Zosano Pharma Corp
Form S-1/A
March 13, 2017
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As filed with the Securities and Exchange Commission on March 13, 2017.

Registration No. 333-216410

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

FORM S-1

REGISTRATION STATEMENT

under

THE SECURITIES ACT OF 1933

ZOSANO PHARMA CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

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

34790 Ardentech Court

Fremont, California 94555

(510) 745-1200

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

Konstantinos Alataris

President and Chief Executive Officer

34790 Ardentech Court

Fremont, California 94555

(510) 745-1200

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

Copies to:

Stacie S. Aarestad, Esq.	**Stuart Bressman, Esq.**
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Boston, Massachusetts 02110	
(617) 832-1000	

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Stock, par value $0.0001 per share	19,550,000	$2.35	$45,942,500	$5,324.74

(1) Includes 2,550,000 shares which the underwriters have the option to purchase from the registrant.
(2) Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(a), as amended.
(3) Previously paid

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

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated March 13, 2017

PROSPECTUS

17,000,000 Shares

Common Stock

$ per share

Zosano Pharma Corporation is offering shares of its common Trading symbol: The NASDAQ Capital Market ZSAN. stock.

On March 10, 2017, last reported sale price of our common stock on The NASDAQ Capital Market was $2.35 per share. The actual offering price per share will be as determined between us and the underwriters at the time of pricing.

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

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 10 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount[(1)(2)]	$	$
Proceeds, before expense, to Zosano Pharma Corporation	$	$

(1) We refer you to Underwriting beginning on page 44 of this prospectus for additional information regarding total underwriter compensation.
(2) The underwriters will also be reimbursed for certain expenses incurred in this offering.
We have granted the underwriters a 30-day option to purchase up to 2,550,000 additional shares of our common stock on the same terms and conditions described herein, solely to cover over-allotments, if any.

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

The underwriters expect to deliver the shares against payment therefor on or about , 2017.

Piper Jaffray **Guggenheim Securities**

The date of this prospectus is , 2017.

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You should rely only on the information contained in this prospectus, including the information incorporated by reference herein, and any related free writing prospectus that we may provide you in connection with this offering.

You should rely only on the information that we have included or incorporated by reference in this prospectus and any related free writing prospectus that we may authorize to be provided to you. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. This prospectus and any related free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information contained in this prospectus or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference herein or therein is correct on any date subsequent to

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the date of the document incorporated by reference, even though this prospectus or any related free writing prospectus is delivered, or securities are sold, on a later date.

This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading Where You Can Find More Information.

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

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus and in the documents we incorporate by reference. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus, any applicable free writing prospectus and the documents incorporated by reference herein and therein. You should read all such documents carefully, especially the risk factors and our consolidated financial statements and the related notes included or incorporated by reference herein or therein, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to Zosano, Company, we, us and our refer to Zosano Pharma Corporation and its subsidiary.

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, while avoiding the gastrointestinal tract (GI tract), consistent drug delivery 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.

Recent Developments

Phase 2/3 Trial Results

On February 13, 2017, we announced the completion and results of our ZOTRIP trial. The 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. As illustrated in the table below, the ZOTRIP trial results demonstrated that the 3.8 mg M207 dose demonstrated

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statistically significant pain freedom and most bothersome symptom freedom at two hours, the co-primary endpoints of the study.

ZOTRIP Trial Co-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

* 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.

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. While the 1.0mg and 1.9mg doses of M207 demonstrated statistical significance in pain freedom at two hours, they did not demonstrate statistical significance in freedom from most bothersome symptom at two hours.

ZOTRIP Trial Secondary Endpoint Results for 3.8mg

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 serious adverse events (SAEs) reported in the ZOTRIP study. 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 no subjects in the placebo group.

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 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

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opportunities with potential strategic partners to ensure our product candidates will receive the best chance of commercial success.

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.

