in thousands)	
Selected Balance Sheets Data:		
Cash, cash equivalents, and marketable securities	$ 15,003	$ 36,933
Working capital	5,457	30,391
Total assets	20,906	45,337
Short-term and long-term debt	12,542	15,270
Accumulated deficit	(196,769)	(166,891)
Total stockholders' equity	4,485	26,502

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

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

Overview

Zosano Pharma Corporation and its subsidiary ("Company") is a clinical stage pharmaceutical company that has developed a proprietary intracutaneous delivery system. It can offer rapid absorption of drug, consistent drug delivery, improved ease of use and room-temperature stability, benefits that we believe differentiate our delivery platform from other non-oral formulations or injections. 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 intracutaneous patch consists of an array of titanium microneedles that is coated with our proprietary formulation of a previously approved drug that is attached to an adhesive patch. When the patch is applied with our hand-held applicator, the microneedles penetrate the skin resulting in dissolution and absorption of the drug through the capillary bed. We believe our system enables rapid and consistent delivery of the drug that is easy and convenient to administer. We focus on developing our microneedle patch system for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, for markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, M207. M207 is our proprietary formulation of zolmitriptan coated onto our patented intracutaneous microneedle patch, which is then applied with our proprietary applicator to ensure uniform, and consistent application. Zolmitriptan is, one of a class of serotonin receptor agonists known as triptans, used for the treatment of migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. The objective of M207 is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding the GI tract. In July 2016, we announced the dosing of the first subject in the M207 pivotal efficacy trial, known as ZOTRIP trial. In February 2017, we announced the completion and results of the ZOTRIP trial, in which M207 achieved both co-primary endpoints of pain freedom and most bothersome symptom freedom at 2 hours.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the United States Food and Drug Administration ("FDA") or equivalent foreign regulatory bodies, to market and sell our product candidate. Accordingly, our success depends not only on the development, but also on our ability to finance the development of the product. We will require substantial additional funding to complete development and seek regulatory approval for these products. Additionally, we currently have no sales, marketing or distribution capabilities and thus our ability to market our products in the future will depend in part on our ability to develop such capabilities either alone or with collaboration partners.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of

contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the accounting policies discussed below are those that are most critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Revenue recognition

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. Revenue under collaboration and license arrangements is recognized based on the performance requirements of the contract.

Research and Development Expenses

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

Stock-Based Compensation

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

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

Financial Operations Overview

General

As of December 31, 2016, we had an accumulated deficit of approximately $196.8 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we

advance our product candidates into later stages of development and, if approved, commercialization. We cannot assure you that we will receive additional capital or collaboration revenue in the future, pursuant to any partnership that we might pursue. In 2015, our collaboration agreements with Novo Nordisk A/S and Eli Lilly and Company, were terminated.

We expect our research and development expenses and manufacturing expenses related to the development of our M207 product candidate to increase as we continue to advance this program towards regulatory filing and approval. Because of the numerous risks and uncertainties associated with our technology and drug development, we cannot forecast with any degree of certainty the timing or amount of expenses incurred or when, or if, we will be able to achieve profitability.

In addition to the proceeds received upon the closing of our initial public offering and concurrent private placement in January 2015, and our August 2016 private placement, additional capital will be required to undertake our planned research and development activities and to meet our operating requirements beyond 2016. We intend to raise such capital through the issuance of additional equity through public or private offerings, debt financing, strategic alliances with pharmaceutical partners, or any combination of the above. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to further reduce our operating expenses and delay or reduce the scope of our M207 development program, out-license intellectual property rights to our intracutaneous delivery technology, or a combination of the above, which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all.

Debt Financing

We have funded, and will continue to fund, our operations in part through debt financing. In June 2014, we entered into a $4.0 million term loan facility with Hercules Capital, Inc. (“Hercules”), previously known as Hercules Technology Growth Capital, Inc. In June 2015, we entered into a first amendment to the loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million (the Hercules Term Loan). Upon the execution of the first amendment to the loan and security agreement, we used approximately $11.4 million of the Hercules Term Loan to prepay all amounts owing under the secured promissory note held by BMV Direct SOTRS LP, an affiliate of BioMed Realty Holdings, Inc. The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance will be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. The interest rate on the secured term loan with Hercules was 7.95% for the years ended December 31, 2016 and 2015. In addition, we will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date we prepay the Hercules Term Loan and a $351,135 end of term charge on the earlier of loan maturity or at the date we prepay the Hercules Term Loan. We may prepay all, but not less than all, of the Hercules Term Loan subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties.

Revenue

Our revenue to date has been generated primarily from non-refundable license fee payments and reimbursements for research and development expenses under our prior collaboration and license agreements with Asahi Kasei Pharma Corporation (“Asahi”) and our prior collaboration, development and license agreement with Novo Nordisk. Through December 31, 2015, we received a non-refundable upfront license fee payment of $1.0 million from Novo Nordisk under the collaboration, development and license agreement, which was recorded as deferred revenue. Based on Novo Nordisk’s notification to us in July 2015 of its intention to discontinue the collaboration agreement, we recognized the remaining deferred revenue under this

collaboration agreement in 2015. Reimbursements from Novo Nordisk for development support services and out-of-pocket expenses in connection with the collaboration agreement were recognized as service revenue when service was rendered and cost of material was incurred. As a result of the termination of the agreement in 2015, the collaboration with Novo Nordisk is no longer a source of revenue for us.

Research and development expenses

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

Research and development expenses consist of:

- production costs which include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation expense and fees paid to conduct clinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;
- expenses related to the purchase of active pharmaceutical ingredients and raw materials for the production of our intracutaneous delivery system, including fees paid to contract manufacturing organizations ("CMOs");
- fees paid to contract research organizations ("CROs"), clinical consultants, clinical trial sites and vendors, including institutional review boards ("IRBs"), in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- fees paid to conduct clinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;
- other consulting fees paid to third parties; and
- allocation of certain shared costs, such as facilities-related costs and IT support services.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2016 and 2015, and from our inception to December 31, 2016:

	Year Ended December 31,		For the Period from inception to December 31, 2016
	2016	2015	
		(In thousands)	
Product candidate:			
M207 (1)	$ 13,281	$ 4,425	$ 19,107
Suspended programs (2)	126	9,289	52,402
Collaborative development support (3)	-	117	2,630
Other research projects (4)	1,984	978	12,573
Unallocated research and development expenses (5)	5,066	5,557	75,134
Total research and development expenses	$ 20,457	$ 20,366	$ 161,846

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

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

(3) 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.

(4) 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.

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

The project-specific expenses summarized in the table above include costs directly attributable to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and indirect costs to our product candidates on a project-specific basis, and we include these costs in the project- specific expenses. We expect our research and development expenses to increase in the future. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors including but not limited to: the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. In situations in which third parties have control over the clinical development of a product candidate, the estimated completion dates are largely under the control of such third parties and not under our control. Additionally a future collaborative partner may only be interested in applying our technology in the development and advancement of their own product candidates as we have previously experienced.

For the immediate future, our research and development efforts and resources will be focused primarily on advancing the development of M207. While we currently intend to continue clinical development of M207 through commercialization in the United States ourselves, we remain open to opportunities with potential strategic partners to ensure M207 will receive the best chance of commercial success. We are actively seeking opportunities to evaluate collaborations with strategic partners to further the clinical and commercial development of our other product candidates. We cannot forecast with any degree of certainty 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 these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development. As a public company, we expect to invest significant resources to comply with evolving laws, regulations and standards, including the implementation of effective internal controls over financial reporting and compliance with Sarbanes-Oxley Act.

Other income and expense

Interest expense, net. Interest expense, net consists primarily of interest costs related to our short-term borrowings and long-term debt and the amortization of debt discount and issuance costs. Interest expense for the year ended December 31, 2016 consisted of accrued interest related to the Hercules Term Loan and the related amortization of debt discount and issuance costs. Interest expense for the year ended December 31, 2015 consisted of accrued interest on the related parties convertible promissory notes, which were converted to equity upon the closing of our IPO, accrued interest on the BMR Note, which was paid in full in June 2015, as well as accrued interest related to the Hercules Term Loan and the related amortization of debt discount and issuance costs.

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

Warrant revaluation. In 2015, we recorded warrant revaluation income resulting from the re-measurement of our common stock warrant liability issued in connection with the Hercules Term Loan.

Loss on debt extinguishment . Loss on debt extinguishment was related to the restructuring and consolidation of our outstanding debt in June 2015. In June 2015, we amended our loan and security agreement with Hercules to increase the aggregate principal amount of the loan to $15.0 million. The amended Hercules Term Loan has substantially different terms than the original loan and in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP") the original debt was considered extinguished. We accounted for the extinguishment based on the relative fair value of the loan and recorded a loss on debt extinguishment of $0.4 million in 2015.

Results of Operations

Comparison of the year ended December 31, 2016 and 2015

	Year Ended December 31,		Change	
	2016	2015	Amount	%
	(In thousands)			
Revenue				
License fees	$ -	$ 170	$ (170)	(100%)
Collaboration revenue	-	143	(143)	(100%)
Total revenue	$ -	$ 313	$ (313)	(100%)

Total revenue decreased $0.3 million, or 100%, for the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decrease was primarily due to the completion of the feasibility study and conclusion of work under our now terminated collaboration agreement with Novo Nordisk which was terminated in 2015.

Research and development expenses

	Year Ended December 31,		Change	
	2016	2015	Amount	%
	(In thousands)			
Research and development	$ 20,457	$ 20,366	$ 91	-%

Research and development expenses increased approximately $91,000, and there was no percentage difference for the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decision to suspend development of product candidates, Daily B104, Weekly B206 and D107, resulted in a decrease of approximately $9.3 million for those product candidates, offset primarily by an increase of $8.9 million in spending for development of M207 and an increase of $0.4 million in other research projects.

General and administrative expenses

	Year Ended December 31,		Change	
	2016	2015	Amount	%
	(In thousands)			
General and administrative	$ 8,176	$ 6,315	$ 1,861	29%

General and administrative expenses increased $1.9 million, or 29%, for the year ended December 31, 2016 as compared to the same period in 2015. The increase was primarily due to approximately $0.4 million of the postemployment severance and benefits paid to our former Chief Executive Officer, approximately $0.5 million increase in stock based compensation, approximately $0.4 million increase in personnel costs, and $0.4 million related to consulting and insurance costs.

Other income and expense

	Year Ended December 31,		Change	
	2016	2015	Amount	%
	(In thousands)			
Interest expense, net	$ (1,192)	$ (1,564)	$ 372	24%
Other expense, net	(7)	(97)	90	93%
Warrant revaluation income	-	48	(48)	(100%)
Loss on debt extinguishment	-	(446)	446	100%

Interest expense, net, decreased approximately $0.3 million for the year ended December 31, 2016 as compared to the same period in 2015. The decrease in interest expense was primarily due to savings from the restructuring of our term loan with Hercules in June 2015 at a lower interest rate.

Other expense, net decreased approximately $90,000 for the year ended December 31, 2016 as compared to the same period in 2015. For the year ended December 31, 2016, we recorded a gain of approximately $51,000 on a sale of equipment, offset by a loss in other expenses of approximately $57,000 on the sale of Zosano Inc., a public shell corporation that was a subsidiary of the Company with no operations and no assets. For the year ended December 31, 2015, other income and expense, net consisted of an impairment charge on our long-term investment in Zosano, Inc. of $145,000, partially offset by income related to the recovery of prior year property damage claim received from an insurance company.

Warrant revaluation income decreased approximately $48,000 for the year ended December 31, 2016 as compared to the same period in 2015. In 2015, warrant revaluation income resulted from the re-measurement of our common stock warrant liability issued in connection with the Hercules Term Loan. In the first fiscal quarter of 2015, the warrants issued to Hercules Capital Inc. in connection with the Company's entry into the loan and security agreement in June 2014 was reclassified from liability to equity treatment.

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

Income Taxes

As of December 31, 2016, we had net deferred tax assets of $18.9 million. The deferred tax assets primarily consisted of federal and state tax net operating losses and research and development tax credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these tax assets, a full valuation allowance has been established to offset our deferred tax assets. As of December 31, 2016, we had federal net operating loss carryforwards of approximately $35.2 million and state net operating loss carryforwards of approximately $35.5 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 2017.

As of December 31, 2016, we had federal and state research and development credit carryforwards of approximately $0.5 million and $4.2 million, respectively. As of December 31, 2015, we had federal and state research and development credit carryforwards of approximately $4.0 million and $4.0 million, respectively. If not utilized, the federal tax credits will begin to expire in 2026; state tax credits currently do not expire.

