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, 2020

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	Trading Symbol	Name of Each Exchange on Which Registered
Common stock, par value $0.0001 per share	ZSAN	The Nasdaq Stock Market

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

None

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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. ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2020 (the last business day of the registrant's most recently completed second quarter) was approximately $49,001,935.

As of March 9, 2021, the registrant had a total of 106,289,885 shares of its common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Annual Report on Form 10-K, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2021, which definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year ended December 31, 2020.

Zosano Pharma Corporation
Annual Report on Form 10-K
For the Fiscal Year ended December 31, 2020

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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," "anticipate," "believe," "estimate," "project," "predict," "potential," or the negative of those terms, and similar expressions and comparable terminology intended to reference future periods. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- our plans for resubmission of our 505(b)(2) New Drug Application ("NDA") for Qtrypta to the U.S. Food and Drug Administration (the "FDA"), including our plan to conduct an additional pharmacokinetic study and the willingness of the FDA's Division of Neurology II to review the study protocol and provide comments prior to the initiation of the study;
- our expectations regarding the clinical effectiveness and safety of our product candidates;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved product;
- our manufacturing capabilities and strategy, and our ability to establish and maintain relationships with contract manufacturing organization(s) to expand our manufacturing capacity;
- the anticipated timing, costs and conduct of our planned clinical trials and preclinical studies;
- 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 our product candidates;
- our ability to establish and maintain development partnerships;
- our ability to attract or retain key personnel;
- our expectations regarding federal, state and foreign regulatory requirements; and
- regulatory developments in the United States and foreign countries.

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

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.

Risk Factors Summary

The following is a summary of the principal risks that could materially adversely affect our business, results of operations, and financial condition, all of which are more fully described in Item 1A, “Risk Factors.” This summary should be read in conjunction with the Item 1A, “Risk Factors” and should not be relied upon as an exhaustive summary of the material risks we face.

Below is a summary of some of the principal risks we face.

- We will need substantial additional funding to fund our operations, and we may not be able to continue as a going concern if we are unable to do so. We could also be forced to delay, reduce or terminate our product development, other operations or commercialization effort.
- 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 lead product candidates.
- Our build-to-suit arrangement with Trinity Funding 1, LLC (“Trinity”), the successor to Trinity Capital Fund III, L.P., imposes restrictions on our business, and if we default on our obligations, Trinity would have a right to request payment in full of the build-to-suit obligation.
- We have limited operating history and capabilities.
- The development and commercialization of our product candidates are subject to many risks. For example, we received a complete response letter from the FDA in response to our NDA for Qtrypta, and based on feedback from the FDA, we are planning to conduct an additional pharmacokinetic study for inclusion in an NDA resubmission package. However, there is no guarantee that we will be able to adequately address the issues raised to the FDA’s satisfaction. If we do not successfully develop, receive approval for, and commercialize our product candidates, our business will be adversely affected.
- If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.
- Clinical trials are very expensive, time-consuming and difficult to design and implement.
- The COVID-19 pandemic could adversely impact our business, including our clinical trials.
- The results of our clinical trials may not support the intended use of Qtrypta or any other product candidates we may develop.
- Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- We use customized equipment to coat and package our transdermal microneedle system; any production or equipment performance failures could negatively impact the clinical trials of our product candidates that we may develop or sales of our product candidate(s), if approved.
- We currently depend primarily on third-party suppliers for manufacture of our product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of materials for clinical trials or commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize Qtrypta or any other product candidates we may develop.
- We rely on contract manufacturing organizations ("CMOs") for various components of our transdermal microneedle system, and our business could be harmed if those third parties fail to provide us with sufficient quantities of those components at acceptable quality levels and prices or fail to maintain or achieve satisfactory regulatory compliance.

- We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to comply with applicable regulatory requirements or to meet deadlines for the completion of such trials.
- We have no experience selling, marketing or distributing approved product candidates and have no internal capabilities to do so, and will rely on Eversana and other third parties for the commercialization of Qtrypta, and we and they may not be able to effectively market, sell and distribute Qtrypta, if approved.
- 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.
- The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.
- If we are unable to maintain listing of our securities on the Nasdaq Capital Market or another reputable stock exchange, it may be more difficult for our stockholders to sell their securities.

PART I

Item 1. BUSINESS

Overview

Zosano Pharma Corporation is a clinical-stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics and other bioactive molecules to patients using our proprietary transdermal microneedle system (the “System”). Our System is designed to facilitate rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. The System consists of a $3cm^2$ to $6cm^2$ array of titanium microneedles approximately 200-350 microns in length, coated with a hydrophilic formulation of drug, mounted on an adhesive patch. The patch is applied with a reusable 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 microneedles penetrate the stratum corneum to allow the drug to be absorbed into the microcapillary system of the skin. We are focused on developing products for indications in which we believe rapid onset, ease of use and product stability may offer significant therapeutic and practical advantages, and on developing products where rapid administration of approved drugs with established safety and efficacy profiles provides an increased benefit to patients, in markets where patients remain underserved by existing therapies. We anticipate that many of our current and future development programs may enable us to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards potential commercialization.

Our development efforts are currently focused on our product candidate, Qtrypta™ (M207) ("Qtrypta"). Qtrypta is our proprietary formulation of zolmitriptan delivered utilizing our System. 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. Qtrypta was developed with the intent of providing faster onset of efficacy and sustained freedom from migraine symptoms. Qtrypta is designed for rapid absorption of zolmitriptan into the bloodstream without dependence on the gastrointestinal ("GI") tract.

We submitted a 505(b)(2) New Drug Application (“NDA”) for Qtrypta to the U.S. Food and Drug Administration (the “FDA”) on December 20, 2019, and on October 20, 2020, we received a Complete Response Letter (“CRL”) from the FDA with respect to the NDA. The CRL cited inconsistent zolmitriptan exposure levels observed across clinical pharmacology studies, which had been previously identified in the FDA’s discipline review letter that we received on September 29, 2020. Specifically, the CRL noted differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in our clinical trials and inadequate pharmacokinetic bridging between the lots that made interpretation of some safety data unclear. The CRL referenced unexpected high plasma concentrations of zolmitriptan observed in five study subjects enrolled in our pharmacokinetic studies. The FDA recommended that we conduct a repeat bioequivalence study comparing lots manufactured with the equipment used during development. The CRL noted that additional product quality validation data, which were planned to be submitted following approval, if received, were required to be submitted with the application. In addition, the CRL mentioned that due to U.S. Government and/or Agency-wide restrictions on travel, inspections of our contract manufacturing facilities were not able to be conducted but would be required before the application may be approved.

On January 29, 2021, we held a Type A meeting with the FDA Division of Neurology II (the “Division”) regarding the requirements for resubmission of the Qtrypta NDA. Based on feedback from the Type A meeting held with the Division, we plan to conduct an additional pharmacokinetic (“PK”) study for inclusion in an NDA resubmission package. During the meeting, the Division did not request that we conduct any further clinical efficacy studies to support the resubmission. On February 19, 2021, we received the official Type A meeting minutes from the FDA. The Type A meeting minutes were generally consistent with our expectations to conduct an additional PK study for inclusion in an NDA resubmission package. In a post-meeting comment, the FDA recommended a skin assessment on patients in the planned PK study to generate additional safety information. This assessment is included in the proposed study protocol, which has been submitted to the FDA. The Division indicated willingness to review the study protocol and provide comments prior to the initiation of the study. Our plans for resubmitting the NDA are based on our discussions with the FDA and may be subject to change upon receipt of the FDA’s comments to the proposed study protocol. We will incur additional costs and delays in our previously anticipated timeline for potential commercialization due to the additional PK study, and our plan to resubmit the NDA may be further delayed and we may incur higher than anticipated additional costs depending on the feedback we receive from the FDA on the study protocol and the time it takes to complete the PK study, or any additional studies or other requirements of the FDA. In addition, there is no guarantee that we will be able to adequately address the issues raised to the FDA’s satisfaction.

We do not anticipate realizing product revenues unless and until the FDA approves our Qtrypta NDA and we begin commercializing Qtrypta, which may never occur.

If approved, we plan to use contract manufacturing organizations ("CMOs") for the commercial production of Qtrypta. These CMOs include companies that will produce the various components that comprise our patch, our applicator, as well as the final packaging of the finished product. If approved, our CMOs will be required to produce commercial supply of Qtrypta in accordance with the FDA's current good manufacturing practices ("cGMP") regulations. These companies are located in the United States and have expertise and experience in contract manufacturing.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the FDA, or equivalent foreign regulatory bodies, to market and sell our product candidates. Accordingly, our success depends not only on the development, but also on our ability to finance the development of each of our product candidates. We will require substantial additional funding to complete development and seek regulatory approval for these products.

On August 6, 2020, we entered into a master services agreement (the "Eversana Agreement") with Eversana Life Science Services, LLC ("Eversana") for the commercialization of Qtrypta in the United States, if approved by the FDA. Under the terms of the Eversana Agreement, Eversana and we will cooperate to conduct activities over the term of the Eversana Agreement pursuant to a commercialization budget estimated at approximately $250.0 million. We maintain ownership of the Qtrypta NDA as well as all legal, regulatory and manufacturing responsibilities for Qtrypta. Eversana receives an exclusive right to conduct agreed commercialization activities and will utilize its internal sales organization along with its other commercial capabilities for market access, marketing, distribution and patient support services for Qtrypta. Eversana will receive reimbursement of certain commercialization costs and a low double digit to mid-teen percentage of product profits if and when our net sales for Qtrypta surpass certain costs incurred by the parties pursuant to the commercialization budget.

The term of the Eversana Agreement is five years following the date, if any, that the FDA approves the NDA. Upon expiration or termination of the Eversana Agreement, we will retain all profits from product sales consummated after expiration or termination and assume all future corresponding commercialization responsibilities. We may terminate the Eversana Agreement if Eversana fails to provide pre-commercial or commercial plans and budgets by specified dates, if we decide to discontinue development or commercialization efforts for Qtrypta in the United States (subject to a termination payment if such termination occurs within a specified time period), or upon a change of control. Either party may terminate the Eversana Agreement if FDA approval is not received by July 31, 2021, if net profits are not realized within a specified time period following commercial launch, for material breach of the Eversana Agreement by the other party that is not cured within a defined time period, for insolvency of the other party, if Qtrypta is subject to a safety recall in the United States or if Qtrypta is not commercially launched within a specified time period after FDA approval of the NDA (other than by reason of the terminating party's failure to perform its obligations under the Eversana Agreement). Due to the CRL and additional PK study, we do not expect that FDA approval of the NDA will be received by July 31, 2021.

We currently have no internal sales, marketing or distribution capabilities and we plan to rely on Eversana and other third parties for the commercialization of Qtrypta, if approved.