Intellectual Property

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

Warrant Exercises

After December 31, 2016 and through March 1, 2017, 1,716,825 shares of common stock had been issued in connection with the exercise of outstanding Series A warrants at an exercise price of $1.45 per share and 881,825 shares of common stock had been 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 $3.86 million.

Available Information

Our website address is *www.zosanopharma.com*. The information contained in, or accessible through, our website does not constitute part of this prospectus. We make available free of charge on our website our annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission, or the SEC. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website as part of this prospectus.

Risks Associated with our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the Risk Factors section of this prospectus immediately following this prospectus summary and in Part I, Item 1A Risk Factors of our Annual Report on Form 10-K filed with the SEC on March 1, 2017, which is incorporated by reference in this prospectus. These risks include, but are not limited to, the following:

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

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 product candidates.

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Our loan facility with Hercules Capital, Inc., or Hercules, imposes restrictions on our business, and if we default on our obligations, Hercules would have a right to foreclose on substantially all of our assets, including our intellectual property and proceeds of this offering.

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.

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.

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

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

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

We use customized equipment to coat and package our microneedle patch system, making us vulnerable to production and supply problems that could negatively impact the clinical trials of our product candidates or sales of our product candidates, if approved.

We have no experience selling, marketing or distributing approved product candidates and have limited internal capability to do so, and we have limited experience manufacturing our proposed product candidates.

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.

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

Our failure to obtain and maintain patent protection for our technology and our 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.

We may not successfully manage our growth.

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. As of December 31, 2016, Zosano Pharma Corporation had one wholly owned subsidiary, ZP Opco, Inc., through which the Company conducts its primary research and development activities. 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 dissolved on December 30, 2016.

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Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. Our telephone number is (510) 745-1200. Our website address is www.zosanopharma.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

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

Implications of Being an Emerging Growth Company

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

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

We may take advantage of these exemptions until December 31, 2019 or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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The Offering

Common stock offered by us	17,000,000 shares (19,550,000 shares in the event the underwriters elect to exercise in full their over-allotment option to purchase additional shares from us.)
Common stock to be outstanding after this offering	33,815,997 shares (36,365,997 shares in the event the underwriters elect to exercise in full their over-allotment option to purchase additional shares from us).
Option to purchase additional shares	The underwriters have the option to purchase from us up to a maximum of 2,550,000 additional shares of common stock. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $36.7 million, or approximately $42.3 million if the underwriters exercise in full their over-allotment option, assuming an offering price of $2.35 per share, the last reported sales price of our common stck on Nasdaq Capital Markets on March 10, 2017, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The actual offering price per share will be as determined between us and the underwriters at the time of pricing. We plan to use the net proceeds from this offering to fund the manufacture of M207 in sufficient quantities to support our long term safety study and associated regulatory activities necessary to file for product approval, and to fund a substantial portion of the long term safety study itself, and for working capital and general corporate purposes. See Use of Proceeds on page 15 for additional information.
Risk factors	An investment in our common stock involves a high degree of risk. You should read the Risk Factors section beginning on page 10 and the similarly titled sections in the documents incorporated by reference for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Capital Market symbol	ZSAN

Outstanding Shares

The number of shares of our common stock to be outstanding after this offering set forth above is based on 16,815,997 shares of our common stock outstanding as of December 31, 2016.

The number of shares of common stock to be outstanding after this offering set forth above excludes:

- 4,800,000 shares of common stock issuable upon the exercise of Series A warrants at an exercise price of $1.45 and 4,800,000 shares of common stock issuable upon the exercise of Series B warrants at an exercise price of $1.55 outstanding as of December 31, 2016;

31,674 shares of common stock issuable upon the exercise of warrants at an exercise price of $8.84 and 40,705 shares of common stock issuable upon the exercise of warrants at an exercise price of $7.37 outstanding as of December 31, 2016;

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- 2,516,058 shares of common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan, our Amended and Restated 2014 Equity and Incentive Plan and in connection with an inducement award in September 2016 as of December 31, 2016, including 670,000 shares of common stock issuable upon the exercise of stock options that were granted to certain executive officers on November 2, 2016 and that are subject to approval by our stockholders of an amendment to the 2014 Equity and Incentive Plan to increase the number of shares available for issuance by an amount sufficient to cover such grants, at a weighted average exercise price of $1.45 per share; and

- 55,815 shares of common stock available for future issuance under our Amended and Restated 2014 Equity and Incentive Plan as of December 31, 2016.