Utilization of net operating loss carryforwards and research and development credit carryforwards may also be subject to an annual limitation due to the ownership change limitations. These annual limitations may result in the expiration of the net operating loss carryforwards and research and development credit carryforwards before utilization. We have performed an analysis under Internal Revenue Code Section 382 and 383 to determine the amount of our net operating loss carryforwards and research and development credit carryforwards that will be subject to annual limitation. As a result of the analysis, a portion of the net operating

loss carryforwards and research and development credit carryforwards have been derecognized due to the annual limitation.

Liquidity and Capital Resources

As of December 31, 2016, the Company has an accumulated deficit of $196.8 million as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the next twelve months from issuance of these financial statements. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidate. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate sources.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations.

Since our inception in October 2006, we have funded our operations primarily through a combination of equity offerings, secured and unsecured borrowings from private investors, bank credit facilities, and licensing and service revenue from our license and collaboration agreements. We have incurred recurring operating losses and negative cash flows from operating activities since inception, and as of December 31, 2016, had an accumulated deficit of $196.8 million. We expect to incur additional losses in the future to conduct research and development of our M207 product candidate and to conduct pre-commercialization manufacturing activities.

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

As of December 31, 2016, we had approximately $15.0 million in cash and cash equivalents. Presently, the Company does not have sufficient cash resources to meet its plans in the next twelve months following the date of the Report of Independent Registered Public Accounting Firm on page F-2 of this Form 10-K.

We will continue to require additional financing to develop our product candidates and fund operating losses. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate partners, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the scope, progress, expansion, costs, and results of our clinical trials;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- the timing of and costs involved in obtaining regulatory approvals;
- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- our ability to establish and maintain development partnering arrangements;
- the timing, receipt and amount of contingent, royalty, and other payments from any of our future development partners;
- the emergence of competing technologies and other adverse market developments;

- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and, if approved, commercializing our product candidates;
- our ability to draw funds from our loan and security agreement; and
- the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves. This raises substantial doubt about our ability to continue as a going concern. As of December 31, 2016, the Company had an accumulated deficit of $196.8 million and the Company does not have sufficient cash resources to meet its plans in the next twelve months following the issuance of these financial statements.

The following table shows a summary of our cash flows for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (25,686)	$ (24,155)
Investing activities	30,272	(30,946)
Financing activities	3,771	60,533
Net increase in cash and cash equivalents	$ 8,357	$ 5,432

Operating Cash Flow: Net cash used in operating activities was $25.7 million and $24.2 million for the years ended December 31, 2016 and 2015, respectively. Net cash used during 2016 was primarily the result of clinical development costs and professional fees and administrative expenses incurred in the course of continuing operation. Net cash used in 2015 was primarily the result of clinical and non-clinical development costs, personnel costs related to hiring key personnel with critical manufacturing know-how to ramp up our production of clinical trial material in preparation of our planned Phase 2 and Phase 3 clinical trials for our Daily B104, Weekly B206, D107, and M207 clinical programs, professional fees and administrative expenses incurred in the course of continuing operation.

Investing Cash Flow: Net cash provided by investing activities was $30.3 million for the year ended December 31, 2016, and net cash used in investing activities was $30.9 million for the year ended December 31, 2015. Net cash provided by investing activities during 2016 resulted primarily from $30.2 million in proceeds from maturities of our investments in marketable securities. Net cash used in investing activities during 2015 was primarily due the purchase of $42.6 million of marketable securities for investment, partially offset by maturities of $12.1 million of our investments in marketable securities.

Financing Cash Flow: Net cash provided by financing activities was $3.8 million and $60.5 million for the years ended December 31, 2016 and 2015, respectively. Net cash generated from financing activities during 2016 included $6.6 million of net proceeds from our private investment in public equity (“PIPE”) financing, partially offset by $2.9 million in repayment of loan principal and accrued interest to Hercules. Net cash generated from financing activities during 2015 included approximately $60.3 million of net proceeds from our initial public offering of securities and concurrent private placement with Eli Lilly.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2016:

	Payment Due by Period				
	Total	Less than One Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Contractual Obligations					
Short and long-term debt obligations (including interest) (1)	$13,618	$ 6,671	$ 6,947	$ -	$ -
Operating lease obligations (2)	1,451	637	814	-	-
Total contractual obligations	$15,069	$ 7,308	$ 7,761	$ -	$ -

(1) Short and long-term debt obligations

Secured financing with Hercules

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

The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance will be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. In addition, we will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date we prepay the Hercules Term Loan and a $351,135 end of term charge on the earlier of loan maturity or at the date we prepay the Hercules Term Loan. We may prepay all, but not less than all, of the Hercules Term Loan subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of our tangible and intangible properties and assets, including intellectual properties.

The loan and security agreement with Hercules contains customary conditions related to borrowing, events of default, and covenants, including covenants limiting our ability to dispose of collateralized assets, undergo a change of control, incur debt or incur liens, subject to certain exceptions. The loan and security agreement also requires us to comply with certain basic affirmative covenants, such as maintenance of financial records, insurance and prompt payment of taxes.

(2) Operating leases

We have an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings, for our office, research and development, and manufacturing facilities in Fremont, California. We entered into a fifth amendment to the lease in April 2012 which extended the lease term through March 2019 and provided a reduction in annual rents due to a potential reduction of premises from a recapturable premises clause.

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

In November 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-18, *Statement of Cash Flows* . This ASU provides guidance on the presentation of cash and restricted cash equivalents in the statement of cash flows to reduce the current diversity in practice. The amendments in this update are effective for public business entities for fiscal year beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. Adoption of this standard is not expected to have a material impact on the financial statements.

In March 2016, the FASB issued Accounting Standards Update (ASU) 2016-09, *Improvements to Employee Share-Based Payment Accounting* . This Update is part of the FASB's simplification initiative. The areas of simplification involve several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. The Company has adopted this standard for its fiscal year 2017. Adoption of this standard will not have a material impact on the financial statements.

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

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

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standard Updated (ASU), No. 2014-09, *Revenue from Contracts with Customers* . This ASU outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the ASU by one year to December 15, 2017 for fiscal years, and interim periods, beginning after that date. Early adoption is permitted, but not before the original effective date (annual periods beginning after December 15, 2016). Adoption of this standard to have a material impact on the financial statements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. We had cash and cash equivalents of $15.0 million and $6.6 million as of December 31, 2016 and 2015, respectively, which consist of bank deposits and money market funds. Any interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, a hypothetical immediate 10% change in

interest rates during any of the periods presented would not have had a material impact on our financial statements.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 of Part II of this Annual Report on Form 10-K are appended to this report and are incorporated herein by reference. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Business Officer and Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, our Chief Executive Officer and our Chief Business Officer and Interim Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Business Officer and Interim Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate controls over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Business Officer and Interim Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2016 based on the guidelines established *in Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Our internal control over financial reporting includes policies and procedures that provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. GAAP.

Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2016. We reviewed the results of management's assessment with our Audit Committee.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to the deferral allowed under the JOBS Act for emerging growth companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth fiscal quarter of the annual reporting period ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Directors and Key Employees

Our executive officers, directors and key employees, their positions and their ages as of February 15, 2017 are set forth below:

Name	Age	Position
John Walker	68	Chairman of the Board of Directors
Joseph P. Hagan (1) (2) (3)	48	Director
Bruce Steel	50	Director
Troy Wilson (1) (2) (3)	48	Director
Kleanthis G. Xanthopoulos (1) (2) (3)	58	Director
Konstantinos Alataris	46	President, Chief Executive Officer, and Director
Winnie Tso (4)	55	Chief Financial Officer
Georgia Erbez (4)	50	Chief Business Officer and Interim Chief Financial Officer
Donald Kellerman	62	VP Clinical Development and Medical Affairs
Hayley Lewis	41	VP Regulatory Affairs and Quality

(1) Member of the Audit Committee
(2) Member of the Nominating and Corporate Governance Committee.
(3) Member of the Compensation Committee.
(4) Effective May 13, 2016, Winnie Tso, Chief Financial Officer has been on medical leave of absence. On June 15, 2016, the board of directors appointed Georgia Erbez as Interim Chief Financial Officer of the Company.

Business Experience

The following is a brief description of the education and business experience of our current directors and executive officers:

John Walker has served as a member of our Board of Directors since May 2016. Mr. Walker is currently the Executive Chairman and interim Chief Executive Officer of Vizuri Health Sciences, LLC and served as a Managing Director of Four Oaks Partners, a life sciences transaction advisory firm, which he co-founded in March 2012 until January 2015. As part of his activities with Four Oaks Partners, Mr. Walker served as the Chairman and Interim Chief Executive Officer of Neuraltus Pharmaceuticals, Inc., a privately held biopharmaceutical company, until October 2013. From February 2009 until July 2010, Mr. Walker was the Chief Executive Officer at iPierian Inc., a company focused on the use of inducible stem cells for drug discovery. From 2006 until 2009, Mr. Walker served as the Chairman and Chief Executive Officer of Novacea, Inc., a pharmaceutical company that merged with Trancept Pharmaceutials, Inc., in 2009. Since 2001, Mr. Walker, acting as a consultant, was Chairman and Interim Chief Executive Officer at Kai Pharmaceuticals, Guava Technologies, CentaurPharmaceuticals, Inc., and Chairman and Chief Executive Officer of Bayhill Therapeutics. From 1993 until 2001, Mr. Walker was the Chairman and Chief Executive Officer of Arris Pharmaceuticals Corporation and its successor, Axys Pharmaceutials Inc. Mr. Walker previously served on the board of directors of Geron Corporation and Evotec AG. Mr. Walker is a graduate of the Advance Executive Program at the Kellogg School of Management at Northwestern University and holds a B.A. from the State University of New York at Buffalo. We believe Mr. Walker's 40 years in the life sciences industry and his experience as Chairman and Chief Executive Officer of a number of development and commercial stage companies qualify him to serve as a member of our Board of Directors.

Joseph P. Hagan has served as a member of our board of director since May 2015. Mr. Hagan has served as Regulus' Chief Operating Officer, Principal Financial Officer and Principal Accounting Officer since January 2016.

From 2011 to December 2015, Mr. Hagan served as Orexigen's Chief Business & Financial Officer. From May 2009 to June 2011, Mr. Hagan served as Orexigen's Senior Vice President, Corporate Development, Strategy and Communications. Prior to Orexigen, Mr. Hagan worked at Amgen, from September 1998 to April 2008, where he served in various senior business development roles, including founder and Managing Director of Amgen Ventures. Prior to starting the Amgen Ventures fund, Mr. Hagan was Head of Corporate Development at Amgen, leading such notable transactions as the acquisition of Immunex and Tularik and the spinouts of Novatrone and Relypsa, as well as numerous other business development efforts totaling over $15 billion in value. Before joining Amgen, Mr. Hagan spent five years in the bioengineering labs at Genzyme and Advance Tissue Sciences. He received an M.B.A. from Northwestern University and a B.S. in Physiology and Neuroscience from the University of California, San Diego. We believe that Mr. Hagan's education and professional background in science and business management, and his work as a senior executive in the biotechnology industry qualify him to serve as a member of our Board of Directors.

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

Troy Wilson has served as a member of our board of directors since June 2014. Dr. Wilson has been President and Chief Executive Officer and a member of the board of directors of Kura Oncology, Inc., a public company, since August 2014. He has served as President and Chief Executive Officer and a member of the board of managers of Avidity NanoMedicines LLC, a private biopharmaceutical company, since November 2012 and as President and Chief Executive Officer and a member of the board of managers of Wellspring Biosciences LLC, a private biopharmaceutical company, since July 2012 and May 2012, respectively. He has been a Director of Puma Biotechnology, Inc., a public company, since October 2013. He has also been a member of the board of managers of Araxes Pharma LLC, a private biopharmaceutical company, since May 2012. Previously, Dr. Wilson served as President and Chief Executive Officer and a member of the board of directors of Intellikine, Inc., a private biopharmaceutical company, from April 2007 to January 2012 and from August 2007 to January 2012, respectively, until its acquisition by Takeda Pharmaceuticals. Dr. Wilson holds a J.D. from New York University and graduated with a Ph.D. in bioorganic chemistry and a B.A. in biophysics from the University of California, Berkeley. We believe that Dr. Wilson's senior executive experience managing, leading and developing various biopharmaceutical companies and his extensive industry knowledge and board-level experience in the biopharmaceutical industry qualify him to serve as a member of our board of directors.