Our Strategy

Our goal is to make transdermal drug delivery a preferred delivery modality for indications where rapid onset, ease of use and room temperature stability of the formulation may offer significant therapeutic and practical advantages to patients. Our near-term focus is the development and commercialization, if approved, of our lead product candidate, Qtrypta. The key elements of our strategy are to:

Develop and commercialize Qtrypta. We believe that Qtrypta, if approved by the FDA, will offer the following meaningful therapeutic and practical advantages:

- *Rapid absorption:* We believe Qtrypta is the only triptan currently formulated to be delivered transdermally to have a rapid onset of action. In a Phase I pharmacokinetic trial, Qtrypta provided rapid and reproducible zolmitriptan delivery. The amount of time it took zolmitriptan to reach the maximum concentration (Tmax) was less than 20 minutes and was similar to subcutaneously administered sumatriptan. In the pivotal Phase 2/3 clinical trial, Qtrypta demonstrated pain relief beginning as early as 15 minutes (becoming statistically significant by 60 minutes).
- *Symptom relief:* In the pivotal Phase 2/3 clinical trial, Qtrypta demonstrated significant pain freedom, pain relief and freedom from most bothersome symptom ("MBS") at two hours post-treatment, with most patients not requiring additional rescue medications. Post-hoc analyses of patients with difficult to treat migraine, such as morning migraine, migraine with nausea, migraine with severe pain and patients who delayed treatment, showed

clinically significant pain freedom and relief as compared to placebo. Additionally, the efficacy results from our Long-Term Safety Study ("LTSS") of Qtrypta were similar to those of our pivotal Phase 2/3 clinical trial.

- *Durability:* In the pivotal Phase 2/3 trial, Qtrypta demonstrated durable impact on pain freedom and pain relief through 24 and 48 hours compared to placebo.
- *Favorable Safety Findings:* In the LTSS, data from safety assessments showed that Qtrypta was well-tolerated throughout the 12 months of repeated use. The most common adverse events were redness and swelling at the application site of which more than 95% were classified as mild. Moreover, 80% of these site reactions resolved within 48 hours.

Pursue additional product candidates We have conducted initial feasibility studies on a number of compounds which suggest that our System may have potential for further evaluation with large molecules, small molecules, and vaccines. We are focused on programs where we believe rapid drug delivery, ease of use and formulation room temperature stability may offer meaningful therapeutic and practical advantages to patients and healthcare providers. We are pursuing these programs with certain strategic partners to further the clinical and commercial development of such product candidates.

Qtrypta for Migraine

The focus of our development efforts is on our product candidate Qtrypta, our proprietary formulation of zolmitriptan, delivered via our System, which is a member of a class of serotonin receptor agonists known as triptans, used for the acute 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. A migraine often lasts between four and 24 hours but may last as long as three days. Our Qtrypta System is applied to an individual’s upper arm to deliver zolmitriptan to the systemic circulation, with the objective of:

- Providing rapid absorption of drug;
- Clinically meaningful pain freedom and pain relief;
- Clinically meaningful freedom from most bothersome symptom;
- Sustained freedom from migraine symptoms up to 48 hours post-treatment; and
- Avoiding exposure to the GI tract.

According to the American Research Foundation, migraine is a prevalent, chronic and disabling neurological disease impacting one billion patients globally, making it the third most common disease in the world. The World Health Organization places migraine as one of the 10 most disabling medical illnesses. 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.

In the United States, migraine affects approximately 39 million people, 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. For more than 90% of those affected, migraine interferes with education, career or social activities. Migraine attacks are estimated to lead to lost productivity costs as high as $36 billion annually in the United States.

According to published studies, many patients experience difficult to treat migraine with:

- 41% reporting severe headache attacks are present upon awakening or morning migraine;
- 44% report persistent frequent nausea during a migraine;
- 49% report avoiding or delaying taking migraine medication; and
- 53% report severe headache attacks come on very quickly.

While new classes of drugs for the acute treatment of migraine have been recently approved, triptans remain the standard of care for an acute migraine attack. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice recommends:

- Treating early after the onset of a migraine attack;
- Choosing a non-oral route of administration for selected patients;
- Accounting for tolerability and safety issues; and
- Using migraine-specific agents (triptans & Dihydroergotamine) for moderate or severe attacks.

Patients however remain dissatisfied with their acute treatments. Patient reported outcomes from the Unmet Acute Treatment Needs from the 2017 Migraine in America Symptoms and Treatment Study (the "2017 MAST Study") showed that:

- 74% of patients had inadequate treatment response; and
- Approximately 50% experienced inadequate pain freedom.

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 according to the 2017 MAST Study, 82% of patients discontinued using an injectable triptan due to side effects.

Two new classes of drugs, a Calcitonin gene-related peptide receptor ("CGRP") antagonist and a 5-HT (1F) agonist for the acute treatment of migraine were approved in 2019, and one additional CGRP antagonist was approved in 2020. While these new acute treatment medications offer clinicians and patients greater choice, we believe these products also have limitations:

- These drugs are oral tablets, and with many migraine patients reporting nausea with their attacks, taking a tablet can be difficult.
- Published clinical studies on the CGRP receptor antagonists showed less than optimal therapeutic gain (active-placebo percentages) for pain freedom and sustained pain freedom.
- FDA labeling with the 5-HT (1F) agonist drug includes an eight-hour driving restriction and is a DEA scheduled drug.

ZOTRIP Phase 2/3 Trial Achieved Statistical Significance on Co-primary Endpoints with the 3.8mg Dose

On February 13, 2017, we announced the results of our ZOTRIP pivotal efficacy trial for Qtrypta. The ZOTRIP trial was a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of Qtrypta (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 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 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 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 was not associated with any serious adverse events ("SAEs"). While the 1.0mg and 1.9mg doses of Qtrypta 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 at 2 hours	14.3%	41.5%	0.0001
Most bothersome symptom free at 2 hours	42.9%	68.3%	0.0009

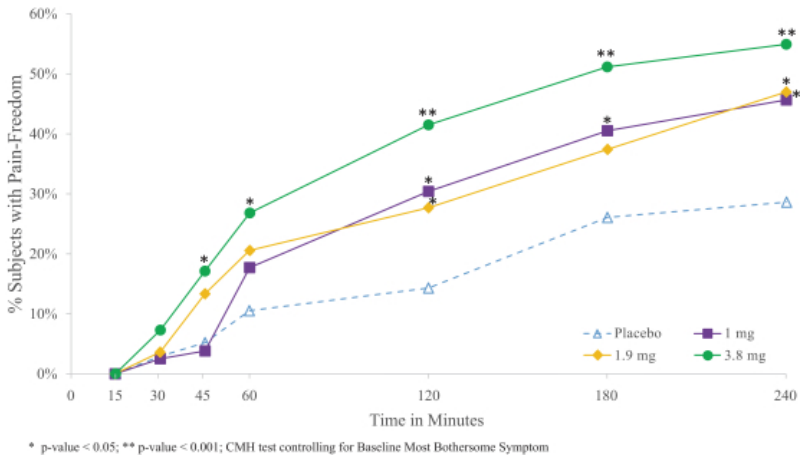
ZOTRIP Trial Secondary Endpoint Results for 3.8mg

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

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

General disorders and administration site conditions	Placebo	ZP-Zolmitriptan 1 mg	ZP-Zolmitriptan 1.9 mg	ZP-Zolmitriptan 3.8 mg
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%

The ZOTRIP trial results demonstrating pain freedom after treatment with Qtrypta™ are illustrated below:



Preplanned subgroup 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

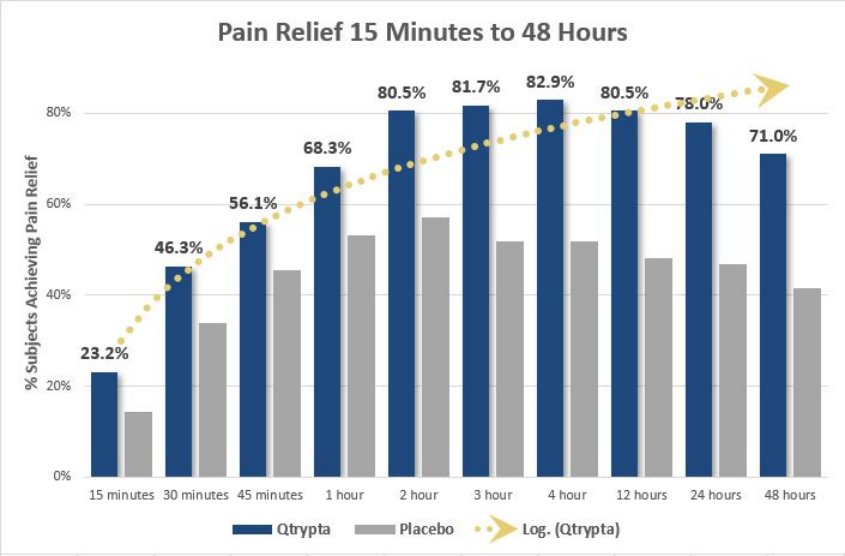
Pain Relief	Placebo	3.8mg M207	p-value*
1 Hour	53.2%	68.3%	< 0.05
2 Hours	57.1%	80.5%	< 0.05

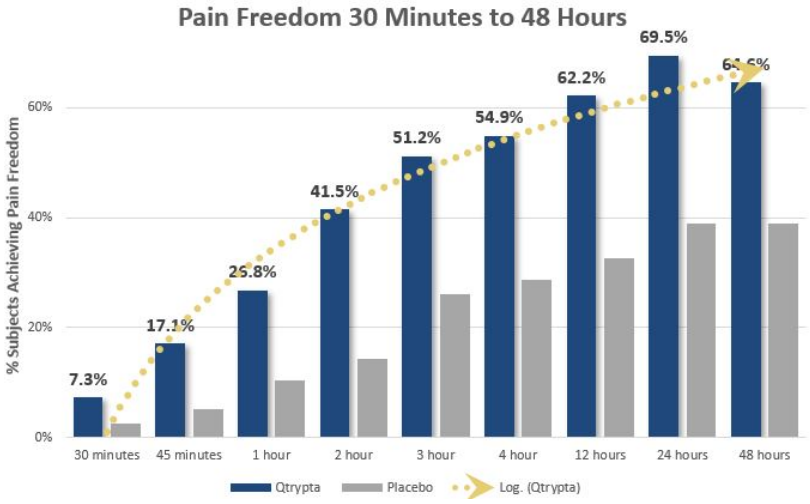
Sustained Pain Relief	Placebo	3.8mg M207	p-value*
2 – 24 Hours	37.7%	68.3%	< 0.0001
2 – 48 Hours	32.5%	63.4%	< 0.0001

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

* The "p" value is the probability of an event occurring by chance alone. p-values are nominal because of order of statistical testing.

The following figures illustrate the percent of subjects who reported pain relief or pain freedom following Qtrypta or placebo treatment at the various time points from 15 minutes to 48 hours (pain relief) or 30 minutes to 48 hours (pain freedom):





M207 LTSS

In November 2017, we initiated our LTSS for Qtrypta as an acute treatment of migraine. The LTSS was an open label study evaluating the safety of the 3.8 mg dose of Qtrypta 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 the LTSS was to assess safety of Qtrypta 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 LTSS 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 LTSS with more than 50 evaluable subjects completing one year of treatment with Qtrypta.

In September 2019, final results from the LTSS were presented at the 19th Congress of the International Headache Society in Dublin, Ireland. In the trial, 257 subjects were treated on average for two or more migraines per month for six months and 127 subjects were treated on average for two or more migraines a month for twelve months. Data from safety assessments showed that Qtrypta was well-tolerated throughout the 12 months of repeated use. The most common adverse events were redness and swelling at the application site following patch application, of which more than 95% were classified as mild. More than 80% of these site reactions were gone within 48 hours. Patients treated with Qtrypta reported less triptan-like neurological side effects than are typically found with the class, with less than 2% of patients reporting effects such as dizziness and paresthesia.