After December 31, 2016 and through March 1, 2017, 1,716,825 shares of common stock had been issued in connection with the exercise of outstanding Series A warrants and 881,825 shares of common stock had been issued in connection with the exercise of outstanding Series B warrants.

Except as otherwise noted, all information in this prospectus:

- assumes no exercise of outstanding options or warrants described above; and

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

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Summary Financial Data

We derived the consolidated statements of operations data presented below for the years ended December 31, 2016 and 2015 from our audited financial statements. Our historical results are not necessarily indicative of the results that should be expected in the future. The following information should be read in conjunction with our consolidated financial statements and related notes incorporated by reference in this prospectus from our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

The as adjusted balance sheet data as of December 31, 2016 reflects receipt of the estimated net proceeds of $36.7 million from the sale of the common stock in this offering, based on an assumed public offering price of $2.35 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 10, 2017, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, as if our receipt of the estimated net proceeds from this offering had occurred as of December 31, 2016. The actual offering price per share will be as determined between us and the underwriters as the time of pricing. The as adjusted summary financial data are not necessarily indicative of what our financial position would have been if this offering had been completed as of the date indicated, nor are these data necessarily indicative of our financial position for any future date or period.

	Year Ended December 31,	
	2016	2015
	(in thousands, except per share amounts)	
Consolidated Statements of Operations and Comprehensive Loss:		
Revenue:		
License fees	$	$ 170
Collaborative 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

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	As of December 31, 2016	
	Actual	As Adjusted[1]
Selected Balance Sheet Data:		
Cash and cash equivalents	$ 15,003	$ 51,712
Working capital	5,457	42,166
Total assets	20,906	57,615
Secured promissory note, net of issuance costs (including accrued interest)	12,542	12,542
Accumulated deficit	(196,769)	(196,769)
Total stockholders equity	4,485	41,194

(1) As adjusted to reflect the sale of the 17,000,000 shares being offered in this offering, and the receipt of the estimated net proceeds of $36.7 million from the sale of these shares, at the assumed public offering price of $2.35 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 10, 2017, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed public offering price of $2.35 per share, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) by approximately $15.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders equity (deficit) by $2.2 million, assuming the assumed public offering price of $2.35 per share remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should carefully consider the following risks and uncertainties, and those discussed under the Section captioned Risk Factors contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which is incorporated by reference in this prospectus, together with the information included in this prospectus and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. 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.

Risks Related to This Offering

Management will have broad discretion as to the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion over the use of proceeds from this offering, including for any of the purposes described in the section of this prospectus entitled Use of Proceeds. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our business strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. In addition, the net proceeds from this offering may not be sufficient for our anticipated uses, and we may need additional resources to progress our product candidates to the stage we expect. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

If you purchase shares of our common stock in this offering, you will experience immediate and substantial dilution in the net tangible book value of your shares.

If you purchase shares of our common stock in this offering, you will experience immediate and substantial dilution, as the public offering price of our common stock will be substantially greater than the net tangible book value per share of our common stock. Based on an assumed offering price of $2.35 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 10, 2017, if you purchase our common stock in this offering, you will suffer immediate and substantial dilution of approximately $1.13 per share. In addition, if the underwriters exercise their over-allotment option, or if outstanding options and warrants to purchase our common stock are exercised, you will experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section entitled Dilution.

Any issuances of shares of common stock or securities convertible into or exercisable for shares of common stock, debt financing, entering into license and collaboration agreements, as well as the exercise of options and warrants outstanding, following this offering, will dilute your ownership interests and may adversely affect the future market price of our common stock.