Kleanthis G. Xanthopoulos has served as a member of our board of directors since April 2013. Dr. Xanthopoulos was the President and Chief Executive Officer and a member of the board of directors of Regulus Therapeutics Inc. until June 2015, having joined Regulus in 2007. Dr. Xanthopoulos is also currently chairman of the board of directors of Apricus Biosciences, Inc., a public company, a member of the board of directors of Biotechnology Industry Organization (BIO) and Senté Inc., and is a member of the executive board of BIOCOM, Southern California's life science industry association. Prior to joining Regulus, Dr. Xanthopoulos was a managing director of Enterprise Partners Venture Capital. Dr. Xanthopoulos co-founded and served as President and Chief Executive Officer of Anadys Pharmaceuticals from its inception in 2000 to 2006, and remained a Director until its acquisition by Roche in 2011. Dr. Xanthopoulos was Vice President at Aurora Biosciences, which was acquired by Vertex Pharmaceuticals, from 1997 to 2000. Dr. Xanthopoulos participated in The Human Genome Project as a Section Head of the National Human Genome Research Institute from 1995 to 1997. Previously, Dr. Xanthopoulos was an Associate Professor at the Karolinska Institute, in Stockholm, Sweden, after completing a Postdoctoral Research Fellowship at The Rockefeller University, New York. An Onassis Foundation scholar, Dr. Xanthopoulos received his B.Sc. in Biology with honors from Aristotle University

of Thessaloniki, Greece, and received both his M.Sc. in Microbiology and Ph.D. in Molecular Biology from the University of Stockholm, Sweden. We believe that Dr. Xanthopoulous's senior executive experience managing and developing a major biotechnology company and his extensive industry knowledge and leadership experience in the biotechnology industry qualify him to serve as a member of our board of directors.

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

Winnie W. Tso has served as our Chief Financial Officer since April 2014. From January 2014 to April 2014, Ms. Tso served as a consultant to us. Prior to joining us in January 2014, Ms. Tso served as Vice President, Finance and Corporate Controller of SciClone Pharmaceuticals, a publicly-traded specialty biopharmaceutical company, in 2013. Prior to that, Ms. Tso served in various Vice President and Principal Accounting Officer positions from 2009 to 2013, including at Velti plc where Ms. Tso helped lead Velti's U.S. public offering raising in excess of $150 million in equity financing. Prior to Velti, Ms. Tso held senior finance positions at several publicly-traded biopharmaceutical companies, including ARYx Therapeutics, Titan Pharmaceuticals and Genelabs Technologies, where she was responsible for building the finance and accounting infrastructures and implementing systems of internal controls. Ms. Tso is a Certified Management Accountant, a Certified Financial Manager, a Certified Public Accountant licensed in the State of California and a member of the American Institute of Certified Public Accountants. Ms. Tso received her B.S. degree in Business Administration from the Haas School of Business at the University of California, Berkeley. Ms. Tso is currently on medical leave of absence.

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

Donald Kellerman, Pharm.D. has served as our Vice President of Clinical Operations since July 2015. Prior to joining us, Dr. Kellerman served as Senior Vice President of Clinical Development and Regulatory Affairs at

Tonix Pharmaceuticals from April 2014 to April 2015. Previously, from 2008 to 2013, Dr. Kellerman served as Senior Vice President of Clinical Development and Medical Affairs at MAP Pharmaceuticals, Inc. (acquired by Allergan, Inc.). Dr. Kellerman also held the position of Senior Vice President of Development at Inspire Pharmaceuticals, Inc. from 1999 to 2008, where he was responsible for all aspects of drug development, including clinical research, regulatory affairs, project management and biostatistics. He also led groups responsible for running several clinical programs in the respiratory, ophthalmology and cardiovascular areas. In addition, Dr. Kellerman has served in various clinical and project leadership positions at Glaxo Wellcome, Sepracor, Inc., and E.R. Squibb and Sons, Inc. He has more than 25 years of experience in the development of prescription pharmaceuticals and has lead- or co-authored more than 80 publications. Dr. Kellerman holds Doctor of Pharmacy and Bachelor of Science degrees from the College of Pharmacy at the University of Minnesota.

Hayley Lewis has served as our Vice President of Regulatory Affairs and Quality since October 2015. Prior to joining the Company, Ms. Lewis was Vice President of Regulatory Affairs and Quality at Carbylan Therapeutics from May 2014 until May 2015. While at Carbylan, Ms. Lewis was part of the executive team that took the company public in April 2015, as well as being responsible for all regulatory and quality activities, both internally and for Carnylan's external development programs. From 2003 to 2014, Ms. Lewis held positions of increasing responsibility, most recently as the Senior Director of Regulatory Affairs at Depomed, Inc. During her tenure, she led the company in the approvals of three NDAs, Proquin ® , Glumetza ® , and Gralise ® , as well as approvals of several supplemental NDAs for Gralise ® , Cambia ® , Zipsor ® and Lazanda ® , including a line extension for Glumetza ® , CMC, and labeling changes for the neurology and pain product lines for Depomed's portfolio. Ms. Lewis received a B.S. in Pharmaceutical Sciences from the University of Greenwich, and completed the Executive Program for Women Leaders at the Stanford Graduate School of Business.

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file reports of ownership of, and transactions in, our securities with the Securities and Exchange Commission. These directors, executive officers and ten-percent stockholders are also required to furnish us with copies of all Section 16(a) forms they file.

Based solely on a review of the copies of such forms received by us, and on written representations from certain reporting persons, we believe that during fiscal year 2016 our directors, executive officers and ten-percent stockholders complied with all applicable Section 16(a) filing requirements.

Code of Ethics

We have adopted a written code of ethics that applies to our directors, executive officers and employees, and we also have adopted corporate governance guidelines. A copy of our code of ethics is posted on our website, which is located at www.zosanopharma.com, under "Investors — Corporate Governance." If we make any substantive amendments to, or grant any waivers from, a provision of our code of ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

Audit Committee

Our board of directors has established an audit committee. The audit committee, which is one of three standing committees of our board of directors, operates under a charter that has been approved by our board of directors.

The current members of our audit committee are Mr. Hagan, Dr. Wilson, and Dr. Xanthopoulos. Our board of directors has determined that Mr. Hagan, Dr. Wilson, and Dr. Xanthopoulos satisfy the NASDAQ Stock Market

independence standards and the independence standards of Rule 10A-3(b)(1) of the Exchange Act. Each of the members of our audit committee meets the requirements for financial literacy under applicable rules and regulations of the SEC and the NASDAQ Stock Market. The board of directors has also determined that Mr. Hagan qualifies as an "audit committee financial expert," as defined by applicable rules of the NASDAQ Stock Market and the SEC.

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

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

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

Item 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information regarding compensation earned by our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer who served as executive officers as of December 31, 2016. We refer to these individuals as our named executive officers.

	Year	Salary	Bonus	Fair Value of Option Awards (4)	Other	Total
Konstantinos Alataris	2016	449,148	-(9)	385,808	-	834,956
President and Chief Operating Officer	2015	105,288	18,750 (1)	1,297,504 (5)	-	1,421,542
Georgia Erbez	2016	110,160	-(9)	143,161	99,536 (6)	352,857
Chief Business Officer and Interim Chief Financial Officer (3)						
Donald Kellerman	2016	297,083	-(9)	98,742	-	395,825
Vice President Clinical Development and Medical Affairs (2)	2015	151,347	28,984 (1)	157,758 (5)	-	338,089
Vikram Lamba	2016	6,528	-(9)	-	440,102 (8)	446,630
Chief Executive Officer (7)	2015	424,360	85,000	-	-	509,360

(1) Represents cash bonus awarded in respect to 2015 and paid in March 2016. Bonus amounts were determined pursuant to applicable employment agreements and based on achievement of individual and company performance goals and other factors deemed relevant by our Compensation Committee and Board of Directors.

(2) Mr. Kellerman joined the Company as Vice President Clinical Development and Medical Affairs on June 8, 2015.

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

(4) Represents the aggregate grant date fair value of option awards granted in fiscal year 2015 and 2016 and in accordance with ASC718, *Compensation-Stock Compensation.* For information regarding the assumptions used in calculating these amounts, see Note 10. Stock-Based Compensation included in this Annual Report.

(5) The aggregate grant date fair value of option awards granted in fiscal year 2015 includes the impact of the options exchanged pursuant to the 2015 Stock Option Exchange Program. For a description of the 2015 Stock Option Exchange Program, see Note 10. Stock-Based Compensation included in this Annual Report.
(6) Ms. Erbez was a consultant to the Company from June 6, 2016 to September 6, 2016; these amounts represent consulting fees paid.
(7) Mr. Lamba's employment with the Company terminated on January 6, 2016. He was succeeded as our President and Chief Executive Officer by Dr. Alataris.
(8) Represents payments of severance and accrued vacation in connection with the Termination of Mr. Lamba's employment.
(9) The bonus amount is not calculable as of the date of this filing. We expect this information will be determined on or about March 1, 2017 and will be reported on or before April 30, 2017.

Narrative Disclosure to Summary Compensation Table

We review compensation annually for all of our employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long- term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

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

We have a formal employment agreement with Konstantinos Alataris, our President, Chief Executive Officer and Chief Operating Officer. We also have an executed employment offer letter with Georgia Erbez, our Chief Business Officer and Interim Chief Financial Officer and with Donald Kellerman, our Vice President, Clinical Development. We had a formal employment agreement with Vikram Lamba, our former Chief Executive Officer, until Mr. Lamba's employment with the Company was terminated on January 6, 2016. Dr. Alataris' employment agreement provides for an initial base salary of $375,000, subject to increase from time to time. In February 2016, we amended Dr. Alataris' employment agreement to reflect his capacity to serve as our Chief Executive Officer starting January 2016 at a base salary of $450,000. The amended employment agreement provides for a target annual bonus of 50% of his annual base salary for 2016, to be determined by the board of directors in its discretion based on company performance against goals established annually by the compensation committee, as well as the Company's then prevailing cash position. Ms. Erbez's employment letter agreement provides for an initial base salary of $350,000, subject to increase from time to time. Ms. Erbez joined the Company on September 7, 2016. Ms. Erbez employment letter agreement provides for a target annual bonus of 40% of her annual base salary, to be determined by the board of directors in its discretion after consideration of a proposal from the CEO based on company performance against goals established annually by the compensation committee, as well as the Company's then prevailing cash position. Mr. Kellerman's employment offer letter agreement provides for an initial base salary of $265,000. At the end of 2016, Dr. Kellerman's annual base salary was $320,000. Dr. Kellerman's employment offer letter provides for a targeted bonus of 30% of his annual base salary, to be awarded and paid in accordance with the terms of the Company's bonus program adopted by our Compensation Committee in February 2015 and based on achievement of company performance and individual goals and other factors deemed relevant by our Compensation Committee.

Outstanding Equity Awards at Year-End

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2016.

	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Option Exercise Price ($)	Option Expiration Date	Option Grant Date
Konstantinos Alataris	52,349	209,394 (1)	$ 2.26	12/15/2025	12/15/2015
	-	200,000 (2)	$ 2.34	2/3/2026	2/3/2016
Georgia Erbez	-	252,000 (3)	$ 0.77	9/7/2026	9/7/2016
Donald Kellerman	7,500	30,000 (1)	$ 2.26	12/15/2025	12/15/2015
	27,000	27,000 (4)	$ 2.57	3/29/2026	3/29/2016

(1) This option became exercisable for 25% of the underlying shares on December 15, 2016, and thereafter becomes exercisable for the remaining underlying shares in equal monthly installments over three years, resulting in the option being exercisable for 100% of the underlying shares on the fourth anniversary of the grant date.

(2) This option becomes exercisable for 25% of the underlying shares on February 3, 2017, and thereafter becomes exercisable for the remaining underlying shares in equal monthly installments over three years, resulting in the option being exercisable for 100% of the underlying shares on the fourth anniversary of the grant date.

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

(4) This option becomes exercisable for 25% of the underlying shares on March 29, 2017, and thereafter becomes exercisable for the remaining underlying shares in equal monthly installments over three years, resulting in the option being exercisable for 100% of the underlying shares on the fourth anniversary of the grant date.