Post-hoc Efficacy Analyses of Qtrypta

In June 2020, we presented new post-hoc efficacy analyses of Qtrypta as a virtual oral presentation on the 2020 American Headache Society's Virtual Annual Scientific Meeting Platform. Six different measurements of pain reduction from the exploratory efficacy results in the LTSS were examined and compared to the positive clinical results observed in the Phase 2/3 Zotrip study. Across all six efficacy measurements, which included pain freedom and pain relief at 2 hours, clinical activity observed in the LTSS during the one-year trial period treating approximately 5,600 migraine episodes was consistent with the positive pivotal study results.

Parameter	ZOTRIP (Single Dose)		Open-Label
	Placebo	M207 3.8 mg	Long-Term
	(n = 77)	(n = 82)	M207 3.8 mg
			(5,617 migraine episodes*)
Pain Freedom at 2 hours	14 %	42 %	44 %
Pain Relief at 2 hours	57 %	81 %	81 %
Sustained Pain Freedom 2-24 hour	10 %	32 %	38 %
Sustained Pain Freedom 2-48 hour	9 %	27 %	35 %
Sustained Pain Relief 2-24 hour	38 %	68 %	70 %
Sustained Pain Relief 2-48 hour	33 %	63 %	65 %

* For sustained endpoints, data from all time points 2-24 (48) hours had to be present

Similar to the pivotal study, the most common adverse events observed in the LTSS were redness and swelling at the application site, of which more than 95% were classified as mild. 80% of these site reactions were generally resolved within 48 hours. Subjects treated with Qtrypta reported less triptan-like neurological side effects than are typically found with the class, with less than 2% of subjects in the LTSS reporting effects such as dizziness and paresthesia.

On February 1, 2021, we announced that early onset of action data for Qtrypta were presented at the Annual Headache Cooperative of the Pacific Winter Conference. In a post-hoc retrospective analysis of data from the previously published ZOTRIP trial involving 365 subjects who received Qtrypta 3.8 mg or placebo, of 82 Qtrypta-treated subjects, 38 reported pain relief at 30 minutes, and 28 of the 38 subjects (74%) were pain free at two hours. All 6 subjects treated with Qtrypta who reported pain freedom at 30 minutes were pain-free at two hours. This compares to nine of 26 subjects (35%) in the placebo group (n=77) who reported pain relief at 30 minutes that were pain free at 2 hours, and 1 of 2 subjects that were pain free at 30 minutes being pain free at 2 hours.

Migraine Assessment of Current Therapy Scores

Migraine Assessment of Current Therapy (“Migraine-ACT”) scores for Qtrypta were evaluated at each clinical visit during the LTSS. The Migraine-ACT score is established using a questionnaire that assesses four key components of effective migraine treatment, including: (1) global assessment of relief (2-hour pain freedom), (2) headache impact, (3) consistency of response and (4) emotional response. At the last time point assessed (after 48 weeks of therapy) (n=184), we observed that the Migraine-ACT scores as of August 1, 2019, remained highly favorable across the four questions evaluated:

Question	Proportion who answered “Yes”
Does your migraine medication work consistently, in the majority of your attacks?	96%
Does the headache pain disappear within 2 hours?	85%
Are you able to function normally within 2 hours?	84%
Are you comfortable enough with your medication to be able to plan your daily activities?	94%

C213 for the Treatment of Cluster Headache

In October 2019, we announced that we had begun enrolling patients in our Acute Treatment of Cluster Headache placebo-controlled Phase 2/3 clinical trial to evaluate the efficacy of C213 for the acute treatment of cluster headache. Like Qtrypta for the potential acute treatment of migraine, C213 for the potential acute treatment of cluster headache consists of our investigational proprietary formulation of zolmitriptan delivered utilizing our System. Due to the novel coronavirus (“COVID-19”) pandemic, new enrollment into the clinical trial was temporarily suspended between March 2020 and June 2020. Subject enrollment resumed in July 2020, however, at a rate slower than originally anticipated. In November 2020, we decided to end enrollment of new subjects into the clinical trial as of December 31, 2020 to conserve resources. We plan to continue to evaluate subjects enrolled prior to December 31, 2020. Subjects enrolled in the Phase 2/3 study prior to December 31, 2020 were randomized to receive 1.9 mg of C213, 3.8 mg of C213, or placebo in a 1:1:1 fashion. The co-primary endpoints of the study are the proportion of patients who achieve pain relief at 15 minutes and the proportion of patients whose pain relief is sustained from 15 minutes to 60 minutes. A total of 42 subjects were randomized in the trial.

Our Research Programs

Our internal research and development programs use molecules with established safety and efficacy that are formulated to enable delivery through our proprietary System. In selecting our development candidates, we consider the therapeutic advantage of rapid onset, the size of the market, the level of competition and the commercial value.

Our System consists of a $3cm^2$ to $6cm^2$ array of titanium microneedles approximately 200-350 microns in length, coated with a hydrophilic formulation of drug, 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 $2cm^2$, $3cm^2$ and $6cm^2$ microneedle arrays. In the pivotal trial for Qtrypta, we used two $3cm^2$ 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 $6cm^2$ microneedle array while maintaining acceptable tolerability. The patch is applied with a hand-held reusable 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 targeted patch wear time is generally thirty to sixty minutes.

We have tested our 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 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 and cluster headache is highly competitive. Several key competitive factors have the potential to affect Qtrypta, if approved. These include safety, efficacy, convenience, price, the level of generic competition and the availability of coverage and reimbursement from payers and government institutions.

We expect to have considerable competition from major pharmaceutical, biotechnology, specialty pharmaceutical and medical device 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 in preclinical and clinical development, manufacturing, regulatory compliance and global commercialization.

Companies marketing products or that have products in development to treat migraine or cluster headache which may compete with our Qtrypta or C213 product candidates include, but are not limited to, Teva Pharmaceutical Industries, GlaxoSmithKline, Eli Lilly & Company, AstraZeneca, Novartis, Allergan, Biohaven Pharmaceuticals, Lundbeck, Amgen, Merck & Co., Pfizer, Janssen Pharmaceutica, Endo International, Assertio, Upsher-Smith Laboratories, Satsuma Pharmaceuticals, Supernus Pharmaceutical, Currax Pharmaceuticals, Impel NeuroPharma, Axsome Therapeutics, electroCore, eNeura, Cefaly, Theranica, Amneal Pharmaceuticals and generic manufacturers of acute and preventive therapies.

Competition in Drug Delivery Platforms

In addition to competition for our product candidates, as we develop opportunities to expand our product pipeline utilizing our drug delivery System, we face additional competition from companies that are developing or that may develop and license drug delivery platforms similar to ours. Such companies include, but are not limited to 3M Company, Corium International, Inc., Radius Health Inc., Vaxxas Inc., Becton, Dickinson and Company, NanoPass Technologies Ltd., Inovio Pharmaceuticals and Noven Pharmaceuticals, Inc.

Manufacturing and Research and Development

The manufacturing process for our System consists of three primary operations: (1) the formation of the microneedle array, involving etching of titanium foil and subsequent array forming, (2) the application of the drug formulation to the microneedle array and (3) the manufacturing of the reusable applicator.

We operate a manufacturing facility in Fremont, California, designed to comply with cGMP and believe we have adequate manufacturing capabilities and capacity to produce our System for preclinical, Phase 1, Phase 2 and for some Phase 3 clinical trials. We continue to expand our manufacturing capabilities and have implemented automation of certain processes to further expand our capacity. We produced three cGMP registration batches of Qtrypta in the third quarter of 2018, which have been used to support our NDA filing with the FDA. We purchase various components or intermediates of our System from third-

party vendors, including titanium foil, active pharmaceutical ingredients and excipients, inner ring, adhesive backing, ring and backing assembly, outer ring and primary and secondary packaging components. The majority of these components and intermediaries are available from multiple sources. We also outsource the manufacturing of our applicators.

We have engaged CMOs to produce commercial supplies of Qtrypta. We have manufactured three cGMP site qualification batches of Qtrypta at a CMO site in Greenville, North Carolina, in order to enable the regulatory approval of this site for commercial manufacturing. Additional CMOs have been engaged for the production of components that comprise our System and these CMOs are currently building out facilities, installing equipment, and developing and validating the processes necessary to manage commercial operations for Qtrypta. The CRL received from the FDA mentioned that due to U.S. Government and/or Agency-wide restrictions on travel, inspections of Zosano's contract manufacturing facilities were not able to be conducted but that such inspection would be required before the Qtrypta NDA may be approved.

As of December 31, 2020, our research and development group consisted of 32 employees, located at our headquarters location 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 System. The group has particular expertise in two areas critical to our success: developing drug formulations that can be delivered using our System and optimizing the technology to deliver those drugs.

The goals of our research and development efforts are to identify and develop drugs that can be delivered using our System. For the years ended December 31, 2020 and 2019, we incurred $21.6 million and $25.4 million, respectively, of research and development expense. See Part II. Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this report for additional detail regarding our research and development activities.

Intellectual Property

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

As of January 31, 2021, we held exclusive licenses to or owned 26 U.S. patents and seven pending U.S. patent applications, covering key features of our System, such as formulation, methods of treatment, coating, array design, patch anchoring, patch application, delivery, manufacturing and packaging.

We have licensed all of these patents and patent applications from ALZA Corporation, a subsidiary of Johnson & Johnson ("ALZA"), on an exclusive basis for all countries, with the exception of (i) one issued U.S. patent and four pending U.S. patent applications, and nine foreign (including two European) patent applications covering the formulation of Qtrypta, (ii) two U.S. patents and one European patent, and a pending European patent application covering stable glucagon peptide formulation, (iii) one pending U.S. patent application covering transdermal active agent delivery devices having coronavirus vaccine coated microprotrusions, (iv) one pending U.S. patent application covering transdermal drug delivery devices having psilocybin, lysergic acid diethylamide ("LSD") or 3,4-methylenedioxymethamphetamine ("MDMA") coated microprotrusions, and (v) a new applicator design described below. These patents and patent applications are foundational and apply generally to our product candidates and applicator. Under the terms of the license agreement with ALZA, we are responsible for all development and development costs related to our System. We are also responsible for commercializing our 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 utilize the intellectual property covered by the licensed patents or any intellectual property that may be developed by us based on certain ALZA know-how or inventions, and to pay ALZA amounts equal to the greater of royalties in the low to mid- single digits on sales by our sublicensees of such products or a percentage in the mid-teens to low twenties of royalties received by us on sales by our sublicensees of such products. We are also obligated to pay ALZA a percentage of non-royalty revenue that we receive from our sublicensees based on sales of such products. The license agreement will terminate upon the expiration of our obligations to make the royalty and other payments described above to ALZA. Additionally, we may terminate the agreement at any time for convenience upon prior written notice to ALZA, and either party may terminate the agreement upon a material breach of the agreement by the other party.

We have filed six pending U.S. patent applications and ten pending foreign applications covering our single-use applicator and formulations of zolmitriptan, stable glucagon peptide, and applicator devices having coronavirus vaccine, psilocybin, LSD or MDMA-coated microprotrusions. The last of our issued technology platform patents are projected to expire in 2027.

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 partners, and have restricted access to our manufacturing facilities and other technology.

We have one registered trademark to Zosano, “ZOSANO PHARMA", Reg. No. 3705884 and six pending trademark applications: Trademark App. No. 87525805 for "ADAM", Trademark App. No. 87851807 for "QNOVIS", Trademark App. No. 87851814 for "QTRYPTA", Trademark App. No. 87855458 for "TIZOVIAL", Trademark App. No. 87855469 for "QIXONTI", and Trademark App. No. 87855481 for "AXILARIM".