The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund completion of clinical development of any of our product candidates. Accordingly, unless and until we generate revenues and become profitable, we will need to raise additional capital to continue to operate our business, including after the consummation of this offering. We expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. The issuance of additional shares of our common stock could be dilutive to shareholders if they do not invest in future offerings, and our participation in a debt financing or license or collaboration agreement will also be dilutive to shareholders.

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In addition, we have a significant number of options and warrants to purchase shares of our common stock outstanding. If these securities are exercised, you may incur further dilution. Moreover, to the extent that we issue additional options or warrants to purchase, or securities convertible into or exchangeable for, shares of our common stock in the future and those options, warrants or other securities are exercised, converted or exchanged, shareholders may experience further dilution.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of our common stock stockholders intend to sell shares, could cause the market price of our common stock to decline significantly. Upon the completion of this offering, the 17,000,000 shares sold in this offering will be freely tradable to the extent purchased by non-affiliates and substantially all of the remaining outstanding shares of our common stock will be available for sale in the public market beginning 90 days after the date of this prospectus following the expiration of lock-up agreements between some of our stockholders and the underwriters. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time, which would allow for earlier sales of shares in the public market.

Upon completion of this offering, based on our shares outstanding as of December 31, 2016, we will have 33,815,997 shares of common stock outstanding based on the issuance and sale of 17,000,000 shares of our common stock in this offering. Of these shares, only 2,726,883 are subject to a contractual lock-up with the underwriters for this offering for a period of 90 days following this offering. The balance of our outstanding shares of common stock, including any shares purchased in this offering, may be resold into the public market immediately without restriction, unless owned or purchased by our affiliates.

In addition, as of December 31, 2016, we had outstanding stock options to purchase an aggregate of 2,516,058 shares of our common stock under our equity incentive plans and in connection with a September 2016 inducement award, and the issuance of all of these shares is or will soon be registered under the Securities Act of 1933, as amended, or the Securities Act, on a registration statement on Form S-8. These shares when registered on Form S-8, once vested and issued upon exercise, will be able to be freely sold in the public market, subject to the volume limits of Rule 144 under the Securities Act in the case of our affiliates and the lock-up agreements described above, to the extent applicable. In addition, as of December 31, 2016, we had outstanding warrants to purchase an aggregate of 9,672,379 shares of our common stock and the re-sale of 9,640,705 of these shares is registered under the Securities Act of 1933, as amended, or the Securities Act, on a registration statement on Form S-3. These shares registered on Form S-3, once issued upon exercise of the warrants, will be able to be freely sold in the public market, subject to the lock-up agreements described above, to the extent applicable. After December 31, 2016 and through March 1, 2017, 1,716,825 shares of common stock had been issued in connection with the exercise of outstanding Series A warrants and 881,825 shares of common stock had been issued in connection with the exercise of outstanding Series B warrants.

The long-term safety study for M207 is an important next step in the development of M207. The proceeds from this offering will support the initiation of the long-term safety study, but additional funding will be required to complete the study. If we cannot raise the additional funding needed to complete the study, 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. In addition to the proceeds from this offering, to complete

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this safety study, we will need to raise additional capital. 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. If we are unable to raise additional capital, whether through equity or debt financings or other arrangements with third parties when needed, the regulatory approval process could be delayed and our business could be adversely affected.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and all the documents incorporated by reference herein contain forward-looking statements. All statements, other than statements of historical facts, included in this prospectus or the documents incorporated herein by reference regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. In some cases, you can identify these statements by forward-looking words such as may, could, should, would, intend, will, anticipate, believe, estimate, continue, plan, potential predict, project or the negative of those terms or similar words. Any statemen herein that are not statements of historical facts may be deemed to be forward-looking statements. You should read these statements carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. These forward-looking statements include, among other things, statements about:

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

our expectations regarding federal, state and foreign regulatory requirements; and

regulatory developments in the United States and foreign countries.