Severance and Change in Control Arrangements

Pursuant to the terms of Mr. Alataris' employment agreement, if the Company terminates Dr. Alataris other than for cause or Dr. Alataris resigns for good reason, then the Company will continue to pay Dr. Alataris his base salary for twelve months following termination, pay Dr. Alataris a bonus equal to the amount of the annual bonus awarded to him in respect of the year prior to termination, and continue to provide Dr. Alataris with group health and dental benefits for twelve months following termination. In addition, the vesting schedule for any outstanding stock options held by Dr. Alataris will automatically accelerate so that 25% of the total option shares will immediately become exercisable upon termination. If during the one -year period following a change in control of our company, either we terminate Dr. Alataris's employment without cause or Dr. Alataris resigns due to a constructive termination, he will be entitled to receive (i) continued salary for twenty-four months and a lump sum cash amount equal to 229.56% multiplied by the total cost of the projected premiums for group medical, dental and vision insurance for a period of twenty-four months covering the period from and after the date of termination, (ii) a bonus equal to the amount of the annual bonus awarded to him in respect of the year prior to termination, and (iii) his then outstanding equity awards that were granted after the effective date of the Alataris Employment Agreement and that are subject to time based vesting will accelerate vesting in full.

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

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

Director Compensation

Each of our independent directors receives compensation as follows:

- for serving as a member of our board of directors, an annual cash retainer of $35,000 and an annual grant of a non-statutory stock option to purchase a number of shares of our common stock equal to approximately 0.0555% of our then outstanding common stock on a fully-diluted basis (at a per share exercise price equal to fair market value on the date of grant) vesting in equal monthly installments over a period of one year; and
- for serving as the chairperson of the audit committee of the board of directors, an annual cash retainer of $10,000; for serving as the chairperson of the compensation committee of the board of directors, an annual cash retainer of $7,000; and for serving as the chairperson of the nominating and corporate governance committee of the board of directors, an annual cash retainer of $7,000.

The cash fees described above are paid in monthly installments, in arrears. Non-employee directors are also reimbursed upon request for travel and other out-of-pocket expenses incurred in connection with their attendance at meetings of the board and of committees on which they serve.

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our non-employee directors during 2016. For information concerning the compensation paid to Dr. Alataris and Ms. Erbez in their capacities as executive officers, see "Summary Compensation Table" above.

	Fees Earned or Paid in Cash	Option Awards (1)	Total
Joseph P. Hagan	$ 45,000	$ 9,742	$54,742
Bruce D. Steel (3)	-	-	-
John Walker (2)	39,516	26,868	66,384
Troy Wilson	42,000	9,742	51,742
Kleanthis G. Xanthopoulos	42,000	9,742	51,742

(1) Represents the aggregate grant date fair value of stock options and restricted stock awards granted in fiscal year 2016 in accordance with *ASC 718, Compensation-Stock Compensation* . For information regarding the assumptions used in calculating these amounts, see Note 10. Stock-Based Compensation included in this Annual Report.

(2) On May 4, 2016, our Board of Directors appointed John Walker as a Class I director and the Chairman of the Board of Directors.

(3) Only our independent directors receive compensation for service on the Board of Directors. Mr. Steel is not an "independent director" as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules.

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

	Number of Shares Underlying Outstanding Restricted Stock Units	Number of Shares Outstanding in Restricted Stock Awards	Number of Shares Subject to Outstanding Options
Joseph P. Hagan	-	-	48,000
Bruce D. Steel	-	-	-
John Walker	9,478	-	36,813
Troy Wilson	-	3,000	48,301
Kleanthis G. Xanthopoulos	-	6,000	48,301

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is an officer or employee of our company, nor has any of them ever been an officer or employee of our company.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Portions of the response to this item are incorporated herein by reference from the discussion responsive thereto under the caption "Information about Common Stock Ownership" in the 2017 Proxy Statement.

Securities Authorized for Issuance under Equity Compensation Plans

We have two compensation plans under which equity securities are currently authorized for issuance: our Amended and Restated 2014 Equity and Incentive Plan and our 2012 Stock Incentive Plan. In connection with the consummation of our initial public offering of common stock in January 2015, our board of directors terminated the 2012 Stock Incentive Plan effective as of January 27, 2015 and no further awards may be issued under the 2012 Incentive Plan, except that the awards outstanding under the 2012 Stock Incentive Plan at the time of its termination continue to be governed by the terms of the 2012 Stock Incentive Plan. Our 2014 Equity and Incentive Plan was approved by our stockholders in July 2014 and our 2012 Stock Incentive Plan was approved by our stockholders in April 2012. The following table provides information regarding the securities authorized for issuance as of December 31, 2016 under our equity compensation plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,594,058	$ 1.93	55,815
Equity compensation plans not approved by security holders	922,000 (1)	$ 0.62	-
Total	2,516,058		55,815

(1) Represents 670,000 conditional stock options granted to certain executive officers and a nonstatutory stock option to purchase 252,000 shares granted as an inducement grant to our Chief Business Officer and Interim Chief Financial Officer. The conditional stock option grants are subject to approval by the Corporation's stockholders of an amendment to the 2014 Plan while the inducement grant was granted outside of the equity compensation plans approved by security holders.

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

The response to this item is incorporated herein by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Person Transactions", "Information about our Board of Directors and Management — Board Composition" and "Information about our Board of Directors and Management — Committees of the Board of Directors".

Director Independence

As of the date of this report and based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Jay Hagan, John Walker, Troy Wilson and Kleanthis Xanthopoulos is an "independent director" as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules and Rule 10A-3 under the Exchange Act, and that Bruce Steel is not an "independent director." In making this determination, our board of directors considered the relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining the independence of such directors, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

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

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

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

- approves the compensation and benefits of our executive officers;
- reviews and makes recommendations to the board of directors regarding benefit plans and programs for employee compensation; and
- administers our equity compensation plans.

Nominating and Corporate Governance Committee . Our nominating and corporate governance committee is comprised entirely of independent directors. The current members of our nominating and corporate governance committee are Mr. Hagan, Dr. Wilson and Dr. Xanthopoulos, and each of whom is an independent director. The nominating and corporate governance committee:

- identifies individuals qualified to become board members;
- recommends to the board of directors nominations of persons to be elected to the board; and
- advises the board regarding appropriate corporate governance policies and assists the board in achieving them.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table represents aggregate fees billed to us for the years ended December 31, 2016, and 2015, by Marcum LLP, our independent registered public accounting firm:

	Year ended December 31,	
	2016	2015
Audit fees (1)	$ 128,130	$ 133,000
Audit-related fees (2)	-	-
Tax fees (3)	-	-
All other fees (4)	-	-
Total fees	$ 128,130	$ 133,000

(1) Represents fees for professional services primarily related to the audit of our annual consolidated financial statements, the review of our quarterly consolidated financial statements; comfort letters, consents and assistance with the review of documents filed with the SEC; and other accounting services necessary to comply with the standards of the Public Company Accounting Oversight Board (United States).

(2) Represents fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees." There were no audit-related fees for services rendered during 2016 and 2015.

(3) Represents fees for preparation of federal and state tax returns and for tax advice. There were no tax fees for services rendered during 2016 and 2015.

(4) Represents any other fees billed by our principal accountant and not reported under "Audit Fees," "Audit-related fees," and "Tax fees." There were no "All other fees" rendered during 2016 and 2015.

Pre-Approval Policies and Procedures

Our Audit Committee's pre-approval policies or procedures do not allow our management to engage Marcum LLP to provide any audit, review or attestation services or any permitted non-audit services without specific Audit Committee pre-approval of the engagement for those services. All of the services provided by Marcum LLP during 2015 and 2016 were pre-approved.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) FINANCIAL STATEMENTS

Financial Statements—See index on page F-1 to Consolidated Financial Statements on Item 8 of this Annual Report on Form 10-K.

(2) FINANCIAL STATEMENT SCHEDULES

Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZOSANO PHARMA CORPORATION

By: /s/ Konstantinos Alataris
Konstantinos Alataris
President and Chief Executive Officer
Date: February 28, 2017

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Konstantinos Alataris **Konstantinos Alataris**	Chief Executive Officer and President (Principal Executive Officer)	February 28, 2017
/s/ Georgia Erbez **Georgia Erbez**	Chief Business Officer and Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2017
/s/ Joseph Hagan **Joseph Hagan**	Director	February 28, 2017
/s/ Bruce Steel **Bruce Steel**	Director	February 28, 2017
/s/ John Walker **John Walker**	Director	February 28, 2017
/s/ Troy Wilson **Troy Wilson**	Director	February 28, 2017
/s/ Kleanthis G. Xanthopoulos **Kleanthis G. Xanthopoulos**	Director	February 28, 2017

Zosano Pharma Corporation and Subsidiary
Financial Statements
December 31, 2016 and 2015
Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Zosano Pharma Corporation and subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years ended December 31, 2016 and 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Zosano Pharma Corporation and subsidiary, as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for the years ended December 31, 2016 and 2015 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 of the consolidated financial statements, the Company's recurring losses and negative cash flows from operations and the need for additional capital raise substantial doubt about the Company's ability to continue as a going concern. Management plans in regard to these matters is also discussed in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA
February 28, 2017

ZOSANO PHARMA CORPORATION AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value and share amounts)

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,003	$ 6,646
Interest receivable	-	101
Short-term investments in marketable securities	-	30,287
Prepaid expenses and other current assets	273	237
Total current assets	15,276	37,271
Restricted cash	35	35
Property and equipment, net	5,455	7,660
Other long-term assets	140	371
Total assets	$ 20,906	$ 45,337
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,445	$ 1,209
Accrued compensation	1,377	1,275
Secured promissory note, current portion (net of issuance costs and including accrued interest)	5,992	3,360
Other accrued liabilities	1,005	1,036
Total current liabilities	9,819	6,880
Deferred rent	52	45
Secured promissory note, net of issuance costs (including accrued interest)	6,550	11,910
Total liabilities	16,421	18,835
Commitments and contingencies (note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares and none authorized; none issued and outstanding as of December 31, 2016 and 2015, respectively	-	-
Common stock, $0.0001 par value; 100,000,000 shares authorized as of December 31, 2016 and 2015; 16,815,997 shares and 11,966,958 shares issued and outstanding as of December 31, 2016 and 2015, respectively	2	1
Additional paid-in capital	201,252	193,438
Accumulated deficit	(196,769)	(166,891)
Accumulated other comprehensive loss	-	(46)
Stockholders' equity	4,485	26,502
Total liabilities and stockholders' equity	$ 20,906	$ 45,337

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

ZOSANO PHARMA CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share amounts)

	Year Ended December 31,	
	2016	2015
Revenue:		
License fees	$ -	$ 170
Collaboration revenue	-	143
Total revenue	-	313
Operating expenses:		
Research and development	20,457	20,366
General and administrative	8,176	6,315
Total operating expenses	28,633	26,681
Loss from operations	(28,633)	(26,368)
Other income (expense):		
Interest expense, net	(1,192)	(1,564)
Other expense, net	(7)	(97)
Warrant revaluation income	-	48
Loss on debt extinguishment	-	(446)
Net loss	(29,832)	(28,427)
Other comprehensive loss:		
Unrealized loss on marketable securities, net of tax effect	-	(46)
Comprehensive loss	$ (29,832)	$ (28,473)
Net loss per common share – basic and diluted	$ (2.17)	$ (2.49)
Weighted-average shares used in computing net loss per common share – basic and diluted	13,773	11,414

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

ZOSANO PHARMA CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
Balance at December 31, 2014	5,165	$ 1	$ 125,062	$ (138,464)	$ -	$ (13,401)
Issuance of common stock in connection with the Company's initial public offering in January 2015, net of offering cost of $5.2 million	4,500	-	44,215	-	-	44,215
Issuance of common stock in connection with the private placement concurrent with the IPO in January 2015, net of offering cost of $0.5 million	1,364	-	14,475	-	-	14,475
Issuance of common stock upon the conversion of convertible bridge notes in January 2015	792	-	7,407	-	-	7,407
Issuance of common stock to employees upon the exercise of stock options for cash at $1.28 to $1.40 per share	27	-	37	-	-	37
Issuance and release of restricted stock to certain board members as remuneration	9	-	91	-	-	91
Issuance of common stock in connection with the exercise of the overallotment option of the IPO in February 2015, net of offering cost of $0.1 million	110	-	1,125	-	-	1,125
Issuance of warrant in connection with debt restructuring (June 23, 2015)	-	-	212	-	-	212
Reclassification of warrant liability to equity	-	-	252	-	-	252
Stock-based compensation	-	-	562	-	-	562
Net loss	-	-	-	(28,427)	-	(28,427)
Unrealized loss on marketable securities	-	-	-	-	(46)	(46)
Balance at December 31, 2015	11,967	1	193,438	(166,891)	(46)	26,502
Issuance of common stock in connection with PIPE offering in August 2016, net of issuance costs	4,800	1	6,642	-	-	6,643
Redemption of common stock upon cashless exercise of stock options	(96)	-	(1)	-	-	(1)
Issuance of common stock to employees upon the exercise of stock options for cash at $1.81 to $2.28 per share	145	-	5	-	-	5
Stock-based compensation	-	-	1,168	-	-	1,168
Net loss	-	-	-	(29,878)	46	(29,832)
Balance at December 31, 2016	16,816	$ 2	$ 201,252	$ (196,769)	$ -	$ 4,485