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. Our product candidates are subject to regulation by the FDA as a drug/device combination product. 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. 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 of 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 Qtrypta program and we believe the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our Qtrypta product candidate. Accordingly, we have investigated Qtrypta through the Investigational New Drug ("IND") application framework and are seeking approval through the NDA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the device component of Qtrypta, but this could change during its review of any marketing application that we may submit.

In the United States, the FDA regulates drugs and devices pursuant to the Federal Food, Drug and Cosmetic Act ("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 marketing applications, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

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:

- completion of preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA’s Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials in the United States may begin;
- approval by an independent institutional review board ("IRB") or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials, in accordance with good clinical practice ("GCP") requirements, to establish the safety and efficacy of the drug for each proposed indication to the FDA’s satisfaction;
- submission to the FDA of an NDA after completion of all pivotal trials;
- FDA acceptance and review of the NDA, which may require an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of select clinical trial sites, and the manufacturing facility or facilities at which the drug, along with its device components, is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA 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, analytical data, product chemistry, controls and a proposed clinical trial protocol, 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. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCPs which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. 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. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Clinical trials necessary for product approval are typically conducted in the following three sequential phases, but the phases may overlap.

- *Phase 1*: In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.
- *Phase 2*: Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.
- *Phase 3*: Phase 3 trials help obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances.

Phase 4 clinical trials are conducted after FDA approval to gain additional experience from the treatment of patients in the intended therapeutic indication or otherwise when requested by the FDA in the form of post-market commitments. Failure to promptly conduct any required Phase 4 post-market studies could result in withdrawal of FDA approval.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Assuming successful completion of the required clinical testing in accordance with all applicable regulatory requirements, 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. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that such NDA is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept the NDA for filing. The FDA reviews NDAs through a two-tiered classification system, Standard Review and Priority Review. The FDA endeavors to review Standard Review applications within ten to twelve months, whereas FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity. 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 refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA does not approve of the NDA or the manufacturing facilities, it will issue a CRL to indicate that the review cycle for an application is complete and that the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information required for the FDA to reconsider the application. If a CRL is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy (“REMS”) to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be

established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

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 Qtrypta 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.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Hatch-Waxman Act

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman Amendments, which provide alternative pathways to regulatory approval through Sections 505(j) and 505(b)(2) of the FDCA, were enacted. 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. Section 505(j) permits applicants with generic drug products to submit an abbreviated new drug application ("ANDA") in reliance 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. Under these pathways, 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 a Section 505(b)(2) applicant.

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

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. A certification that the new product will not infringe the RLD's listed patents or that such patents are invalid is called a Paragraph IV certification. 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 new application. The application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity or orphan drug exclusivity, listed in the Orange Book for the RLD has expired.

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 sponsor and to all patent holders for the RLD once the applicant's ANDA or Section 505(b)2 NDA has been accepted for filing by the FDA. The NDA sponsor 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 ANDA or Section 505(b)(2) NDA by imposing a 30-month automatic stay on approval, 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 market exclusivity for new chemical entities which prevents the FDA from accepting ANDA and Section 505(b)(2) applications containing the protected active ingredient until the expiration of the five year market exclusivity. The Hatch-Waxman Act also provides three years of data 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. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application that relies on the information supporting the approval of the drug or the change to the drug for which the information was submitted and the exclusivity granted until after that three-year exclusivity period has expired. However, the FDA can accept an application and begin the review process during the three-year exclusivity period.

Coverage, Pricing and Reimbursement

Sales of products that we may market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of coverage and the 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 will be required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of any of our products, if approved, 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 product candidates are approved by the FDA, we intend to work with payers to demonstrate the clinical benefits of our products over other delivery modalities and we intend to secure adequate and commercially favorable pricing and reimbursement levels, but we cannot guarantee that coverage or adequate reimbursement will be available.

In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payors. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product or product candidates to be medically necessary or cost-effective compared to other available therapies.

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products or product candidates if approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates once approved or additional pricing pressures.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 ("ACA"), which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- An annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act of 2017 ("Tax Act") was enacted, which, among other things, removed the penalties for not complying with the ACA's individual mandate to carry health insurance.

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the ACA was invalid due to the legislative repeal of the individual mandate. This decision was subsequently appealed, and on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the decision of the district court that the individual mandate, as amended by the Tax Act, was unconstitutional. The Fifth Circuit remanded the case to the district court to consider a remedy, including to consider and explain which provisions of the ACA are inseverable and invalid. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of two percent (2%) per fiscal year, which went into effect in April 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken.

If we establish international operations, we will be subject to compliance with the Foreign Corrupt Practices Act (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.

Other Healthcare Laws and Compliance Requirements

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. 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, many of which may become more applicable to us if any of our product candidates are approved and we begin commercialization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and physician sunshine transparency laws and regulations with respect to drug pricing and payments and other transfers of value made to physicians and other healthcare providers, including those described below.

The federal Anti-Kickback Statute, prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal transparency requirements known as the federal Physician Payments Sunshine Act, implemented under the ACA, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians (as defined by statute), certain other healthcare providers beginning in 2022, and teaching hospitals, and information regarding ownership and investment interests held by physicians and their immediate family members.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We are also and may become subject to analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers. In addition, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/or imprisonment.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act ("CCPA"), the California Privacy Rights Act ("CPRA") and the General Data Protection Regulation ("GDPR"), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

As of December 31, 2020, we had 45 employees, all of whom were employed full time and located in the United States, with 43 located at our corporate headquarters in Fremont, California. The majority of our employees are salaried. Of the 45 employees, 32 were focused on research and development activities including pre-clinical, clinical and pre-commercial manufacturing activities and the remainder were focused on general and administrative activities. Four of our employees hold doctorate degrees in their respective scientific and pharmaceutical fields. None of our employees are represented by labor unions. Additionally, we make extensive use of third-party contractors, consultants and advisors to perform many of our present activities. Our Code of Ethics provides for equal employment opportunity without discrimination or harassment on the basis of race, color, national origin, religion, sex, age, sexual orientation, disability, or any other status protected by law.

We use a combination of fixed and variable pay including base salary, bonuses and stock-based compensation. Our annual bonuses are linked to overall company performance, as well as each individual's contribution to the results achieved. The principal purposes of our equity incentive plans are to attract, retain and motivate employees and directors through the granting of stock-based compensation awards. The emphasis on overall company performance is intended to align the employee's financial interests with the interests of stockholders. We are committed to providing comprehensive benefit options and it is our intention to offer benefits that will allow our employees and their families to live healthier and more secure lives. We provide our full-time employees and their families with access to health programs and services for mental health, elder care and various personal support services through our Employee Assistance Program. Our health and welfare benefits are supplemented with specific programs to manage or improve common health conditions, a variety of voluntary benefits and paid time away from work programs.

Corporate Information

We were incorporated under the laws of the State of Delaware as ZP Holdings, Inc. in January 2012, and changed our name to Zosano Pharma Corporation in June 2014. Our business was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006. We were originally incorporated under the name The Macroflux Corporation, and changed our name to Zosano Pharma, Inc. in 2007 following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of ZP Holdings was merged with and into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of ZP Holdings. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc. ZP Group LLC, a former subsidiary that was originally formed as a joint venture with Asahi Kasei Pharmaceuticals USA (Asahi), ceased operations in December 2013 and was dissolved on December 30, 2016. On November 1, 2017, ZP Opco, Inc. merged with and into Zosano Pharma Corporation, with Zosano Pharma Corporation as the surviving corporation of the merger.

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

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, as well as general economic and business risks, and all of the other information contained in this Annual Report on Form 10-K and other documents that we file with the U.S. Securities and Exchange Commission ("SEC"). Any of the following risks could have a material adverse effect on our business, operating results, financial condition and prospects and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. Any of the following risks and uncertainties are, and will be, exacerbated by COVID-19 pandemic and any worsening of the global business and economic environment as a result. You should also refer to the other information contained in this Annual Report on Form 10-K, including our condensed financial statements and the related notes thereto.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We will need substantial additional funding to fund our operations, and we may not be able to continue as a going concern if we are unable to do so. We could also be forced to delay, reduce or terminate our product development, other operations or commercialization effort.

Developing and commercializing biopharmaceutical products, including launching new products into the marketplace and conducting preclinical studies and clinical trials, is an expensive and highly uncertain process that takes years to complete. As of December 31, 2020, we had an accumulated deficit of $332.2 million and approximately $35.3 million in cash and cash equivalents as well as negative cash flows from operating activities. We do not have sufficient cash and cash equivalents to fund our anticipated level of operations as they become due during the twelve months following the date of issuance of this Annual Report on Form 10-K. The aforementioned factors raise substantial doubt about our ability to continue as a going concern.

There is no assurance that additional funds will be obtained for our ongoing operations or that we will succeed in our future operations. Specifically, the COVID-19 pandemic has caused volatility in the global financial markets and threatened a slowdown in the global economy, which may adversely affect our ability to raise additional capital on attractive terms or at all. A recession, depression or other sustained adverse market event resulting from the spread of COVID-19 may also limit our ability to obtain financing for our operations. In addition, our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 include an explanatory paragraph regarding our ability to continue as a going concern which may discourage some third parties from contracting with us and some investors from purchasing our stock or providing alternative capital financing, which could adversely affect our business, financial condition, results of operations and prospects.

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

Since inception, we have incurred significant operating losses. For the twelve months ended December 31, 2020, we incurred a net loss of $33.4 million. As of December 31, 2020, we had an accumulated deficit of $332.2 million. We expect to continue to incur additional significant operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue the development of our product candidate, Qtrypta, or any other product candidates that we develop. These expenditures will be incurred for manufacturing, development, clinical trials, regulatory compliance and infrastructure. Even if we succeed in developing, obtaining regulatory approval for and commercializing Qtrypta or any other product candidates that we develop, because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict that we will ever be able to manufacture, distribute and sell any of our products profitably, and we may never generate revenue that is significant enough to achieve or maintain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

We expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

However, adequate and additional funding may not be available to us on acceptable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends on our common stock.

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

If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our development or future commercialization efforts or partner with third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The amount and timing of our future financing requirements will depend on many factors, including:

- the scope, progress, expansion, and costs of manufacturing our product candidates;
- the scope, progress, expansion, costs, and results of our clinical trials;
- the timing of, and costs involved in, obtaining regulatory approvals;
- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- our ability to establish and maintain development partnering arrangements;
- the timing, receipt and amount of contingent, royalty, and other payments from any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing, and if approved, commercializing our product candidates, including expenses we are obligated to incur under our commercialization agreement with Eversana for Qtrypta, if approved; and
- the costs associated with being a public company.

Our build-to-suit arrangement with Trinity imposes restrictions on our business, and if we default on our obligations, Trinity would have a right to request payment in full of the build-to-suit obligation.

We agreed to covenants in connection with the Trinity build-to-suit arrangement that may limit our ability to take some actions without the consent of Trinity, as applicable. In particular, without Trinity's consent under the terms of the build-to-suit arrangement, we are restricted in our ability to:

- create liens on our property;
- sell, transfer, or otherwise dispose of all or substantially all of our assets;
- transfer, dispose or relocate financed equipment;
- acquire or merge with another entity; and
- engage in a transaction that would constitute 50% or more in change in control.

Our indebtedness to Trinity may prevent us from engaging in activities that could be beneficial to our business and our stockholders unless we repay the outstanding obligation, which may not be desirable or possible.