These forward-looking statements reflect our management s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the Risk Factors section, that could

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cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

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

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INDUSTRY AND MARKET DATA

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

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USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $36.7 million, or approximately $42.3 million if the underwriters exercise their over-allotment option in full, based on an assumed public offering price of $2.35 per share, the last reported sales price at our common stock on the Nasdaq Capital Market on March 10, 2017, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The actual offering price per share will be as determined between us and the underwriters at the time of pricing.

We plan to use the net proceeds from this offering to fund the manufacture of M207 in sufficient quantities to support our long term safety study and associated regulatory activities necessary to file for product approval, and to fund a substantial portion of the long term safety study itself, and for working capital and general corporate purposes.

Our planned use of the net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Due to the many variables that are inherent in the development of our lead product candidate at this time, such as the timing and results of long term safety study and the timing of regulatory submissions and evolving regulatory requirements, the amount and timing of our actual expenditures will depend upon such variables and we cannot currently predict the stage of development we expect the net proceeds of this offering to achieve for our long term safety study and lead product candidate.

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

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MARKET PRICE OF OUR COMMON STOCK

Our common stock has been listed on The NASDAQ Capital Market under the symbol ZSAN since January 27, 2015. Prior to that date, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported by The NASDAQ Capital 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

On March 10, 2017, the closing price of our common stock as reported on The NASDAQ Capital Market was $2.35 per share. As of February 20, 2017, we had 41 holders of record of our common stock.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently expect to retain all available funds and future earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in any future financing instruments, provisions of applicable law and other factors the Board deems relevant. Additionally, our secured term loan facility with Hercules, contains covenants that restrict our ability to pay dividends.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2016 on:

- An actual basis; and
- An as adjusted basis, giving effect to the sale of 17,000,000 shares of our common stock offered in this offering, assuming a public offering price of $2.35 per share, the last reported sales price for our common stock on the Nasdaq Capital Market on March 10, 2017, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read the following table in conjunction with our consolidated financial statements, including the related notes, and Management s Discussion and Analysis of Financial Condition and Results of Operations from our Annual Report on Form 10-K for year ended December 31, 2016, as amended, which are incorporated by reference into this prospectus.

	As of December 31, 2016	
	Actual	as Adjusted
	(in thousands, except par value and share amounts)	
Cash and cash equivalents	$ 15,003	51,712
Secured promissory note, net of issuance costs (including accrued interest)	$ 12,542	12,542
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value, 5,000,000 shares and none authorized; none issued and outstanding, actual and as adjusted		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of December 31, 2016; 16,815,997 and 33,815,997 shares issued and outstanding, actual and as adjusted, respectively	2	4
Additional paid-in capital	201,252	237,959
Accumulated deficit	(196,769)	(196,769)
Total stockholders equity (deficit)	4,485	41,194
Total capitalization	$ 17,027	53,736

The foregoing table and calculations are based on 16,815,997 shares of our common stock outstanding as of December 31, 2016, and excludes:

- 4,800,000 shares of common stock issuable upon the exercise of Series A warrants at an exercise price of $1.45 and 4,800,000 shares of common stock issuable upon the exercise of Series B warrants at an exercise price of $1.55 outstanding as of December 31, 2016;
- 31,674 shares of common stock issuable upon the exercise of warrants at an exercise price of $8.84 and 40,705 shares of common stock issuable upon the exercise of warrants at an exercise price of $7.37 outstanding as of December 31, 2016;

2,516,058 shares of common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan, our Amended and Restated 2014 Equity and Incentive Plan and in connection with a September 2016 inducement award as of December 31, 2016, including 670,000 shares of common stock issuable upon the exercise of stock options that were granted to certain executive officers on November 2, 2016 and that are subject to approval by our stockholders of an amendment to the 2014 Equity and Incentive Plan to

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increase the number of shares available for issuance by an amount sufficient to cover such grants, at a weighted average exercise price of $1.45 per share; and

55,815 shares of common stock available for future issuance under our Amended and Restated 2014 Equity and Incentive Plan as of December 31, 2016.

