Zosano Pharma Corp
Form 10-K
March 25, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-36570
ZOSANO PHARMA CORPORATION
(Exact name of registrant as specified in its charter)

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

34790 Ardentech Court
Fremont, CA 94555
(Address of principal executive offices) (Zip Code)
(510) 745-1200
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated

filer" and "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	x		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2018 (the last business day of the registrant's most recently completed second quarter) was approximately $42,236,103.

As of March 7, 2019, the registrant had a total of 11,973,039 shares of its common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

No documents are incorporated by reference into this Annual Report Form on 10-K.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

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

- the anticipated timing, costs and conduct of our planned clinical trials and preclinical studies, as applicable, for our candidate, Qtrypta™ M207;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- our expectations regarding the clinical effectiveness and safety of our product candidate;
- the ability to obtain and maintain regulatory approval of our product candidate, and the labeling for any approved product;
- our manufacturing capabilities and strategy, and our ability to establish and maintain relationships with contract manufacturing organization(s) to expand our manufacturing capacity;
- our intellectual property position and our ability to obtain and maintain intellectual property protection for our product candidate;
- 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 candidate;
- the size and growth of the potential markets for our product candidate and the ability to serve those markets;
- the rate and degree of market acceptance of our product candidate;
- our ability to establish and maintain development partnerships;
- our ability to attract or retain key personnel;
- our expectations regarding federal, state and foreign regulatory requirements; and
- regulatory developments in the United States and foreign countries.

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

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

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PART I

Item 1. BUSINESS

Overview

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM, technology. In February 2017, we announced positive results from our ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated Qtrypta™ (M207), which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. In February 2019, we announced the completion of the final milestone in our long-term safety study for Qtrypta™ (M207). We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, in markets where patients remain underserved by existing therapies.

ADAM is our proprietary, investigational intracutaneous delivery system designed to offer rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. ADAM consists of an array of drug-coated titanium microneedles mounted on an adhesive backing that is pressed on to the skin using a reusable handheld applicator. The microneedles penetrate the stratum corneum and allow the drug to be absorbed into the microcapillary system of the skin. We focus on developing products based on our ADAM technology for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, in markets where there is a need for more effective therapies.

Our development efforts are currently focused on our product candidate, Qtrypta™ (M207). Qtrypta™ (M207) is our proprietary formulation of zolmitriptan delivered utilizing our ADAM technology. Zolmitriptan is one of a class of serotonin receptor agonists known as triptans and is used as an acute treatment for 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 Qtrypta™ (M207) is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding exposure to the gastrointestinal ("GI") tract. Feedback from the United States Food and Drug Administration ("FDA") on Qtrypta™ (M207)’s regulatory path has confirmed that one positive pivotal efficacy study, in addition to the required safety study, is sufficient for submission of a New Drug Application, ("NDA"), seeking approval of Qtrypta™ (M207) for the treatment of migraine, if the results are favorable.

ZOTRIP Phase 2/3 Trial Results

The ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of Qtrypta™ (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 showed that the 3.8mg Qtrypta™ (M207) dose demonstrated statistically significant greater pain freedom and most bothersome symptom freedom at two hours, the co-primary endpoints of the study.

ZOTRIP Trial Primary Endpoints Results

Primary endpoint	Placebo	3.8mg M207	p-value*
Pain freedom at 2 hours	14.3%	41.5%	0.0001
Most bothersome symptom freedom at 2 hours	42.9%	68.3%	0.0009

* The "p" value is the probability of an event occurring by chance alone.

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 Qtrypta™ (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 Endpoints Results

Pain Freedom	Placebo	3.8mg M207	p-value*

Pain freedom at 45 minutes	5.2%	17.1%	0.0175
Pain freedom at 60 minutes	10.4%	26.8%	0.0084
Pain freedom at 24 hours	39.0%	69.5%	0.0001
Pain freedom at 48 hours	39.0%	64.6%	0.0013

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* 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.

Qtrypta™ (M207) was generally well-tolerated with no serious adverse events ("SAE") reported in the ZOTRIP study. The most frequently reported adverse event are shown in the following table:

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

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

M207 Long Term Safety Study

In November 2017, we announced the initiation of enrollment in our long-term safety study for Qtrypta™ (M207) as an acute treatment of migraine (“M207-ADAM”). M207-ADAM was an open label study evaluating the safety of the 3.8mg dose of Qtrypta™ (M207) in migraine patients who had historically experienced at least two migraines per month. Patients were expected to treat a minimum of two migraines per month on average, with no maximum treatment limits. The study was conducted at 31 sites in the United States with a defined data set per protocol in which 150 subjects received repeated doses for six months and 50 subjects received repeated doses for one year. The study was open-label, with investigator visits at months one, two, three, six, nine and twelve to record adverse events, if any. The primary objective of M207-ADAM was to assess safety of Qtrypta™ (M207) during repeated use over six and twelve months. Other endpoints were electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response.