We have pledged substantially all of our assets, including our intellectual property, to secure our obligations to Trinity. If we default on our obligations prior to repaying this indebtedness and are unable to obtain a waiver for such default, Trinity would have a right to accelerate our payments under the build-to-suit arrangement, as applicable, and possibly foreclose on the collateral, which would potentially include our intellectual property. Any such action on the part of Trinity would significantly harm our business and our ability to operate.

We have limited operating history and capabilities.

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

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

Our operations continue to be focused on pre-commercialization efforts for Qtrypta, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our product candidates.

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

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We face risks related to the Paycheck Protection Program loan, which could adversely affect our future cash flows and financial condition.

On April 21, 2020, we entered into a note (the "PPP Note") with Silicon Valley Bank pursuant to the Paycheck Protection Program ("PPP"), which provides for a loan in the amount of $1.6 million (the "PPP Loan"). The PPP, established as part of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), provides for loans to qualifying businesses and is administered by the U.S. Small Business Administration ("SBA"). The PPP Note is subject to the terms and conditions applicable to loans administered by the SBA under the CARES Act, which are subject to revisions and changes by Congress,

the Treasury Department and SBA. The term of the PPP Loan is two years. The annual interest rate on the PPP Loan is 1.0% and principal and interest payments are deferred until September 21, 2021. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and the maintenance of our payroll levels. We applied for forgiveness of the entire $1.6 million loan amount and accrued interest on October 4, 2020, utilizing the 24-week covered period allowed by the SBA. The lender reviewed the application and submitted it to the SBA on October 7, 2020. No assurance is provided that we will obtain forgiveness of the PPP Loan in whole or in part. If forgiveness is not granted, the PPP Loan will need to be repaid by us, which could have an adverse effect on our future cash flows and financial condition. Additionally, the Treasury Department and SBA continue to develop and issue new and updated regulations and guidance regarding the PPP loan process, including regarding required borrower certifications and requirements for forgiveness of loans made under the PPP. We continue to track the regulations and guidance as they are released and assess and re-assess various aspects of its application as necessary. However, given the potential for additional legislation, regulation or guidance, and based on our projected ability to use the loan proceeds for qualifying expenses, we cannot give any assurance that the PPP Loan will be forgivable in whole or in part. Finally, we may be subject to CARES Act-specific lookbacks and audits conducted by the Treasury, SBA or other federal agencies, including oversight bodies created under the CARES Act. These bodies have the ability to coordinate investigations and audits and refer matters to the Department of Justice for civil or criminal enforcement and other actions.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

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

To date, we have devoted the majority of our research, development and clinical efforts and financial resources toward the development of Qtrypta, our proprietary formulation of zolmitriptan for the acute treatment of migraine headaches. In December 2019, we submitted a 505(b)(2) New Drug Application ("NDA") to the FDA seeking approval for Qtrypta. On September 29, 2020, we received a Discipline Review Letter ("DRL") from the FDA in response to the application. The DRL described two concerns with respect to the clinical pharmacology section of the NDA. First, the FDA raised questions regarding unexpected high plasma concentrations of zolmitriptan observed in five study subjects from two pharmacokinetic studies, and how the data from these subjects affect the overall clinical pharmacology section of the application. Second, the FDA raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in our clinical trials.

On October 20, 2020, we received a complete response letter ("CRL") from the FDA in response to the Qtrypta NDA. The CRL stated that the FDA determined it could not approve the NDA in its present form and provided recommendations to address the remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality. The CRL cited inconsistent zolmitriptan exposure levels observed across clinical pharmacology studies, which had been previously identified in the DRL. Specifically, the CRL noted differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in our clinical trials and inadequate pharmacokinetic bridging between the lots that made interpretation of some safety data unclear. The CRL referenced unexpected high plasma concentrations of zolmitriptan observed in five study subjects enrolled in our pharmacokinetic studies. The FDA recommended that we conduct a repeat bioequivalence study comparing lots manufactured with the equipment used during development to address these issues.

The CRL further noted that additional product quality validation data, which were planned to be submitted following approval, if received, were required to be submitted with the application. In addition, the CRL mentioned that due to U.S. Government and/or FDA-wide restrictions on travel, inspections of our contract manufacturing facilities were not able to be conducted, but that such inspections would be required before the application may be approved.

On January 29, 2021, we held a Type A meeting with the FDA Division of Neurology II (the "Division") regarding the requirements for resubmission of the Qtrypta NDA. Based on feedback from the Type A meeting held with the Division, we plan to conduct an additional pharmacokinetic study for inclusion in an NDA resubmission package. On February 19, 2021, we received the official Type A meeting minutes from the FDA. The Type A meeting minutes were generally consistent with our expectations to conduct an additional PK study for inclusion in an NDA resubmission package. In a post-meeting comment, the FDA recommended a skin assessment on patients in the planned PK study to generate additional safety information. This assessment is included in the proposed study protocol, which has been submitted to the FDA. The Division indicated willingness to review the study protocol and provide comments prior to the initiation of the study. Our plans for resubmitting the NDA are based on our discussions with the FDA and may be subject to change upon receipt of the FDA's comments to the proposed study protocol. We will incur additional costs and delays in our previously anticipated timeline for potential

commercialization due to the additional PK study, and our plan to resubmit the NDA may be further delayed and we may incur higher than anticipated additional costs depending on the feedback we receive from the FDA on the study protocol and the time it takes to complete the PK study, or any additional studies or other requirements of the FDA. In addition, there is no guarantee that we will be able to adequately address the issues raised to the FDA's satisfaction.

In addition to the above factors, the development and commercialization of Qtrypta and any product candidates we may develop and commercialize in the future is subject to many risks including:

- we may be unable to obtain additional funding to develop our product candidates;
- we may experience delays in regulatory review and approval of our product candidates in clinical development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies or trials;
- we will be required to undertake additional clinical trials of Qtrypta before we receive approval of the NDA;
- the FDA may not accept data generated at our clinical trial sites;
- we may be unable to obtain and maintain regulatory approval of our product candidates in the United States and foreign jurisdictions;
- potential side effects of our product candidates could delay or prevent commercialization, limit the indications for any approved product candidate, require the establishment of a risk evaluation and mitigation strategy ("REMS"), or cause an approved product candidate to be taken off the market;
- the FDA may identify deficiencies in our manufacturing processes or facilities or those of our contract manufacturing organizations ("CMOs");
- the FDA may change its approval policies or adopt new regulations;
- we will depend on third-party manufacturers to supply or manufacture our products;
- we depend on contract research organizations to conduct our clinical trials;
- we may experience delays in the commencement of, enrollment of patients in and timing of our clinical trials;
- we may not be able to demonstrate that our product candidates are safe and effective treatments for their intended indications to the satisfaction of the FDA or other similar regulatory bodies;
- we may be unable to establish or maintain collaborations, licensing or other arrangements;
- the market may not accept our product candidates, if approved;
- we may be unable to establish and maintain an effective sales and marketing infrastructure;
- we will depend on Eversana or another third party to commercialize Qtrypta, if approved;
- we may experience competition from existing products or new products that may emerge; and
- we and our licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our product candidates.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to regulatory authorities, which may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of a study. This could result in a delay in approval, or rejection, of our marketing applications. If any of these risks materializes, we could experience significant delays or an inability to successfully commercialize our product candidates, which would have a material adverse effect on our business, financial condition and results of operations.

The LTSS for Qtrypta is an important step in the development of Qtrypta. If the results from the study do not establish the safety of Qtrypta to the FDA's satisfaction, the regulatory approval process could be delayed or failed, and our business could be adversely affected.

In February 2019, we announced the completion of the final phase of our LTSS where more than 50 evaluable subjects were treated for a year, and in September 2019, we announced the presentation of final results from the LTSS at the 19th Congress of the International Headache Society in Dublin, Ireland. The results of the LTSS will need to support the safety of Qtrypta for the acute treatment of migraine. If the results do not provide sufficient evidence for the FDA to determine the safety of Qtrypta, we could be required to conduct additional clinical or preclinical studies or we may be required to delay, limit, reduce or terminate our development of Qtrypta. Also, even though we have discussed our development strategy with the FDA on our Qtrypta program and received feedback from the FDA about the size and the length of the safety study, the FDA may require us to provide more data than we currently anticipate before approving Qtrypta, if ever, which would further delay the regulatory approval process and require additional clinical or preclinical work; for example, in the CRL, the FDA recommended that we conduct a repeat bioequivalence study comparing lots manufactured with the equipment used during development.

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

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

If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidates, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market our product candidates. The time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. The conduct of later-stage clinical trials and the submission of a successful NDA is a complicated process. To date, we have conducted only one Phase 2/3 clinical trial and one LTSS of Qtrypta. In addition, we have limited experience in preparing and submitting regulatory filings, and other than the NDA for Qtrypta, we have not previously submitted an NDA for any product candidate. Consequently, the completion of our clinical trials for Qtrypta for the potential treatment of migraine may not lead to a successful NDA submission. As discussed above, we received a CRL from the FDA in response to the Qtrypta NDA. In addition, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to an NDA submission for any other product candidate we may develop in the future.

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

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

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

Human clinical trials are very expensive, time-consuming and difficult to design and implement, in part because they are subject to rigorous regulatory requirements, and their outcome is inherently uncertain. Furthermore, failure of a product candidate can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials.

Further, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials may be delayed by several factors, including:

- changes in government regulation, administrative action or changes in FDA policy with respect to clinical trials that change the requirements for approval;
- delays in obtaining authorization from regulators and required IRB approval at each site to commence a trial;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authority;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, or failure by such CROs or trial sites to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to end their participation in one of our clinical trials, which would likely have detrimental effect on subject enrollment;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

Disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, as a result of the COVID-19 pandemic, we temporarily suspended new enrollment into our Phase 2/3 clinical trial evaluating C213 for the acute treatment of cluster headache between March 2020 to June 2020. Subject enrollment resumed in July 2020, however, at a rate slower than originally anticipated. In November 2020, we decided to end enrollment of new subjects into the clinical trial as of December 31, 2020.

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

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

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

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

The COVID-19 pandemic could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States, where we have planned or ongoing preclinical studies and clinical trials. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities have been closed and production has been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have limited the number of employees at our principal executive office to essential employees only, primarily research and development employees working in laboratories, with our administrative employees continuing their work outside of our office. We have also limited the number of staff in any given research and development laboratory. These precautionary measures may disrupt and adversely affect our business and operations. If COVID-19 continues to spread in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling subjects in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The results of our clinical trials may not support the intended use of Qtrypta or any other product candidates we may develop.

We cannot be certain that the results from any completed clinical trial or any future clinical trial, if completed as planned, will support the intended use of our products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective in humans for its intended uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of an NDA with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. In addition, our clinical trials to date have involved small subject populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

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

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

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

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

There is no guarantee that data from these clinical trials will be accepted by regulators or considered sufficient for approving our product candidates for commercial sale. In the case of the United States, although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be conducted in accordance with good clinical practices (“GCP”) requirements and conducted such that the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials, it would likely result in the need for additional clinical trials, which would be both costly and time-consuming and likely to delay or permanently halt our development of a product candidate. Similar regulations and risks apply to other jurisdictions as well.

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

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

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

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

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

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

Even if Qtrypta or any other product candidates we develop in the future receive regulatory approval, our business is subject to extensive regulatory requirements which include ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize our products.

The manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for our product candidates will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practice ("cGMP") requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. The regulatory approvals for our product candidates, if any, may be subject to limitations on the indicated uses for which the products may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product candidate.

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

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

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for our products, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly

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

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

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

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the previous administration took several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of a new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, or modifications to approved drugs, to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

We currently do not have any products approved for sale and currently are focusing our clinical development efforts solely on Qtrypta.