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

ZOSANO PHARMA CORPORATION AND SUBSIDIARY
CO NSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (29,832)	$ (28,427)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	2,543	2,452
Stock-based compensation	1,168	653
Loss on debt extinguishment	-	446
Gain on sale of equipment	(51)	-
Loss on sale of Zosano Inc.	(57)	-
Amortization of debt discount/accretion of premium	(31)	(17)
Accretion of interest	259	313
Revaluation of warrants to fair value	-	(48)
Impairment of long-lived assets	-	145
Deferred rent	6	(52)
Change in operating assets and liabilities:		
Accounts receivable	-	111
Interest receivable	101	(101)
Prepaid expenses and other assets	(36)	(222)
Accounts payable	172	724
Accrued compensation and other accrued liabilities	72	38
Deferred revenue	-	(170)
Net cash used in operating activities	(25,686)	(24,155)
Cash flow from investing activities:		
Purchase of property and equipment	(287)	(432)
Proceeds from sales of property and equipment	63	-
Purchase of marketable securities	-	(42,606)
Proceeds from maturities of investments in marketable securities	30,208	12,120
Proceeds from sale of Zosano Inc.	225	-
(Increase) decrease in other investment	63	(28)
Net cash provided by (used in) investing activities	30,272	(30,946)
Cash flow from financing activities:		
Proceeds from issuance of securities in private investment in public equity (PIPE), net	6,642	-
Payments of loan principal	(2,876)	(11,465)
Proceeds from exercise of stock options and issuance of common stock	5	37
Proceeds from debt financing, net of issuance costs	-	11,705
Proceeds from initial public offering of securities, net of underwriting commissions and discounts	-	47,140
Payment of deferred offering costs	-	(1,359)
Proceeds from a private placement concurrent with the initial public offering, net of private placement fee	-	14,475
Net cash provided by financing activities	3,771	60,533
Net increase in cash and cash equivalents	8,357	5,432
Cash and cash equivalents at beginning of period	6,646	1,214
Cash and cash equivalents at end of period	$ 15,003	$ 6,646

	Year Ended December 31,	
	2016	2015
Supplemental cash flow information:		
Interest paid	$ 1,166	$3,591
Non-cash investing and financing activities:		
Acquisition of property and equipment under accounts payable	$ 64	-
Conversion of debt to equity	$ -	$7,407
Issuance of warrant in connection with debt financing	$ -	$ 212
Reclassification of warrant liability to equity	$ -	$ 252

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

Zosano Pharma Corporation and Subsidiary
Notes to Consolidated Financial Statements
For the Years Ended December 31, 2016 and 2015

1. Organization

The Company

Zosano Pharma Corporation and subsidiary (the Company) is a clinical stage pharmaceutical company focused on providing rapid symptom relief to patients using the Company's proprietary intracutaneous delivery system to administer drugs through the skin. The Company is focused on developing products that deliver established molecules with known safety and efficacy profiles primarily for treatment of central nervous system indications. Our intracutaneous technology offers rapid onset, consistent drug delivery, improved ease of use and room-temperature stability benefits that we believe would provide a potentially favorable alternative to using oral formulations or injections.

The Company had one wholly owned subsidiary, ZP Opco, Inc. ("Opco"), as of December 31, 2016, through which the Company conducts its primary research and development activities. As of December 31, 2015, the Company had two wholly owned subsidiaries, Opco and ZP Group LLC. ZP Group LLC was originally a joint venture with Asahi Kasei Pharmaceuticals USA (Asahi). The joint venture ceased operations in December 2013 and ZP Group LLC was later dissolved on December 30, 2016.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of the accompanying consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Liquidity and Substantial Doubt in Going Concern

As of December 31, 2016, the Company has an accumulated deficit of $196.8 million as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the next twelve months from issuance of these financial statements. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidate. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate sources.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year from the issuance of the statement. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations.

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

The Company has incurred significant operating losses and had an accumulated deficit of $196.8 million as of December 31, 2016. The Company has financed its operations primarily through the sale of equity securities, debt financing and payments received under its former licensing and collaboration agreements with pharmaceutical companies. To date, none of the Company's product candidates have been approved by the Food and Drug Administration for sale.

The Company will continue to require additional financing to develop its product candidates and fund operating losses. Management intends to seek capital to support company initiatives through equity or debt financing, collaboration or other arrangements with corporate partners, and/or other sources of financing. However, if such financing is not available at adequate levels or on acceptable terms, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of, or eliminate some of its development programs, out-license intellectual property rights, or a combination of the above, which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to meet its scheduled obligations on a timely basis, if at all. Although management has been successful in raising capital in the past, most recently in August 2016, there can be no assurance that the Company will be successful, or that any needed financing will be available in the future at terms acceptable to the Company. This raises substantial doubt about our ability to continue as a going concern. As of December 31, 2016, the Company had an accumulated deficit of $196.8 million and the Company does not have sufficient cash resources to meet its plans in the next twelve months following the issuance of these financial statements.

Consolidation

The consolidated financial statements include the accounts of Zosano Pharma Corporation and Opco. Intercompany balances and transactions have been eliminated in consolidation.

Segment Reporting

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

Cash Equivalents

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

Investments in Marketable Securities

The Company classifies its investments in marketable securities as available-for-sale. Investments with original maturities between three and twelve (12) months are considered short-term investments. Investments with original maturities greater than 12 months are considered long-term investments. The Company's investments that are classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums and discounts are amortized (accreted) over the life of the corresponding security as an adjustment to its yield. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

Restricted Cash

The Company entered into a pledge and security agreement with a bank whereby $35,000 was held as a security for corporate purchasing cards. The balance is classified as restricted cash as of December 31, 2016 and 2015, respectively.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company invests its excess cash in money market funds, U.S. government agency bonds, corporate notes, certificates of deposit and commercial paper. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. Other than for obligations of the U.S. government, the Company's policy is that no more than 5% of its investments may be concentrated in a single issuer. Bank deposits are held by a single financial institution having a strong credit rating and these deposits may at times be in excess of FDIC insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and short-term investments and issuers of investments to the extent recorded on the balance sheets.

Property and Equipment

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

Impairment of Long-Lived Assets

The Company identifies and records impairment losses on long-lived assets used in operations when events and changes in circumstances indicate that the carrying amount of an asset likely is not recoverable. Recoverability is measured by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. No impairment charge was recorded for the years ended December 31, 2016 and 2015.

Long-Term Investment

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

The Company accounted for its investment in the Shell Corporation using the cost method of accounting and classified it as other long-term assets in its consolidated balance sheet. In November 2016, the Company sold its interest in Zosano, Inc. for an aggregate cash selling price of $225,000 and recorded a realized loss of approximately $57,000 in its consolidated income statement under the caption Other expense, net.

Debt Issuance Costs

Deferred issuance costs related to the Company's debt are presented as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts.

Deferred Rent

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

Promissory Notes

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

Revenue Recognition

The Company recognizes revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable, and (iv) collectability is reasonably assured. Revenue under collaboration and license arrangements is recognized based on the performance requirements of the contract.

Research and Development Expenses

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

For the year ended December 31, 2016, the Company incurred research and development costs of approximately $11.9 million in connection with the Company's research and development efforts and approximately $8.6 million in the manufacturing of the Company's intracutaneous delivery system for development of the Company's product candidate. For the year ended December 31, 2015, the Company incurred research and development costs of $0.1 million in support of the Company's collaborative development services to Novo Nordisk A/S (Novo Nordisk), $9.3 million in connection with the Company's research and development efforts, and $10.9 million in the manufacturing of the Company's intracutaneous delivery system for the development of the Company's product candidates.

Clinical Trial Costs

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

Stock-Based Compensation

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

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

Income Taxes

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

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive loss. The only component of the Company's other comprehensive loss is the unrealized losses on the Company's marketable securities at December 31, 2015.

Net Loss Per Common Share

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

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

	December 31,	
	2016	2015
	(in shares)	
Warrants to purchase common stock	9,672,379	72,379
Options to purchase common stock	1,846,058(1)	972,951
	11,518,437	1,045,330

(1) Total does not include 670,000 conditional stock options granted to certain executives since these grants are subject to approval by the Corporation's shareholders of an amendment of the 2014 Plan.

Recently Issued Accounting Standards

In November 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-18, *Statement of Cash Flows* . This ASU provides guidance on the presentation of cash, cash equivalents and restricted cash in the statement of cash flows to reduce the current diversity in practice. The amendments in this update are effective for public business entities for fiscal year beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. Adoption of this standard is not expected to have a material impact on the financial statements.

In March 2016, the FASB issued Accounting Standards Update (ASU) 2016-09, *Improvements to Employee Share-Based Payment Accounting* . This Update is part of the FASB's simplification initiative. The areas of

simplification involve several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. The Company has adopted this standard for its fiscal year 2017. Adoption of this standard will not have a material impact on the financial statements.

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

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

In May 2014, the Financial Accounting Standards Board, or FASB, issued Auditing Standard Updated (ASU), No. 2014-09, *Revenue from Contracts with Customers* . This ASU outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the ASU by one year to December 15, 2017 for fiscal years, and interim periods, beginning after that date. Early adoption is permitted, but not before the original effective date (annual periods beginning after December 15, 2016). Adoption of this standard is not expected to have a material impact on the financial statements.

3. Cash, Cash Equivalents and Investments

The following is a summary of the Company's cash, cash equivalents, and marketable security investments:

	December 31, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Cash in bank	$ 3,342	$ -	$ -	$ 3,342
Money market funds	11,661	-	-	11,661
Certificates of deposit (restricted)	35	-	-	35
	$ 15,038	$ -	$ -	$ 15,038
Classified as:				
Cash and cash equivalent				$ 15,003
Restricted cash				35
				$ 15,038

	December 31, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Cash in bank	$ 2,997	$ -	$ -	$ 2,997
Money market funds	3,649	-	-	3,649
Certificates of deposit (restricted)	35	-	-	35
Certificates of deposit	5,040	-	(4)	5,036
Corporate bonds	11,749	-	(22)	11,727
U.S. government agency bonds	13,544	-	(20)	13,524
	$ 37,014	$ -	$ (46)	$ 36,968
Classified as:				
Cash and cash equivalent				$ 6,646
Restricted cash				35
Short-term investments in marketable securities				30,287
				$ 36,968

Short-term investment in marketable securities as of December 31, 2016 and 2015 were zero and $30.3 million, respectively.

There were no realized gains and losses on available-for-sale securities for the years ended December 31, 2016 and 2015.

4. Fair Value of Financial Instruments

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

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

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

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

The following tables set forth the fair value of the Company's financial instruments as of December 31, 2016 and 2015:

	December 31, 2016			
	Level I	Level II	Level III	Total
	(in thousands)			
Financial Assets:				
Money market funds	$ 11,661	$ -	$ -	$ 11,661
Total financial assets	$ 11,661	$ -	$ -	$ 11,661

	December 31, 2015			
	Level I	Level II	Level III	Total
	(in thousands)			
Financial Assets:				
Money market funds	$ 3,649	$ -	$ -	$ 3,649
Corporate bonds	-	11,727	-	11,727
U.S. government agency bonds	-	13,524	-	13,524
Total financial assets	$ 3,649	$ 25,251	$ -	$ 28,900

There were no transfers between levels within the fair value hierarchy during the periods presented.

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

	Common Stock Warrant Liability
	(in thousands)
Balance at December 31, 2014	$ 300
Change in fair value of freestanding warrant liability	(48)
Reclassification to equity	(252)
Balance at December 31, 2015	$ -

5. Property and Equipment

The following summarizes the Company's property and equipment as of December 31, 2016 and 2015 (in thousands):

	2016	2015
Laboratory and office equipment	$ 1,127	$ 1,112
Manufacturing equipment	10,857	10,730
Computer equipment and software	314	229
Leasehold improvements	15,694	15,534
Construction in progress	1,961	2,066
	29,953	29,671
Less: accumulated depreciation	(24,498)	(22,011)
	$ 5,455	$ 7,660

Depreciation and amortization expense was approximately $2.5 million and $2.5 million for the years ended December 31, 2016 and 2015, respectively.