After December 31, 2016 and through March 1, 2017, 1,716,825 shares of common stock had been issued in connection with the exercise of outstanding Series A warrants and 881,825 shares of common stock had been issued in connection with the exercise of outstanding Series B warrants.

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DILUTION

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

Our historical net tangible book value (deficit) as of December 31, 2016 was $4.5 million, or $0.27 per share of common stock. Our historical net tangible book value (deficit) per share set forth below represents our total assets, excluding intangible assets, less our total liabilities, divided by the number of shares of our common stock outstanding on December 31, 2016.

After giving effect to the sale of 17,000,000 shares of common stock in this offering at an assumed public offering price of $2.35 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 10, 2017, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value (deficit) as of December 31, 2016 would have been $41.2 million, or $1.22 per share. This represents an immediate increase in net tangible book value to existing stockholders of $0.95 per share and an immediate dilution of $1.13 per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting as adjusted net tangible book value per share after this offering from the public offering price per share paid by new investors. The following table illustrates this per share dilution:

Assumed public offering price		$ 2.35
Historical net tangible book value (deficit) per share as of December 31, 2016	$ 0.27	
Increase in net tangible book value per share attributable to investors participating in this offering	0.95	
As adjusted net tangible book value per share after this offering		$ 1.22
Dilution per share to investors participating in this offering		$ 1.13

A $1.00 increase (decrease) in the assumed public offering price of $2.35 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 10, 2017, would increase (decrease) our as adjusted net tangible book value per share after this offering by approximately $0.47, and the dilution per share to new investors purchasing shares in this offering by $0.53, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares to be issued in this offering. An increase (decrease) of 1,000,000 shares offered by us would increase (decrease) our as adjusted net tangible book value per share by $0.03, and (decrease) increase the dilution per share to new investors purchasing shares in this offering by $0.03, respectively, assuming that the assumed public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the underwriters at pricing.

If the underwriters exercise their over-allotment option in full, the as adjusted net tangible book value (deficit) will increase to $1.29 per share, representing an immediate increase in adjusted net tangible book value (deficit) to existing stockholders of $1.02 per share and an immediate dilution of $1.06 per share to new investors.

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The number of shares of our common stock reflected in the discussion and the table above is based on 16,815,997 shares of our common stock outstanding as of December 31, 2016, and excludes:

- 4,800,000 shares of common stock issuable upon the exercise of Series A warrants at an exercise price of $1.45 and 4,800,000 shares of common stock issuable upon the exercise of Series B warrants at an exercise price of $1.55 outstanding as of December 31, 2016;
- 31,674 shares of common stock issuable upon the exercise of warrants at an exercise price of $8.84 and 40,705 shares of common stock issuable upon the exercise of warrants at an exercise price of $7.37 outstanding as of December 31, 2016;
- 2,516,058 shares of common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan, our Amended and Restated 2014 Equity and Incentive Plan and in connection with a September 2016 inducement award as of December 31, 2016, including 670,000 shares of common stock issuable upon the exercise of stock options that were granted to certain executive officers on November 2, 2016 and that are subject to approval by our stockholders of an amendment to the 2014 Equity and Incentive Plan to increase the number of shares available for issuance by an amount sufficient to cover such grants, at a weighted average exercise price of $1.45 per share; and
- 55,815 shares of common stock available for future issuance under our Amended and Restated 2014 Equity and Incentive Plan as of December 31, 2016.

To the extent that any options or warrants are exercised, new options are issued under our equity incentive plans or we otherwise issue additional shares of common stock in the future at a price less than the public offering price, there may be further dilution to new investors purchasing common stock in this offering.

After December 31, 2016 and though March 1, 2017, 1,716,825 shares of common stock had been issued in connection with the exercise of outstanding Series A warrants and 881,825 shares of common stock had been issued in connection with the exercise of outstanding Series B warrants.