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

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

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

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

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following market approval, if any.

Qtrypta and any other product candidates we develop in the future may have undesirable side effects or have characteristics that are unexpected. These could be attributed to the active ingredient or class of drug or to our unique formulation of our product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials, including the imposition of clinical holds, and could result in a more restrictive label or delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

In addition, if a product candidate receives marketing approval, and we or others later identify serious adverse events or undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to implement REMS, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product;

- we may be required to limit the patients who can receive the product;
- we may be subject to limitations on how we promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

We may encounter manufacturing risks or failures that could impede or delay supply for our clinical trials of our product candidates.

While we previously manufactured Qtrypta internally, we have entered into agreements with third-party CMOs related to the development, manufacture, and supply of Qtrypta. Any failure or delay in our internal manufacturing operations or those of our CMOs, or the technology transfer process in connection with our plan to transition to rely on such CMOs for manufacture and supply, could delay the development or regulatory approval of Qtrypta. We and our CMOs may encounter difficulties involving, among other things, material supplies, production yields, regulatory compliance, quality control and quality assurance, and shortages of qualified personnel. The manufacturing facilities in which Qtrypta, or our other product candidates, are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. We may incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Regulatory approval of Qtrypta or our other product candidates could be impeded, delayed, limited or denied if the FDA does not authorize the manufacturing processes and facilities in which such product candidates are made.

Difficulties in relevant manufacturing processes and facilities implicated could result in supply shortfalls of Qtrypta, if approved, or any other product candidates, and could delay our preclinical studies, clinical trials and regulatory submissions with respect thereto. In addition, supplies of Qtrypta or our other product candidates that have been produced and are stored for later use, may degrade, become contaminated or suffer other quality defects (including in connection with any shipment thereof), which may cause the affected drug product to no longer be suitable for its intended use in clinical trials or other development activities. If the defective drug product cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidate.

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

We have limited experience manufacturing our product candidate, Qtrypta, and other product candidates, and to date have only manufactured our product candidates for our clinical trials. If Qtrypta is approved, we will need to scale up our own capabilities or those of our CMOs to support the production of commercial level quantities of our product candidate, which may require expensive process improvements.

While we intend to rely on CMOs to support commercial scale manufacture of Qtrypta and have entered into agreements regarding the same, we may nevertheless not be able to successfully produce, develop and market Qtrypta or our other product candidates, or we may be delayed in doing so. Significant scale up of manufacturing may also require process improvements as well as additional technologies and validation studies, which are costly, may not be successful and which the FDA must review and authorize. If we or our CMOs are unable to establish a new manufacturing facility or expand existing manufacturing facilities, purchase equipment, hire adequate personnel to support our manufacturing efforts, or comply with cGMPs, or implement necessary process improvements, we may be unable to produce commercial materials or meet demand, if any should develop, for Qtrypta or our other product candidates. Any such failure would have a material adverse effect on our business, financial condition and results of operations.

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

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

If approved for marketing, the commercial success of Qtrypta or any product candidates we develop in the future will depend upon their acceptance by the medical community, including physicians, patients and health care payers. The degree of market acceptance of any product candidate will depend on a number of factors, including:

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

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

Even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our product candidates

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

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

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

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We use customized equipment to coat and package our transdermal microneedle system; any production or equipment performance failures could negatively impact the clinical trials of our product candidates that we may develop or sales of our product candidate(s), if approved.

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

We currently depend primarily on third-party suppliers for manufacture of our product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of materials for clinical trials or commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize Qtrypta or any other product candidates we may develop.

We have contracted with CMOs to produce, in collaboration with us, Qtrypta, for commercial use, if approved, in the United States. We have not entered into any agreements with any alternate suppliers for Qtrypta product or API. Even if we were able to enter into other long-term agreements for manufacture of commercial supply on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of Qtrypta. Additionally, if Qtrypta is approved for commercial sale in jurisdictions outside the United States or any other product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to contract with a third party to manufacture such products.

Our dependence on single source suppliers with respect to our supply chain for Qtrypta exposes us to certain risks, including the following:

- our supplier may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all;
- delays caused by supply issues may harm our reputation; and
- our ability to progress our business could be materially and adversely impacted if our single-source supplier upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to regulatory or quality compliance, or other legal or reputational issues.

Even though we have agreements with CMOs to supply materials for Qtrypta, and even if we enter into other long-term agreements with other CMOs, the FDA may not approve the facilities of such CMOs, the CMOs may not perform as agreed or the CMOs may terminate their agreements with us. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, maintain or obtain, as applicable, regulatory approval for or market Qtrypta or any other product candidate. In the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts.

The manufacturer(s) of Qtrypta are obliged to operate in accordance with FDA-mandated cGMPs, and we have limited control over the ability of CMOs to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance to cGMPs. In addition, the facilities used by our CMOs to manufacture Qtrypta must be authorized by the FDA and will be subject to inspections that will be conducted prior to any grant or regulatory approval by the FDA. If any of our CMOs are unable to successfully manufacture material that conform to our specifications and the FDA's strict regulatory requirements, and pass regulatory inspections, they will not be able to secure or maintain authorization to manufacture any of our approved products. Additionally, a failure by any of our CMOs to establish and follow cGMPs or to document their adherence to such practices may negatively impact our commercialization or lead to significant delays in the launch and commercialization of any other products that we may have in the future. Failure by our CMOs or us to comply with application regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspensions or withdrawal of approvals, seizures or recalls of product, operating restrictions, and criminal prosecutions.

The manufacturer of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly-enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of Qtrypta will not occur in the future. Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes. If our CMOs were to encounter difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize Qtrypta in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand for Qtrypta will result in the loss of potential revenue and could adversely affect our ability to gain market acceptance for these products.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede commercialization of Qtrypta and could have a material adverse effect on our business, results of operations, financial conditions and prospects.

We rely on CMOs for various components of our transdermal microneedle system, and our business could be harmed if those third parties fail to provide us with sufficient quantities of those components at acceptable quality levels and prices or fail to maintain or achieve satisfactory regulatory compliance.

We rely on CMOs for various components of our transdermal microneedle system, including active pharmaceutical ingredients ("API") raw materials used in manufacturing, and capital equipment. Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance. In addition, CMOs may not be able to comply with cGMP, or similar regulatory requirements outside the United States. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate or any other product candidates that we may develop.

There can be no assurance that our supply of these various components will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers and cannot ensure that they will deliver to us the components we order on time, or at all. Any failure or refusal to supply the components for Qtrypta or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our CMOs were to fail to fill our purchase orders, the development or commercialization of the affected product candidate could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable, the lead time needed to establish a new relationship can be lengthy, and because the expenses relating to the transfer of necessary technology and processes could be significant. It may take several years to establish an alternative source of supply for our product candidate and to have any such new source approved by the FDA, the European Medicines Agency ("EMA"), or any other relevant regulatory authorities.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to comply with applicable regulatory requirements or to meet deadlines for the completion of such trials.

We rely on a third party contract research organizations to manage our clinical trials. In addition, we rely on other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. While we have agreements governing their activities, we will have limited influence over their actual performance, and we will control only certain aspects of their activities. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If there is any dispute or disruption in our relationship with our CROs or if we need to enter into alternative arrangements, that would delay our product development activities.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. In particular, there would be a significant increase in clinical trial expenses, including adopting a new electronic data capture platform or other technology platforms, the need to enter into new contracts and costs associated with the transfer of data, as well as an increased risk of the loss of data. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and may cause delays in our development programs. These investigators and CROs will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely affected. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CRO or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a

sufficient number of patients, our clinical trials may be delayed, or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

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

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund our expenses. We may seek to collaborate with third parties for certain of our development programs, and for the commercialization of our product candidates, if approved. For example, we recently entered into a commercialization agreement with Eversana for the commercialization of Qtrypta, if approved by the FDA.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive collaborative agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential existence of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available on which to collaborate and whether such a collaboration could be more attractive than the one with us for our product candidate. In addition, there have been a significant number of recent business transactions among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

In addition, any current or future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties may be terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

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

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

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

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

RISKS RELATED TO MARKETING AND SALE OF OUR PRODUCTS

We have no experience selling, marketing or distributing approved product candidates and have no internal capabilities to do so, and will rely on Eversana and other third parties for the commercialization of Qtrypta, and we and they may not be able to effectively market, sell and distribute Qtrypta, if approved.

We currently have no internal sales, marketing or distribution capabilities. Even if Qtrypta is approved by the FDA, we may not be able to effectively market and distribute Qtrypta. We have engaged Eversana to conduct agreed commercialization activities, and to utilize its internal sales organization along with its other commercial capabilities for market access, marketing, distribution and patient support services for Qtrypta. Eversana may be unable to identify and retain suitable candidates to fill our direct sales force needs, on our expected launch timeframe or otherwise. To the extent we and Eversana are not successful in retaining qualified sales and marketing personnel, we may not be able to effectively market Qtrypta. Further, there can be no assurance that the capabilities of Eversana will be effective in marketing and selling Qtrypta, or that their personnel will be more effective than an internally developed sales organization. In addition, Eversana may terminate our agreement, including the obligation to provide a revolving credit facility, and can terminate the agreement under certain additional circumstances, including if FDA approval of Qtrypta is not received by July 31, 2021, if net profits are not realized within a specified time period following commercial launch, for material breach of the agreement by us that is not cured within a defined time period, for our insolvency, if Qtrypta is subject to a safety recall in the United States or if Qtrypta is not commercially launched within a specified time period after FDA approval of the NDA. As result of our receipt of the CRL and the additional PK study, it is not likely that we will obtain FDA approval prior to July 31, 2021, which would provide Eversana with the right to terminate our agreement. If we and Eversana fail to hire, train, retain and manage qualified sales personnel, market our product successfully or on a cost-effective basis or otherwise terminate our relationship, our ability to generate revenue will be limited and we will need to identify and retain an alternative organization, or develop our own sales and marketing capability. In such an event, we would have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities. This could involve significant delays and costs, including the diversion of our management's attention from other activities. We may also need to retain additional consultants or external service providers to assist us in sales, marketing and distribution functions, and may be unsuccessful in retaining such services on acceptable financial terms or at all.

If we do perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- inability to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by Qtrypta or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

If we are unsuccessful in building and managing a sales and marketing infrastructure internally or through a third-party partner for any approved product, we will have difficulty commercializing Qtrypta or any other product candidate, if approved, which would materially adversely affect our business, financial condition and results of operations.

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

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

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

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

The development and commercialization of new products to treat migraine is highly competitive. We expect to have considerable competition from major pharmaceutical, biotechnology, specialty pharmaceutical and medical device companies. Companies marketing products or have product candidates that treat migraine that may compete with Qtrypta, include but are not limited, to Teva Pharmaceutical Industries, GlaxoSmithKline, Eli Lilly & Company, AstraZeneca, Novartis, Allergan, Biohaven Pharmaceuticals, Lundbeck, Amgen, Merck & Co., Pfizer, Janssen Pharmaceutica, Endo International, Assertio, Upsher-Smith Laboratories, Satsuma Pharmaceuticals, Supernus Pharmaceutical, Currax Pharmaceuticals, Impel NeuroPharma, Axsome Therapeutics, electroCore, eNeura, Cefaly, Theranica, Amneal Pharmaceuticals and generic manufacturers of acute and preventive therapies.