6. Research and Development Collaboration and License Agreements

Former Collaboration Agreement with Novo Nordisk

Pursuant to the collaboration agreement with Novo Nordisk dated January 31, 2014 related to the development of an intracutaneous presentation of select Novo Nordisk glucagon-like peptide-1 (GLP-1) analogues, the Company received a non-refundable upfront payment of $1.0 million. The upfront payment was recorded as deferred revenue in the consolidated balance sheet and recognized as license fees revenue over the performance period that was consistent with the term of performance obligations under the specified feasibility study plan.

In July 2015, the Company announced that Novo Nordisk had notified the Company of its intention to discontinue the collaboration agreement. The termination became effective on October 27, 2015, and all technology rights licensed to Novo Nordisk related to the field of GLP-1 products reverted to the Company. As of June 30, 2015, the collaboration with Novo Nordisk was no longer a source of revenue or research and development expense for the Company.

For the year ended December 31, 2015, the Company recognized $46,000 as service revenue pursuant to the Novo Nordisk collaboration agreement. The corresponding cost of service revenue is recorded as research and development expense in the consolidated statements of operation. For the year ended December 31, 2015, the Company recorded $53,000 as cost of collaboration service revenue in connection with the Novo Nordisk collaboration agreement.

7. Debt Financing

Conversion of Related Parties Convertible Promissory Notes

In 2013 and 2014, the Company entered into various convertible promissory notes with related party stockholders, BMV Direct SOTRS LP, BMV Direct SO LP, and New Enterprise Associates 12, Limited Partnership. On January 30, 2015, upon the closing of the Company's initial public offering, the principal and all unpaid and accrued interest on the September 2013 and February 2014 and December 2014 convertible promissory notes outstanding as of January 30, 2015, totaling $7.4 million, were automatically converted into an aggregate of 792,182 shares of common stock at a price equal to 85% of the initial public offering price, resulting in the reclassification of liability for such notes to permanent equity.

Senior Secured Term Loan with Hercules

In June 2014, the Company entered into a loan and security agreement with Hercules Capital, Inc. (Hercules), previously known as Hercules Technology Growth Capital, Inc., which provided the Company

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

The first amendment to the loan and security agreement with Hercules provides that the $15.0 million principal balance will be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. The interest rate on the secured term loan with Hercules was 7.95% as of December 31, 2016 and 2015. In addition, the Company will be obligated to pay a $100,000 legacy end of term charge on the earlier of June 1, 2017 or the date the Company prepays the Hercules Term Loan and a $351,135 end of term charge on the earlier of loan maturity or at the date the Company prepays the Hercules Term Loan. The Company may prepay all, but not less than all, of the Hercules Term Loan subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of the Company's tangible and intangible properties and assets, including intellectual properties.

The amended Hercules Term Loan has substantially different terms than the original loan and in accordance with ASC 470-50, *Debt Modifications and Extinguishments* , the original debt was considered extinguished. Accordingly, the Company wrote off the value of the original debt, including unamortized discount, as of the amendment date and recorded a liability for the new debt based on its fair value as determined using the income approach based on a discounted cash flow model. The transaction resulted in the Company recording a loss on debt extinguishment of $0.4 million on its consolidated statement of operations for the year ended December 31, 2015.

In connection with the first amendment to the loan and security agreement with Hercules, the Company issued Hercules a warrant to purchase 40,705 shares of the Company's common stock at an exercise price of $7.37 per share. The warrant was recorded at fair value on the date of issuance and treated as a debt discount which is amortized to interest expense over the term of the loan using the effective interest method. (See Note 8 for a discussion of warrants to purchase common stock.)

In addition, the Company incurred legal and closing costs totaling $0.1 million, including an $85,000 upfront loan origination fee paid to Hercules and $32,000 of legal costs, in connection with the first amendment to the loan and security agreement with Hercules. These debt issuance costs have been recorded as a direct deduction from the related debt liability. The following is a summary of the Company's long-term debt, net of unamortized debt discount and issuance costs, as of December 31, 2016 and 2015 (in thousands):

	December 31, 2016	December 31, 2015
Principal amount	$ 12,122	$ 15,000
Less: unamortized debt issuance costs	(41)	(91)
unamortized fair value of free standing warrant	(75)	(163)
Plus: unamortized fair value debt premium	143	310
accrued terminal interest	310	111
accrued interest	83	103
Secured promissory note, net of unamortized debt issuance cost and premium	$ 12,542	$ 15,270
Secured promissory note, current portion	5,992	3,360
Secured promissory note, long-term portion	6,550	11,910
Secured promissory note, net of unamortized debt issuance cost and premium	$ 12,542	$ 15,270

Secured Financing with BMR

In connection with the recapitalization of the Company in April 2012, the Company renegotiated its lease agreement with its landlord, BioMed Realty Holdings, Inc. and affiliates (BMR Holdings), to include reduced rent obligations. In connection with the rent reduction, the Company issued a secured promissory note (the BMR Note) for the principal amount of approximately $8.6 million to BMR Holdings in 2012, which was subsequently assigned to its affiliate BMV Direct SOTRS LP, one of our largest shareholders, and all previously accrued interest, unpaid rent, future rent obligations and other fees due to BMR Holdings were either rolled into the BMR Note or eliminated. In June 2015, the Company terminated the BMR Note by prepaying the outstanding principal and all accrued interest totaling $11.4 million.

As of December 31, 2016, future minimum payments on the Company's long-term debt, including payment of principal and interest, for each year ending December 31 are as follows:

	Principal	Interest	End of Term Fees
		(in thousands)	
2017	$ 5,806	$ 765	$ 100
2018	6,316	280	351
	$ 12,122	$ 1,045	$ 451

8. Stockholders' Equity

The Company's certificate of incorporation authorizes the Company to issue 30,000,000 shares of common stock. On July 11, 2014, the Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation pursuant to which the Company was authorized to issue up to 100,000,000 shares of common stock and up to 5,000,000 shares of preferred stock. The amendment became effective upon the closing of the Company's IPO in January 2015. Common stockholders are entitled to dividends if and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. Each share of

common stock is entitled to one vote. As of December 31, 2016 and 2015, the Company had 16,815,997 shares and 11,966,958 shares of common stock issued and outstanding, respectively. No shares of preferred stock were issued as of December 31, 2016 and 2015.

Initial Public Offering

On January 30, 2015, the Company completed an initial public offering ("IPO") of its common stock on the NASDAQ Capital Market. The Company sold an aggregate of 4,500,000 shares of common stock under a registration statement on Form S-1, declared effective on January 27, 2015, at a public offering price of $11.00 per share. Net proceeds to the Company were approximately $44.2 million, after deducting underwriting commissions and expenses. On February 27, 2015, the underwriters exercised the overallotment option resulting in the Company's issuing an additional 110,000 shares of its common stock at $11.00 per share, resulting in additional net proceeds of approximately $1.1 million after underwriting discounts.

Concurrent Private Placement – January 2015

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

Private Investment in Public Equity ("PIPE") – August 2016

On August 15, 2016, the Company entered into a Securities Purchase Agreement ("Purchase Agreement") between the Company and certain investors, including members of the Company's Board of Directors and executive management, pursuant to which the Company sold and issued shares of common stock and warrants to purchase shares of common stock for aggregate gross proceeds of $7.5 million. Costs related to the offering were $0.9 million. Pursuant to the Purchase Agreement, the Company sold 4,800,000 common shares at $1.32 per common share, the closing price per share on August 15, 2016, for gross proceeds of $6.3 million. Additionally, 9,600,000 warrants were sold, at a price of $0.125 per warrant, for gross proceeds of $1.2 million. Each warrant grants the holder the right to purchase one share of the Company's common stock. The Company granted 4,800,000 Series A Warrants and 4,800,000 Series B Warrants. Series A Warrants and Series B Warrants have a per share exercise price of $1.45 and $1.55, respectively, and will expire one year and one week and five years, respectively, from the date of issuance, August 19, 2016. Certain of our directors and executive officers purchased an aggregate of 275,454 shares of common stock and an aggregate of 550,908 warrants in this offering at the same price as the other investors.

In connection with the PIPE transaction, the Company filed a registration statement, Form S-3, with the U.S. Securities and Exchange Commission, or SEC, registering for resale the shares of common stock and shares of common stock issuable upon exercise of the warrants. The registration statement was declared effective by the SEC on September 23, 2016.

Hercules Warrants

In connection with the Company's entry into the loan and security agreement with Hercules in June 2014, the Company issued Hercules a warrant to purchase $280,000 worth of the Company's stock. The warrant was initially recorded on the Company's consolidated balance sheet at fair value on the date of issuance and treated as a debt discount that is amortized to interest expense over the debt repayment period using the effective interest method. As a result of the pricing of the Company's IPO on January 27, 2015, and pursuant to the agreement the exercise price was fixed at $8.84 per share, resulting in the warrant being exercisable for 31,674 shares (warrant amount of $280,000 divided by $8.84 per share) of the Company's common stock. Accordingly, management concluded that the requirements for equity classification had been met and effected a reclassification of the warrant liability of $0.3 million to equity. The warrant is exercisable at any time, in whole or in part, until five years from the date of the Company's IPO.

In connection with the Company's entry into the first amendment to loan and security agreement with Hercules in June 2015, the Company issued Hercules a warrant to purchase 40,705 shares of the Company's common stock at an exercise price of $7.37 per share. Hercules can exercise its purchase right under the warrant, in whole or in part, at any time until June 23, 2020. The warrant was recorded at fair value on the date of issuance and treated as a debt discount that is being amortized to interest expense over the term of the loan using the effective interest method. The Company classified the warrant to equity and recorded the fair value of the warrant of $212,000 to additional paid-in capital in its consolidated balance sheet. The warrant fair value was determined by using the Black-Scholes option valuation model with the following assumptions: expected term of 5.00 years; volatility of 89%; risk free interest rate of 1.73% and no dividend yield.

9. Commitments and Contingencies

The Company has an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings, for its office, research and development, and manufacturing facilities in Fremont, California. The Company entered into a fifth amendment to the lease in April 2012 which extended the lease term through March 2019 and provided a reduction in annual rents due to a potential reduction of premises from a recapturable premises clause. In June 2015, the Company entered into a sixth amendment to the lease, pursuant to which the landlord's option to recapture a specified portion of the leased premises (comprising approximately 29,348 square feet of the approximate total 55,588 square feet of leased premises) was suspended.

The Company records rent expense under the lease on a straight-line basis over the term of the lease. The difference between the actual lease payments and the expense recognized under the lease, along with the unamortized tenant improvement allowances, resulted in a net deferred rent liability of $52,000 and $45,000 as of December 31, 2016 and 2015, respectively.

For the years ended December 31, 2016 and 2015, rent expense under operating leases was $0.6 million and $0.6 million, respectively.

As of December 31, 2016, future minimum payments under non-cancelable operating leases for each year ending December 31 are as follows (in thousands):

2017	$ 637
2018	650
2019	164
	$ 1,451

Contractual Commitments

In February 2016, we amended Dr. Alataris' employment agreement to reflect his capacity to serve as our Chief Executive Officer starting January 2016 at a base salary of $450,000. The amended employment agreement provides for a target annual bonus of 50% of his annual base salary for 2016, to be determined by the board of directors in its discretion based on company performance against goals established annually by the compensation committee, as well as the Company's then prevailing cash position. Pursuant to the terms of Mr. Alataris' employment agreement, if the Company terminates Dr. Alataris other than for cause or Dr. Alataris resigns for good reason, then the Company will continue to pay Dr. Alataris his base salary for twelve months following termination, pay Dr. Alataris a bonus equal to the amount of the annual bonus awarded to him in respect of the year prior to termination, and continue to provide Dr. Alataris with group health and dental benefits for twelve months following termination. In addition, the vesting schedule for any outstanding stock options held by Dr. Alataris will automatically accelerate so that 25% of the total option shares will immediately become exercisable upon termination. If during the one-year period following a change in control of our company, either we terminate Dr. Alataris's employment without cause or Dr. Alataris resigns due to a constructive termination, he will be entitled to receive (i) continued salary for twenty-four months and a lump sum cash amount equal to 229.56% multiplied by the total cost of the projected premiums for group medical,

dental and vision insurance for a period of twenty-four months covering the period from and after the date of termination, (ii) a bonus equal to the amount of the annual bonus awarded to him in respect of the year prior to termination, and (iii) his then outstanding equity awards that were granted after the effective date of the Alataris Employment Agreement and that are subject to time based vesting will accelerate vesting in full.