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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, while avoiding the gastrointestinal tract (GI tract), consistent drug delivery 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 Co-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

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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 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.

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 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

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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 two 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.

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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 Co-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

ZOTRIP Trial Secondary Endpoint Results for 3.8mg

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.

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

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

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Most Frequent Adverse Events (³4% 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.

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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 our annual report on Form 10-K for the year ended December 31, 2016, as amended, which is incorporated by reference herein, 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

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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 four 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.

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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.

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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

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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.

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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

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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

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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 prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

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CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Since January 1, 2015, we have engaged in the following transactions with our directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers, and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Agreements with Our Stockholders

Real Property Lease with BMR

We have an operating lease with BMR-34790 Ardentech Court LP, which is an affiliate of BMV Direct SOTRS LP and BMV Direct SO LP, for a 55,000 square foot facility in Fremont, California, where we operate our manufacturing operations and house our engineering, research and development and administrative employees. For the years ended December 31, 2015 and 2016, we recorded rent expense for BMR-34790 Ardentech Court LP in the amount of approximately $0.6 million for each year. In June 2015, we entered into another amendment to the lease, pursuant to which BMR-34790 Ardentech Court LP s option to recapture a specified portion of the leased premises (comprising approximately 29,348 square feet of the approximate total 55,588 square feet of leased premises) was suspended.

February 2014 Bridge Loan

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

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

As consideration for our issuance of the February 2014 bridge notes, each investor paid us an amount equal to the original principal amount of the note issued to the investor. The February 2014 bridge notes matured on September 9, 2014 and accrued simple interest at the annual rate of 8%. As of January 30, 2015, the aggregate outstanding principal and accrued interest under the February 2014 bridge notes was approximately $2.7 million. Upon the closing of our initial public offering of common stock on January 30, 2015, which constituted a qualified financing as defined under the terms of the notes, the principal and all unpaid and accrued interest on each note automatically converted into shares of our common stock at a conversion price equal to $9.35 per share (or 85% of the initial public offering price), resulting in the issuance of 122,882 shares of common stock BMV Direct SOTRS LP, 28,603 shares of common stock to BMV Direct SO LP, and 135,700 shares of common stock to New Enterprise Associates 12, Limited Partnership.

December 2014 Bridge Loan

In December 2014, we issued and sold convertible promissory notes, which we refer to as the December 2014 bridge notes, in the aggregate original principal amount of $1.3 million to our stockholders BMV Direct SOTRS LP and New Enterprise Associates 12, Limited Partnership. The following is the original

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principal amount of December 2014 bridge notes that were issued to our directors, executive officers and holders of more than 5% of our voting securities, and their affiliates or immediate family members:

BMV Direct SOTRS LP, in the original principal amount of approximately $710,000; and

New Enterprise Associates 12, Limited Partnership, in the original principal amount of approximately $620,000.

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

Private Placement with Eli Lilly and Company

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

Interests of Directors in our Financial Relationships

One of our directors, Bruce D. Steel, may be deemed to have an indirect material interest in our financial relationships with certain of our stockholders based on his association with such stockholders. Mr. Steel is a limited partner with a variable economic interest in each of BMV Direct SOTRS LP and BMV Direct SO LP, which entitles him to a percentage of certain distributions of these entities. Mr. Steel does not have voting or dispositive control of either of these entities. Mr. Steel disclaims beneficial ownership in our securities directly held by these entities except to the extent of his pecuniary interest therein.

Participation in our Initial Public Offering

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

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Private Investment in Public Equity (PIPE)

In August 2016, the Company entered into a securities purchase agreement, or Purchase Agreement, between the Company and certain purchasers, 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 our 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.

Name	Common Stock Purchased in Private Placement	Warrants Purchased in Private Placement	Aggregate Purchase Price
The Alataris Family Trust	127,389	254,778	$ 200,001
John Walker	63,700	127,400	100,009
Georgia Erbez	47,750	95,500	