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

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

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

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

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

Insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand

our insurance coverage to include the sale of commercial products if we obtain marketing approval for any product candidate, but we may be unable to obtain commercially reasonable product liability insurance for any product candidate approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or a series of claims brought against us, particularly if judgments exceed our insurance coverage, could cause our stock price to decline and could adversely affect our results of operations and business.

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

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

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, fires, extreme weather conditions, medical pandemics and epidemics, such as the novel coronavirus (COVID-19) outbreak and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We do not carry insurance for all categories of risk that our business may encounter. Many of these events are beyond our control and the occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

We are a party to an Intellectual Property License Agreement dated October 5, 2006, as amended, with ALZA and we may enter into additional license agreements in the future. Our existing license agreement imposes, and we expect that any future license agreements will impose, various diligence, product payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product candidate that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. These risks could delay or prevent us from offering our product candidate(s). We might not have the necessary rights or the financial resources to develop, manufacture or market our current or future product candidates without the rights granted under these licenses, and the loss of sales or potential sales in such product candidate(s) could have a material adverse effect on our business, financial condition, results of operations and prospects. The occurrence of such events could have a material adverse effect on our business, financial condition and results of operations. Determining the scope of licenses and related obligations may be difficult and could lead to disputes between us and the licensor. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under a license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

Additionally, the agreement under which we currently license intellectual property is complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could

narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the third-party's financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous, or we may not be financially able to protect our proprietary rights at all. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third-parties. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives or provide any competitive advantage. In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensor's patent rights are highly uncertain. Our and our licensor's pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The standards which the United States Patent and Trademark Office ("USPTO") and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these non-U.S. countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our product candidates will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue are valid, enforceable and have claims of adequate scope to provide competitive advantage. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensor were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. We may become involved in opposition or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third-parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our product candidate without infringing third-party patent rights.

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

Bearing the costs and other requirements associated with prosecution of pending patent applications and maintenance of issued patents are essential to procurement and maintenance of patents integral to our product candidates, and our patent protection could be reduced or eliminated for non-compliance for these requirements.

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

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

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

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, or third-party with authorized access. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

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

We conduct freedom-to-operate studies to guide our early-stage research and development away from areas where we are likely to encounter obstacles in the form of third-party intellectual property conflicts, and to assess the advisability of licensing third-party intellectual property or taking other appropriate steps to address any freedom-to-operate or development issues. However, with respect to third-party intellectual property, it is impossible to establish with certainty that our product candidates

will be free of claims by third-party intellectual property holders or whether we will require licenses from such third-parties. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications.

In the pharmaceutical industry, significant litigation and other proceedings, including interferences, oppositions, reexamination, *inter partes* review, derivation and post-grant review proceedings before the USPTO and corresponding foreign patent offices, regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such proceedings include:

- we or our collaborators may initiate litigation or other proceedings against third-parties seeking to invalidate the patents held by those third-parties or to obtain a judgment that our products or processes do not infringe those third-parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third-parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and,
- if a license to necessary intellectual property is terminated, the licensor may initiate litigation claiming that our processes or products infringe, misappropriate or otherwise violate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

Third-parties may assert that we are employing their proprietary technology without authorization or have infringed upon, misappropriated or otherwise violated their intellectual property or other rights. Even if we believe third-party claims of infringement against us or our collaborators are without merit, there is a risk that a court would decide that we or our collaborators are infringing the third-party's valid and enforceable patents. If our product candidates, methods, processes or other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

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

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

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

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved product or the FDA's prior findings of safety and effectiveness for a previously approved product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies and that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (Paragraph I) the required patent information has not been filed by the original applicant; (Paragraph II) the listed patent has expired; (Paragraph III) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (Paragraph IV) the listed patent is invalid, unenforceable or will not be infringed by the

proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the listed patents claiming the referenced product candidate have expired.

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

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

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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. If we initiate legal proceedings against a third-party to enforce a patent covering our product candidates, the defendant could counterclaim that the patents covering our product candidates are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including a lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third-parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* reexamination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

There is a risk that a court or administrative body would decide to revoke, cancel or amend our patents in such a way that they no longer cover and protect a product candidate. In addition, a court or administrative body may decide that our patents are invalid, unenforceable or not infringed by a third-party's activities. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. An adverse result in any litigation or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute such claims and we may be reliant on them to do so.

An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third-parties from making, using and selling similar or competitive products. Any of these occurrences could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. Although our policy is to have all employees complete these agreements, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property may not be self-executing and despite such agreement, such inventions may become assigned to third-parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third-parties in their work for us, disputes may arise between us and those third-parties as to the rights in related inventions. We may also be subject to claims that former employees, collaborators, or other third-parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third-parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third-party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

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

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

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

On September 16, 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third- parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in

opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

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

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

We may not be successful in obtaining necessary rights to future product candidates through acquisitions and in-licenses.

Any future programs we choose to pursue may require the use of proprietary rights held by third-parties, and the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property from third- parties that we later identify as necessary for our future product candidates or such intellectual property may not be available on commercially reasonable terms. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources, and greater clinical development and commercialization capabilities.

For example, we may in the future collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable product candidate or program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program on reasonable terms or at all, we may have to abandon development of that product candidate or program and our business and financial condition could materially adversely suffer.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world may be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe can be less extensive than those in the United States and Europe. In addition, the laws of some countries outside the United States and Europe do not protect intellectual property rights to the same extent as federal and state laws in the United States and laws in Europe. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the United States and Europe, or from selling or importing products made using our inventions in and into the United States, Europe or other jurisdictions. Third- parties may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our product and our patents or other intellectual property may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions outside the United States and Europe. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, the reproduction of our manufacturing or other know-how or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our intellectual property rights in jurisdictions outside the United States and Europe, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third- parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third-parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If we do not obtain patent term extensions and data exclusivity for Qtrypta or any of our other product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act and similar legislation in the EU. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not receive an extension, for example, if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our business, financial condition, results of operations, and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our pending or future registered or unregistered trademarks or trade names may not issue and may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

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

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

- Others may be able to make compounds that are the same as or similar to our product candidates, which are aimed initially at the generic market and are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;

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

RISKS RELATED TO LEGISLATION AND ADMINISTRATIVE ACTIONS

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians, certain other healthcare providers beginning in 2022, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

State and foreign laws also govern the privacy and security of health-related and other personal information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Economic Area ("EEA") is governed by the GDPR, which imposes strict requirements for processing personal data of individuals within the EEA. The GDPR provides that EU and EEA Member States may make their own further laws and regulations, which may impose more limitations, including in relation to the processing of genetic, biometric or health data, which may result in differences between Member State laws, limit our ability to use and share personal data, cause our costs to increase, and/or harm our business and/or financial condition. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR ("UK GDPR"), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

In addition, on June 28, 2018, the State of California enacted the CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states. Additionally, a new ballot initiative, the CPRA, recently passed in California. The CPRA will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions.

Efforts to ensure that our business arrangements with third-parties will comply with applicable healthcare laws and regulations will also involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, disgorgement, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

Our ability to commercialize any product candidate for which we receive regulatory approval, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the product candidate will be available from government and health administration authorities, private health maintenance organizations and health insurers, and other third-party payers.

A substantial portion of our potential future revenue depends or will depend, in part, on the extent to which the costs of our products, purchased by our customers are reimbursed by third-party payers, including Medicare, Medicaid, other U.S. government sponsored programs, non-U.S. governmental payers and private payers. Our customers' ability to obtain adequate reimbursement for products and services from these third-party payers affects the selection of products they purchase and the prices they are willing to pay. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. If we are forced to lower the price we will charge for our U.S. product candidates, if approved, our profit margins will decrease, which will adversely affect our ability to invest in and grow our business. With the global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of, and the level of reimbursement for, new therapies. Any limitations on, decreases in or elimination of payments by third-party payers may have an adverse effect on our financial condition, business, prospects and/or results of operations.

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

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 ("ACA") is significantly changing the way healthcare is financed by both governmental and private insurers. From time to time, legislation is implemented to rein in rising healthcare expenditures. The ACA included a number of provisions affecting the pharmaceutical and medical device industries, including annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition, among other things, the ACA also established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. The increased funding and focus on comparative clinical effectiveness research, which compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products, may result in lower reimbursements by payers for our product and decreased profits to us.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") included a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. This decision was subsequently appealed, and on December 18,

2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the decision of the district court that the individual mandate, as amended by the Tax Act, was unconstitutional. The Fifth Circuit remanded the case to the district court to consider a remedy, including to consider and explain which provisions of the ACA are inseverable and invalid. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

Other federal legislative changes have been proposed and adopted since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. These new laws and any other future legislative or policy changes may result in additional reductions in Medicare and other healthcare funding, which may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our out-licensed products and product candidates (if and when approved) and accordingly, our financial results.

If our product candidates become subject to recall it could harm our reputation, business and financial results.

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

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

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

Changes in U.S. tax law could adversely affect our business and financial condition.

Legislation or other changes in tax laws could lead to or increase our tax liability and adversely affect our after-tax profitability. For example, the Tax Act was enacted in the United States on December 22, 2017. Given our valuation allowance position, the Tax Act is not expected to have a significant impact on our effective tax rate, cash tax expenses or net deferred tax assets. Additionally, on March 27, 2020 and December 27, 2020, the United States enacted the CARES Act and the Consolidated Appropriation Act ("CAA"), respectively, as a result of the Coronavirus pandemic, which contain, among other things, numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. We have evaluated the current legislation and, at this time, we do not anticipate that the CARES Act or CCA will have a material impact on our financial statements; however, the future impact of these acts and any other future changes in tax law on holders of our common stock is uncertain and could adversely affect our business and financial condition.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain significant stockholders over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income or tax liability may be limited. We

have experienced such ownership changes in the past (and derecognized certain deferred tax assets as of December 31, 2020 in connection with ownership changes we determined had occurred prior to such date), and we may experience ownership changes in the future as a result of future offerings and/or subsequent shifts in our stock ownership, some of which may be outside our control. Because our ability to use our net operating loss carryforwards and other tax attributes is limited by ownership changes, we may be unable to utilize a material portion of our net operating losses and other tax attributes.

RISKS RELATED TO EMPLOYEE MATTERS, OUR OPERATIONS AND MANAGING GROWTH

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

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

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

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

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

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

On February 1, 2020, Gregory Kitchener resigned as our chief financial officer. We cannot guarantee that we will not face similar turnover in the future. Management transition is often difficult. Our ability to execute our business strategies may be adversely affected by the uncertainty associated with any transition and the time and management attention needed to fill any vacant role could disrupt our business.

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

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

Our operations and employees face risks related to health epidemics that could adversely affect our financial condition and operating results.

Our business could be adversely impacted by the effects of a health epidemic, such as the COVID-19 pandemic. Our sole laboratory, executive team, and most of our employee base are located in the San Francisco Bay Area. In the event of a health epidemic that becomes widespread in or around the San Francisco Bay Area, we may take precautionary measures such as limiting our employees’ travel activities, implementing alternative work arrangements for our employees, and suspending our lab operations. For example, as a result of the COVID-19 pandemic, a majority of our workforce has moved to a remote working environment. With our employees working remotely, we could face operational difficulties that could impair our ability to conduct and manage our business effectively. Furthermore, such health epidemic, even outside of the San Francisco

Bay Area, may also adversely impact the operations of our CMOs, suppliers and business partners as they implement their own precautionary measures, and we would be unable to predict how a health epidemic, such as the COVID-19 pandemic, and the related changing economic conditions will affect our third-party partners. Such conditions could disrupt our operational activities and may result in an inability to meet our operational targets, and therefore our financial condition and operating results could be adversely affected.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions, including civil, criminal or administrative.