In October 2018, we announced the completion of the first phase of our long-term safety study with more than 150 evaluable subjects completing six months of treatment with Qtrypta™. In February 2019, we announced the completion of the second phase of our long-term safety study with more than 50 evaluable subjects completing one year of treatment with Qtrypta™. Throughout the clinical program, as of February 2019, over 5,800 migraine attacks have been treated with Qtrypta™. Investigators reported 831 adverse events, of which 297 were reported as application site reactions and 161 were reported as treatment related adverse events. As of February 2019, following treatment with Qtrypta™, 44% of patients reported pain freedom at two hours, 68% of patients reported relief from most bothersome symptom, while pain relief at two hours was reported for 81% of migraine attacks treated.

Our Strategy

Our goal is to make intracutaneous drug delivery a preferred delivery modality for indications where fast onset provides a therapeutic benefit to patients. Our near-term focus is the continued development of our lead product candidate, Qtrypta™ (M207). The key elements of our strategy are to:

- Develop and commercialize Qtrypta™ (M207). We believe that Qtrypta™ (M207), if approved by the FDA, will offer significant therapeutic and practical advantages as compared to existing migraine therapeutics, including its rapid onset, ease of use and stability. We have retained worldwide commercial rights to Qtrypta™ (M207). While we currently intend to develop Qtrypta™ (M207) through FDA approval and commercialization in the United States

ourselves, we are also considering collaborations with potential strategic partners to maximize the strategic value of our product and our company.

- Focus on regulatory support and market opportunities for Qtrypta™ (M207). We intend to focus our resources on the clinical and other studies, including our long-term safety study, required for NDA filing and, if approved, would support market acceptance and expansion for Qtrypta™ (M207).
- Pursue indications outside migraine. We have performed initial feasibility studies on a number of compounds and have observed that our ADAM intracutaneous delivery system may have potential applications for use with large molecules, small molecules, and vaccines. These programs are in CNS and other therapeutic indications, where rapid drug delivery could

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provide a therapeutic benefit to patients. We are pursuing these indications ourselves but would also consider collaborations with strategic partners to further the clinical and commercial development of such product candidates.

Qtrypta™ (M207) for Migraine

The focus of our development efforts is on our product candidate Qtrypta™ (M207), our proprietary formulation of zolmitriptan, a class of serotonin receptor agonists known as triptans, used for the treatment of migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. Our Qtrypta™ (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 exposure to the GI tract.

According to the Migraine Research Foundation, migraine is the third most prevalent illness in the world. Migraine affects approximately 39 million people in the United States, representing approximately 18% of women, 6% of men and 10% of children in the country. Nearly one in four United States households includes someone who suffers from migraine. Migraines often last between four and 24 hours, but they may last as long as three days. According to published studies, 63% of migraine patients experience one or more migraines per month and 48% of migraine attacks occur in early morning and are already at peak intensity on awakening. Physicians recommend treating migraine at earliest detection. However, because treatment for morning migraines is often delayed, these migraines can be more difficult to treat.

The Migraine Research Foundation provides that, among women, who are disproportionately affected by migraine, 25% of migraine sufferers experience four or more severe attacks per month. Migraine attacks are estimated to lead to lost productivity costs as high as $36 billion annually in the United States and, in 2015, the medical cost of treating chronic migraine was more than $5.4 billion. In addition, more than 90% of migraine sufferers are unable to work or function normally during an attack.

We believe that each of the currently available methods of non-oral administration, including nasal spray and subcutaneous injection, 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. There are other delivery technologies in development, such as pulmonary delivery. However, none has been approved to date.

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 Qtrypta™ (M207). Our ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of Qtrypta™ (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 subjects 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.

589 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, statistical significance cannot be claimed for testing thereafter. Therefore, p-values for secondary endpoints should be considered nominal p-values.

As illustrated in the tables and figure below, the ZOTRIP trial results demonstrated that the 3.8mg Qtrypta™ (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, Qtrypta™ (M207) was not associated with any SAEs. While the 1.0mg and 1.9mg doses of Qtrypta™ (M207) demonstrated statistical significance in pain freedom at two hours, they did not achieve statistical

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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 at 2 hours	14.3%	41.5%	0.0001
Most bothersome symptom free at 2 hours	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

Qtrypta™ (M207) was generally well-tolerated with no SAEs reported in the ZOTRIP trial. The most frequently reported adverse event was redness at the appli