Ms. Erbez's employment letter agreement provides for an initial base salary of $350,000, subject to increase from time to time. Ms. Erbez joined the Company on September 7, 2016. Ms. Erbez employment letter agreement provides for a target annual bonus of 40% of her annual base salary, to be determined by the board of directors in its discretion after consideration of a proposal from the CEO based on company performance against goals established annually by the compensation committee, as well as the Company's then prevailing cash position. Pursuant to the terms of Ms. Erbez's employment agreement, if the Company terminates Ms. Erbez other than for cause, or in the event of her resignation for good reason, then, for the six month period following such termination of her employment, the Company will continue to pay Ms. Erbez her base salary and provide her with group medical, dental and vision insurance. In addition, the vesting schedule for any outstanding stock options held by Ms. Erbez on the date of termination will automatically accelerate so that 25% of the then unvested total option shares will immediately become exercisable upon such termination. If, during the one-year period following a change in control of our Company, either we terminate Ms. Erbez's employment without cause or Ms. Erbez resigns for good reason, then she shall be entitled to receive a lump sum severance payment equal to twelve months of her base salary and a lump sum payment equal to the total cost of projected premiums for group medical, dental and vision insurance for a period of twelve months. In such event, the vesting schedule for any outstanding stock options held by Ms. Erbez will automatically accelerate so that 100% of the total option shares will immediately become exercisable upon such termination.

Indemnification and Guarantees

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2016.

10. Stock-Based Compensation

The 2012 Stock Incentive Plan

The 2012 Stock Incentive Plan (the 2012 Plan) provides for the granting of stock options and restricted stock awards to employees, directors and consultants of the Company. Options granted under the 2012 Plan may be either incentive stock options or nonqualified stock options. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. Options and awards under the 2012 Plan may be granted for periods of up to ten years. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions as determined by the Board of Directors. In connection with the Company's initial public offering of its common stock, the Company's board of directors terminated the 2012 Plan effective as of January 27, 2015 and no further awards may be issued under the 2012 Plan, provided however that the awards outstanding under the 2012 Plan at January 27, 2015 continue to be governed by the terms of the 2012 Plan.

The 2014 Equity and Incentive Plan

The 2014 Equity and Incentive Plan (the 2014 Plan) provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company's common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of December 31, 2016, the Company had reserved 1,400,000 shares of our common stock for issuance under our 2014 Plan, subject to automatic annual increases as set forth in the plan. Options and awards under the 2014 Plan may be granted for periods of up to ten years. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions and the right of repurchase by the Company on unvested shares as determined by the Board of Directors. As of December 31, 2016, the Company had 55,815 shares available for grant under the 2014 Plan.

2015 Stock Option Exchange Program

In November 2015, the Company announced an option exchange program, implemented by way of a tender offer pursuant to applicable SEC rules. Under the exchange program, eligible optionholders had an opportunity to exchange eligible out-of-the-money stock options for a new stock options issued under the Company's 2014 Equity Incentive Plan. On December 15, 2015, the Company issued new stock options to purchase an aggregate of 445,394 shares in exchange for the surrender of out-of-the-money stock options to purchase a like number of shares. The exercise price of the new option was $2.26 per share, which was the closing price of the Company's common stock as reported by the Nasdaq Capital Market on the first business day after the expiration of the exchange offer. The new options granted to employees vest over four years, with 25% of the shares vesting on the first anniversary of the vesting start date and the remaining shares vesting in equal installments over a 36 month period. As a result of the option exchange program, the Company will recognize additional stock-based compensation expense of $0.2 million over the four year vesting period of the new stock options.

On September 7, 2016, the Company awarded an inducement option grant to our Chief Business Officer to purchase 252,000 shares of our common stock at an exercise price of $0.77 per share. This inducement option grant was issued outside of the existing equity compensation plans in accordance with NASDAQ listing rule 5635(c)(4).

On November 2, 2016, the Company granted a total of 670,000 conditional stock options at $0.57 per share to certain executive officers. The grants are subject to approval by the Corporation's stockholders of an amendment to the 2014 Plan that would increase the number of shares available for issuance by an amount sufficient to cover the new grants.

The following table summarizes option and award activity, excluding conditional grants and the inducement grant, for the fiscal years ended December 31, 2015 and 2016:

	Shares Available for Grant	Outstanding Number of Shares	Weighted-Average Exercise Price per Share	Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2014	28,701	497,753	$ 1.59	6.77	
Shares reserved under the 2014 Plan	1,400,000	-			
Options granted	(1,002,788)	1,002,788	$ 5.46		
Options exercised	-	(27,017)	$ 1.38		
Restricted stock vested and released	-	(9,000)	$ -		
Options cancelled/forfeited/exchanged	491,573	(491,573)	$ 8.01		
Shares expired under 2012 Plan	(58,880)	-			
Balance at December 31, 2015	858,606	972,951	$ 2.35	7.40	
Options granted	(1,030,463)	1,030,463	$ 1.67		
Options exercised	-	(145,892)	$ 1.53		
Restricted stock award granted	(9,478)	-	$ -		
Options cancelled/forfeited/expired	263,464	(263,464)	$ 2.73		
Shares expired under 2012 Plan	(26,314)	-			
Balance at December 31, 2016	55,815	1,594,058			
Exercisable at December 31, 2016		398,321	$ 2.14	5.96	$ 1,575
Vested or expected to vest at December 31, 2016		1,501,088	$ 1.95	8.45	$ 18,900

The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company's common stock for in-the-money options at December 31, 2016. The Company completed its initial public offering on January 30, 2015 at a price of $11.00 per common share. As such, management believes the fair value of its common shares at December 31, 2014 closely approximated its value at its initial public offering due to the short time lapse between its fiscal year-end 2014 and the offering date.

The following summarizes the composition of stock options outstanding and exercisable within the approved stock options plans, which excludes conditional grants and the inducement grant, as of December 31, 2016:

	Options Outstanding			Options Exercisable	
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (in years)
$0.57 - $0.57	90,000	9.84	0.57	7,498	0.57
$0.85 - $0.85	400,000	9.97	0.85	-	-
$1.27 - $2.11	256,863	4.58	1.40	220,287	1.39
$2.26 - $2.26	328,394	8.96	2.26	83,349	2.26
$2.34 - $9.29	518,801	8.84	3.04	87,187	4.04

The weighted-average grant-date fair value of options and awards granted within the approved stock options plans during the years ended December 31, 2016 and 2015 were $1.67 and $5.51, respectively. The total fair value of options and awards that vested during the years ended December 31, 2016 and 2015 were $0.5 million and $0.2 million, respectively.

Options Granted to Non-employees

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

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows:

	Period Ended December 31,	
	2016	2015
	(in thousands)	
Research and development	$ 227	$ 213
Manufacturing	226	188
General and administrative	715	252
	$ 1,168	$ 653

At December 31, 2016 and 2015, the Company had $2.6 million and $5.1 million, respectively, of total unrecognized stock-based compensation, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 3.19 years.

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

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

	Year Ended December 31,	
	2016	2015
Dividend yield	0%	0%
Risk-free interest rate	1.06% – 2.20%	1.07% – 2.01%
Expected volatility	89%	89%
Expected term (years)	6.08	6.08

11. Restructuring and Severance

In January 2016, the Company terminated the employment of its Chief Executive Officer (CEO). Pursuant to the terms of his employment agreement, the Company was obligated to its former CEO for certain severance payments, continuation of benefits, and acceleration of vesting of the remaining outstanding unvested stock

options. In the first fiscal quarter of 2016, the Company had recorded a liability and an expense of $0.4 million for postemployment severance and benefits and a stock-based compensation expense of approximately $16,000 related to the acceleration of vesting of the former CEO's stock options. For the year ended December 31, 2016, the Company had paid $0.4 million of the postemployment severance and benefits.

In March 2016, the Company consolidated its operations with the primary focus on continued development of M207, our product candidate (previously known as ZP-Triptan). In accordance with ASC 420, Exit or Disposal Cost Obligations, the aggregate restructuring charges of approximately $0.5 million represent one-time termination benefits, comprised principally of severance, benefit continuation costs and outplacement services. In the first fiscal quarter of 2016, the Company had recorded $0.5 million as a liability and an expense and a stock-based compensation expense of approximately $5,000 on the acceleration of vesting of certain stock options related to the elimination of certain senior positions in connection with the workforce reduction. For the year ended December 31, 2016, the Company paid approximately $0.5 million.

12. Income Taxes

The Company has incurred cumulative net operating losses since inception and, consequently, has not recorded any income tax expense for the years ended December 31, 2016 and 2015 due to its net operating loss position.

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

	Year Ended December 31,			
	2016		2015	
Federal statutory tax rate	(34.00)	%	(34.00)	%
State statutory tax rate	(5.83)	%	(5.83)	%
Derecognition due to Section 382 and 383	231.11	%	-	%
Warrant revaluation	-	%	0.07	%
Stock-based compensation	1.00	%	0.62	%
Permanent items	(3.17)	%	(1.97)	%
Change in valuation allowance	(189.11)	%	41.11	%
	-	%	-	%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2016 and 2015, the Company had net deferred tax assets of $18.9 million and $75.8 million, respectively. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance decreased by approximately $56.9 million during the year ended December 31, 2016, and increased by approximately $13.7 million during the year ended December 31, 2015.

Significant components of the Company's net deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Net operating loss carryforwards	$ 14,034	$ 68,593
Research and development credits	2,617	5,251
Depreciation and amortization	345	(147)
Accruals	658	551
Deferred rent	1,066	1,540
Capital loss carryforward	$ 33	$ -
Stock-based compensation	190	48
Other	2	3
Net deferred tax assets	18,945	75,839
Valuation allowance	(18,945)	(75,839)
	$ -	$ -

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately $35.2 million and state net operating loss carryforwards of approximately $35.5 million. Of the total net operating loss carryforwards, approximately $26.4 thousand for federal and $26.4 thousand for state, related to windfall stock option deductions which, when realized, will be credited to equity. As of December 31, 2015, the Company had federal net operating loss carryforwards of approximately $172.7 million and state net operating loss carryforwards of approximately $169.6 million. Of the total net operating loss carryforwards, approximately $26.4 thousand for federal and $26.4 thousand for state, related to windfall stock option deductions which, when realized, will be credited to equity. If not utilized, the federal net operating loss carryforwards will expire from 2026 through 2036, and state net operating loss carryforwards will expire from 2017 through 2036.

If the Company experiences a greater than 50 percentage point aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company's stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. During the year ended December 31, 2016, the Company completed a 382 study and determined that ownership changes occurred on February 26, 2014 and November 30, 2015. As a result of the ownership changes, approximately $164.8 million and $155.8 million of the NOLs will expire unutilized for federal and California purposes, respectively. As of December 31, 2016, the Company has derecognized NOL related DTAs in the tax affected amounts of $56.0 million and $9.1 million for federal and California purposes, respectively. The ability of the Company to use its remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

In December 2015, Congress passed a tax extenders package, the Protecting Americans from Tax Hikes (PATH) Act of 2015 that permanently extended the federal R&D credit. As of December 31, 2016, the Company had federal and state research and development credit carryforwards of approximately $0.5 million and $4.2 million, respectively. As of December 31, 2015, the Company had federal and state research and development credit carryforwards of approximately $4.0 million and $4.0 million, respectively. If not utilized, the federal tax credits will begin to expire in 2026 and state tax credits currently do not expire. Research and development credits are subject to IRC section 383. In the event of a change in ownership as defined by this code section, the usage of the credits may be limited. As a result of the previously mentioned ownership changes, the Company has derecognized approximately $3.9 million of gross federal R&D credit-related DTAs due to the Section 383 limitation. As of December 31, 2016, the Company has not derecognized any of the California R&D credit-related DTAs because the credits do not expire.

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

Uncertain Income Tax Positions

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

The Company had approximately $0.9 million of unrecognized tax benefits as of December 31, 2016 and approximately $1.6 million of unrecognized tax benefits as of December 31, 2015. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits will reduce the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months. A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows:

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Balance at the beginning of year	$ 1,582	$ 1,415
(Decrease) increase related to prior year tax positions	(4)	-
(Decrease) increase related to current year tax positions	(635)	167
Balance at the end of year	$ 943	$ 1,582

Interest and penalty related to unrecognized tax benefits would be included as income tax expense in the Company's consolidated statements of operations. As of December 31, 2016 and 2015, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

13. Employee Benefit Plan

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

14. Subsequent events

On October 12, 2016, we received a deficiency letter from the Listing Qualifications Department of the NASDAQ Stock Market notifying us that, for the preceding 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on The NASDAQ Capital Market pursuant to NASDAQ Listing Rule 5550(a)(2).

On January 24, 2017, we received a letter from NASDAQ indicating that for 10 consecutive business days, from January 6 to 20, 2017, the closing bid price of the Company's common stock had been at $1.00 per share or greater. Accordingly, the Company has regained compliance with listing rule 5550(a)(2).

In February 2017, 1,685,000 shares of common stock were issued in connection with the exercise of outstanding Series A warrants at an exercise price of $1.45 per share and 850,000 shares of common stock were issued in connection with the exercise of outstanding Series B warrants at an exercise price of $1.55 per share, resulting in aggregate proceeds of $3.76 million.

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EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation	8-K	2/3/2015	3.1	
3.2	Amended and Restated Bylaws of Zosano Pharma Corporation	8-K	2/3/2015	3.2	
4.1	Specimen certificate evidencing shares of common stock of Zosano Pharma Corporation	S-1/A	7/25/2014	4.1	
10.1+	Collaboration, Development and License Agreement, dated January 31, 2014, between Zosano Pharma, Inc. and Novo Nordisk A/S	S-1	6/24/2014	10.1	
10.2	Notice of Termination, dated January 27, 2014, of the Amended and Restated License Agreement dated as of April 1, 2012 among Zosano Pharma, Inc. and Asahi Kasei Pharma Corporation	S-1	6/24/2014	10.2	
10.3	Letter Amendment to Intellectual Property License Agreement, dated February 22, 2011 between ALZA Corporation and Zosano Pharma, Inc.	S-1	6/24/2014	10.3	
10.4+	Intellectual Property License Agreement, dated as of October 5, 2006, between ALZA Corporation and The Macroflux Corporation	S-1/A	7/17/2014	10.4	
10.5	Lease Agreement, dated May 1, 2007, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP	S-1	6/24/2014	10.9	
10.6	First Amendment to Lease, dated June 20, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP	S-1	6/24/2014	10.10	
10.7	Second Amendment to Lease, dated October 16, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP	S-1	6/24/2014	10.11	
10.8	Third Amendment to Lease, dated April 29, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP	S-1	6/24/2014	10.12	
10.9	Fourth Amendment to Lease, dated July 31, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP	S-1	6/24/2014	10.13	
10.10	Fifth Amendment to Lease, dated April 1, 2012, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP	S-1	6/24/2014	10.14	
10.11	Sixth Amendment to Lease, dated as of June 24, 2015, between ZP Opco, Inc. and BMR-34790 Ardentech Court LP	8-K	6/29/2015	10.5	
10.12	Form of Indemnification Agreement for directors associated with an Investment Fund	S-1	6/24/2014	10.15	
10.13	Form of Indemnification Agreement for directors not associated with an Investment Fund	S-1	6/24/2014	10.16	
10.14	Loan and Security Agreement, dated as of June 3, 2014, between Zosano Pharma, Inc. and Hercules Capital, Inc.	S-1	6/24/2014	10.20	

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Exhibit Number	Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.15	First Amendment to Loan and Security Agreement, dated as of June 23, 2015, between ZP Opco, Inc., Hercules Capital, Inc. and Hercules Capital Funding Trust 2014-1	8-K	6/29/2015	10.1	
10.16	Joinder Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Capital, Inc.	S-1	6/24/2014	10.21	
10.17	Supplement to Joinder Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation, Hercules Capital, Inc. and Hercules Capital Funding Trust 2014-1	8-K	6/29/2015	10.2	
10.18	ZP Holdings, Inc. Pledge Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Capital, Inc.	S-1	6/24/2014	10.22	
10.19	Warrant Agreement, dated as of June 3, 2014, between ZP Holdings, Inc. and Hercules Capital, Inc.	S-1	6/24/2014	10.34	
10.20	First Amendment to Warrant Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation and Hercules Capital, Inc.	8-K	6/29/2015	10.4	
10.21	Warrant Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation and Hercules Capital, Inc.	8-K	6/29/2015	10.3	
10.22#	Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona	S-1	6/24/2014	10.25	
10.23#	Amendment to Employment Letter Agreement, dated January 6, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona	S-1	6/24/2014	10.24	
10.24#	Amendment No. 2 to Employment Letter Agreement, dated January 16, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Peter Daddona	S-1	6/24/2014	10.23	
10.25#	Amendment No. 3 to Employment Letter Agreement, dated May 29, 2015, among ZP Opco, Inc., Zosano Pharma Corporation and Peter Daddona	10-Q	8/13/2015	10.1	
	Scientific Advisory Agreement, dated December 31, 2015, by and among Zosano Pharma Corporation, ZP Opco, Inc. and Peter Daddona	8-K	12/31/2015	10.1	
10.26#	Employment Letter Agreement, dated May 11, 2012, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba	S-1	6/24/2014	10.27	
10.27#	Amendment to Employment Letter Agreement, dated December 17, 2013, among Zosano Pharma, Inc., ZP Holdings, Inc. and Vikram Lamba	S-1	6/24/2014	10.26	
10.28#	Employment Letter Agreement, dated April 30, 2014, among Zosano Pharma, Inc., ZP Holdings, Inc. and Winnie Tso	S-1	6/24/2014	10.17	
10.29#	Employment Letter Agreement, dated September 7, 2015, among Zosano Pharma Inc., ZP Holding Inc. and Konstantinos Alataris	10-K	03/29/2016	10.29	
10.30#	Amended and Restated Employer Letter Agreement, dated February 3, 2016, among Zosano Pharma Corporation, ZP Opco, Inc. and Konstantinos Alataris	8-K	03/16/2016	10.1	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.31	Independent Director Agreement, dated as of March 28, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos	S-1	6/24/2014	10.29	
10.32	Letter Amendment to Independent Director Agreement, dated July 15, 2013, between ZP Holdings, Inc. and Kleanthis G. Xanthopoulos	S-1	6/24/2014	10.28	
10.33#	ZP Holdings, Inc. 2012 Stock Incentive Plan	S-1	6/24/2014	10.30	
10.34#	Form of Incentive Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan	S-1	6/24/2014	10.31	
10.35#	Form of Non-Statutory Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan	S-1	6/24/2014	10.32	
10.36#	ZP Holdings, Inc. 2014 Equity and Incentive Plan	S-1	6/24/2014	10.33	
10.37#	Zosano Pharma Corporation Amended and Restated 2014 Equity and Incentive Plan	10-K	3/26/2015	10.33	
10.38	Note Purchase Agreement, dated as of September 9, 2013, among ZP Holdings, Inc., BMV Direct SO LP, BMV Direct SOTRS LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P. and ProQuest Management LLC	S-1	6/24/2014	4.2	
10.39	Form of Subordinated Convertible Promissory Note dated September 9, 2013	S-1	6/24/2014	4.3	
10.40	First Amendment, dated as of June 3, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated September 9, 2013	S-1	6/24/2014	4.8	
10.41	Second Amendment, dated as of September 4, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated September 9, 2013	S-1/A	12/10/2014	4.10	
10.42	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, ProQuest Investments IV, L.P., ProQuest Management LLC, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.	S-1	6/24/2014	10.36	
10.43	Note Purchase Agreement, dated as of February 26, 2014, among ZP Holdings, Inc., BMV Direct SO LP, BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership	S-1	6/24/2014	4.4	
10.44	Form of Subordinated Convertible Promissory Note dated February 26, 2014	S-1	6/24/2014	4.5	
10.45	First Amendment, dated as of June 3, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated February 26, 2014	S-1	6/24/2014	4.9	

Exhibit Number	Description	Incorporated by Reference Form	Date	Number	Filed Herewith
10.46	Second Amendment, dated as of September 4, 2014, to Note Purchase Agreement and 8% Subordinated Convertible Promissory Notes dated February 26, 2014	S-1/A	12/10/2014	4.11	
10.47	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BMV Direct SO LP, New Enterprise Associates 12, Limited Partnership, Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Capital, Inc.	S-1	6/24/2014	10.37	
10.48	Note Purchase Agreement, dated as of December 2, 2014, among Zosano Pharma Corporation, BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership	S-1/A	12/10/2014	4.12	
10.49	Form of Subordinated Convertible Promissory Note dated December 2, 2014	S-1/A	12/10/2014	4.13	
10.50	Subordination Agreement, dated as of December 2, 2014, among BMV Direct SOTRS LP, New Enterprise Associates 12, Limited Partnership, ZP Opco, Inc., Zosano Pharma Corporation and Hercules Capital, Inc.	S-1/A	12/10/2014	10.40	
10.51	Letter Agreement, dated January 9, 2015, regarding Subordinated Convertible Promissory Notes dated September 9, 2013, February 26, 2014 and December 2, 2014	S-1/A	1/9/2015	4.14	
10.52	Subordination Agreement, dated as of June 3, 2014, among BMV Direct SOTRS LP, BioMed Realty Holdings, Inc., Zosano Pharma, Inc., ZP Holdings, Inc. and Hercules Technology Growth Capital, Inc.	S-1	6/24/2014	10.35	
10.53	Independent Director Agreement, dated as June 23, 2014, between Zosano Pharma Corporation and Troy Wilson	S-1	6/24/2014	10.39	
10.54+	Collaboration, Development and License Agreement, dated as of November 21, 2014, between ZP Opco, Inc. and Eli Lilly and Company	S-1/A	12/10/2014 and 1/20/2015	10.41	
10.55	Amendment No. 1 to Collaboration, Development and License Agreement, dated as of August 11, 2015, between ZP Opco, Inc. and Eli Lilly and Company	8-K	8/17/2015	10.1	
10.56	Common Stock Purchase Agreement, dated as of November 21, 2014, between Zosano Pharma Corporation and Eli Lilly and Company	S-1/A	12/10/2014	10.42	
10.57#	Amended and Restated Employment Letter Agreement, dated February 3, 2016, among Zosano Pharma Corporation, ZP Opco, Inc. and Konstantinos Alataris.	8-K	2/4/2016	10.1	
10.58#	Consulting Agreement between the Company and Georgia Erbez, dated June 15, 2016	8-K	6/17/2016	10.1	
10.59#	Employment Letter Agreement, dated September 7, 2016, among Zosano Pharma Corporation, ZP Opco, Inc. and Georgia Erbez.	8-K	9/9/2016	10.1	
10.60	Securities Purchase Agreement, dated August 15, 2016, by and among Zosano Pharma Corporation and the Investors defined therein	8-K	8/16/2016	10.1	

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Exhibit Number	Description	Incorporated by Reference Form	Date	Number	Filed Herewith
21.1	List of Subsidiaries of the Registrant				X
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Chief Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Chief Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended				X
32.1*	Certification of Chief Executive Officer and Chief Financial Officer, as required by rules 13a-14(a) and 15d-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

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

Management contract or compensatory plan or arrangement

* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 21.1

LIST OF SUBSIDIARIES OF ZOSANO PHARMA CORPORATION

NAME OF SUBSIDIARY	JURISDICTION OF INCORPORATION
ZP Opco, Inc.	Delaware, United States

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of Zosano Pharma Corporation on Form S-3 (File No. 333-213567) and Form S-8 (File No. 333-203039) of our report (which includes an explanatory paragraph as to the Company's ability to continue as a going concern) dated February 28, 2017 with respect to our audits of the consolidated financial statements of Zosano Pharma Corporation as of December 31, 2016 and 2015 and for the years ended December 31, 2016 and 2015, which report is included in this Annual Report on Form 10-K of Zosano Pharma Corporation for the year ended December 31, 2016.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA
February 28, 2017

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Konstantinos Alataris, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zosano Pharma Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2017

By: /s/ Konstantinos Alataris
Konstantinos Alataris
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Georgia Erbez, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zosano Pharma Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2017

By: /s/ Georgia Erbez
Georgia Erbez
Interim Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Konstantinos Alataris, the Chief Executive Officer and President of Zosano Pharma Corporation (the "Company"), and Georgia Erbez, the Interim Chief Financial Officer and Chief Business Officer of the Company, hereby certify that, to their knowledge:

1. The Annual Report on Form 10-K for the period ended December 31, 2016 of the Company (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2017

By: /s/ Konstantinos Alataris
Konstantinos Alataris
Chief Executive Officer and President
(Principal Executive Officer)

Date: February 28, 2017

By: /s/ Georgia Erbez
Georgia Erbez
Interim Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)