We may not successfully manage our growth.

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

Risks associated with use of our company-wide enterprise resource planning ("ERP") system may adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

We completed the implementation of a company-wide ERP system in the first fiscal quarter of 2019 to handle the business and financial processes within our operations and corporate functions. The use of the ERP system will increase as we expand our operations, possibly requiring the implementation of additional modules or system functionality. To reap the benefits of our ERP system, we may need to change certain business and financial processes. Our business and results of operations may be adversely affected if we experience operating problems or cost overruns following the implementation process, or if the systems and the associated process changes do not give rise to the benefits that we expect. If we do not effectively maintain or integrate the ERP system as planned or if the systems do not operate as intended, it may adversely affect our ability to manage and run our business operations, file reports with the SEC in a timely manner, and/or otherwise affect our internal control environment. Any of these consequences could have an adverse effect on our results of operations and financial condition.

RISKS RELATING TO AN INVESTMENT IN OUR COMMON STOCK

The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.

Our stock price has been and, in the future, may be subject to substantial volatility. During the period from January 2, 2018 through March 9, 2021, for example, our stock has traded in a range with a low of $0.328 and a high of $25.70. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. We do not, for example, have any explanations for the volatility in our stock price or the heavy volume of trading (on some days exceeding six times the number of shares outstanding) that occurred in our common stock in February and March of 2019. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

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

Moreover, the global stock markets have experienced, and may continue to experience, significant volatility as a result of the COVID-19 pandemic. The COVID-19 pandemic and the significant uncertainties it has caused for the global economy, business activity and business confidence have had, and may continue to have, a significant effect on the market price of securities generally, including our common stock.

We and certain of our current and former executive officers have been named as defendants in a purported securities class action lawsuit, and a related shareholder derivative lawsuit has been filed; defending against these lawsuits could cause us to incur substantial costs and divert management's attention, financial resources and other company assets.

On October 29, 2020 and November 6, 2020, two stockholders filed alleged class action lawsuits against us and certain of our current and former executive officers in the United States District Court for the Northern District of California (the "Court"). The complaints were filed purportedly on behalf of all persons who purchased or otherwise acquired our securities between February 13, 2017 and September 30, 2020. The complaints allege that we and certain of our current and former executive officers made false and/or misleading statements and failed to disclose material adverse facts about our business, operations and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The plaintiffs seek damages, interest, costs, attorneys’ fees and other unspecified relief. On February, 4, 2021, the actions were consolidated and the Court appointed two Co-Lead Plaintiffs and two law firms as Co-Lead Counsel in the consolidated action. The Co-Lead Plaintiffs’ deadline to file a consolidated amended complaint is March 29, 2021. We anticipate filing a motion to dismiss. Pursuant to a stipulated court order, we expect to file the motion on May 13, 2021; the Co-lead Plaintiffs are expected to file their opposition on June 14, 2021; and we expect to file a reply brief on July 6, 2021. The earliest date upon which the Court may hear the motion is July 20, 2021. These dates are

subject to change upon court order or if the Co-Lead Plaintiffs file their consolidated amended complaint prior to the March 29, 2021 deadline.

On February 9, 2021, a stockholder filed a derivative action, purportedly on behalf of the Company (named as a nominal defendant), against certain of our current and former executive officers and directors in the United States District Court for the District of Delaware. The complaint alleges breaches of the defendants' fiduciary duties as directors and/or officers of the Company, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Exchange Act, and for contribution under Sections 10(b) and 21D of the Exchange Act. The plaintiff seeks damages, restitution, interest, attorneys' fees and costs, and other unspecified relief.

These lawsuits and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits, and we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle these or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price. See Item 3. "Legal Proceedings" for additional information regarding the class actions.

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

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

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

On March 26, 2020, we received written notice from Nasdaq indicating that we were not in compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Listing Rule 5550(a)(2). On August 14, 2020, we received a notice from Nasdaq notifying us that we had regained compliance with the $1.00 minimum bid price requirement. On November 12, 2020, we received another written notice from Nasdaq indicating that we were not in compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market. In accordance with Listing Rule 5810(c)(3)(A), we had a period of 180 calendar days to regain compliance with the minimum bid price requirement. On March 4, 2021, we received a notice from Nasdaq notifying us that we had regained compliance with the listing rule. However, as our stock price has been volatile, there can be no assurance that we will not fall out of compliance again in the future.

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

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

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

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

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

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

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

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

We are no longer an "emerging growth company" and may no longer take advantage of certain exemptions from various reporting requirements that are applicable to other public companies.

Effective December 31, 2020, we are no longer an emerging growth company and may no longer take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, such as exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. This increase in reporting requirements will further increase our compliance burden.

As a "smaller reporting company," however, we are still able to take advantage of certain exemptions available to smaller reporting companies. We intend to take advantage of some of these exemptions, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" disclosure; and
- reduced disclosure obligations regarding executive compensation.

In addition, as a non-accelerated filer, we are not required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting.

We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer a smaller reporting company or a non-accelerated filer, as applicable.

GENERAL RISK FACTORS

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third-parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development and manufacturing programs. Our operations depend, in part, on the continued performance of our information technology systems. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptions. Failure of our information technology systems could adversely affect our business, profitability and financial condition. Although we have information technology security systems, a successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. Our third-party service providers have experienced such attacks and we and our third-party service providers may experience attacks in the future.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. It is possible that a cybersecurity attack might not be noticed for some period of time. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our shareholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third-parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to applicable data privacy and security law and regulations. We would be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects. To the

extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed.

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

If our existing stockholders, particularly our directors and executive officers, are perceived by the public market as intending to sell substantial amounts of our common stock, the trading price of our common stock could decline significantly. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, certain holders of our common stock and warrants to purchase our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended ("Securities Act"). As long as the registration statements covering the resale of such shares remain in effect, such shares shall be freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by existing stockholders could have a material adverse effect on the market price of our common stock.

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

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

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

As a public company, we are subject to the reporting requirements of the Exchange Act and the other rules and regulations of the SEC. Compliance with the various reporting and other requirements applicable to public reporting companies require considerable time, attention of management, and financial resources.

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

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

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

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our principal executive offices are located at 34790 Ardentech Court, Fremont, California 94555. We have an operating lease for our headquarters in Fremont, California. Under the Seventh Amendment, we extended the term of the lease for our headquarters through August 31, 2024, with an option to further extend the lease for an additional 60 months, subject to certain terms and conditions. We do not own any real property. We believe our present facilities are sufficient for our current and planned near-term operations.

Item 3. LEGAL PROCEEDINGS

On October 29, 2020 and November 6, 2020, two stockholders filed alleged class action lawsuits against us and certain of our current and former executive officers in the United States District Court for the Northern District of California: Carr v. Zosano Pharma Corporation, et al., Case No. 3:20-cv-07625, and Becerra v. Zosano Pharma Corporation, et al., Case No. 3:20-cv-07850. The complaints were filed purportedly on behalf of all persons who purchased or otherwise acquired our securities between February 13, 2017 and September 30, 2020. The complaints allege that we and certain of our current and former executive officers made false and/or misleading statements and failed to disclose material adverse facts about our business, operations and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The plaintiffs seek damages, interest, costs, attorneys' fees and other unspecified relief. On February 4, 2021, the Carr and Becerra actions were consolidated and the court appointed two Co-Lead Plaintiffs and two law firms as Co-Lead Counsel in the consolidated action. The Co-Lead Plaintiffs' deadline to file a consolidated amended complaint is March 29, 2021. We anticipate filing a motion to dismiss. Pursuant to a stipulated court order, we expect to file the motion on May 13, 2021; the Co-Lead Plaintiffs are expected to file their opposition on June 14, 2021; and we expect to file a reply brief on July 6, 2021. The earliest date upon which the Court may hear the motion is July 20, 2021. These dates are subject to change upon court order or if the Co-Lead Plaintiffs file their consolidated amended complaint prior to the March 29, 2021 deadline.

On February 9, 2021, a stockholder filed a derivative action, purportedly on behalf of the Company (named as a nominal defendant), against certain of our current and former executive officers and directors in the United States District Court for the District of Delaware: Gensemer v. Lo, et al., Case No. 1:21-cv-00168. The complaint alleges breaches of the defendants' fiduciary duties as our directors and/or officers, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Exchange Act, and for contribution under Sections 10(b) and 21D of the Exchange Act. The plaintiff seeks damages, restitution, interest, attorneys' fees and costs, and other unspecified relief. We believe the cases are without merit and we intend to vigorously defend against the claims.

From time to time, we may be involved in other lawsuits and legal proceedings, which arise, in the ordinary course of business. Lawsuits and legal proceedings are subject to inherent uncertainties and an adverse result in any lawsuit or legal proceeding may materially adversely affect our business, financial condition and results of operations. In addition, even if not meritorious, these matters could result in the expenditure of significant financial resources and diversion of management efforts.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is publicly traded and listed on the Nasdaq Capital Market under the symbol "ZSAN".

Holders of Common Stock

As of March 9, 2021, there were 11 holders of record of our common stock based on information furnished by Computershare Trust Company, NA, the transfer agent for our securities. The number of beneficial stockholders is substantially greater than the number of holders of record as a large portion of our common stock is held through brokerage firms.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

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

Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required by this Item.

Recent Sale of Unregistered Securities

Inducement Grant Award

On November 16, 2020, we granted a stock option to purchase 100,000 shares of our common stock to a new employee as an inducement award. The stock option has an exercise price of $0.48 per share, which is equal to the closing price of our common stock on the grant date. 25% of the shares underlying the option will vest on November 16, 2021, and 1/48th of the total shares will vest monthly thereafter, subject to continued service. The award was approved in accordance with Nasdaq Listing Rule 5635(c)(4). We intend to file a registration statement on Form S-8 to register the shares of common stock underlying these options prior to the time at which these options become exercisable.

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

Issuer Purchases of Equity Securities

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

Item 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

Zosano Pharma Corporation is a clinical-stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics and other bioactive molecules to patients using our proprietary transdermal microneedle system (the "System"). Our System is designed to facilitate rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. The System consists of a $3cm^2$ to $6cm^2$ array of titanium microneedles approximately 200-350 microns in length, coated with a hydrophilic formulation of drug, mounted on an adhesive patch. The patch is applied with a reusable 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 microneedles penetrate the stratum corneum to allow the drug to be absorbed into the microcapillary system of the skin. We are focused on developing products for indications in which we believe rapid onset, ease of use and stability may offer significant therapeutic and practical advantages, and on developing products where rapid administration of approved drugs with established safety and efficacy profiles provides an increased benefit to patients, in markets where patients remain underserved by existing therapies. We anticipate that many of our current and future development programs may enable us to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards potential commercialization.

Our development efforts are currently focused on our product candidate, Qtrypta™ (M207) ("Qtrypta"). Qtrypta is our proprietary formulation of zolmitriptan delivered utilizing our System. 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. Qtrypta was developed with the intent of providing faster onset of efficacy and sustained freedom from migraine symptoms. Qtrypta is designed for rapid absorption of zolmitriptan into the bloodstream without dependence on the gastrointestinal ("GI") tract.

We submitted a 505(b)(2) New Drug Application ("NDA") for Qtrypta to the U.S. Food and Drug Administration (the "FDA") on December 20, 2019, and on October 20, 2020, we received a Complete Response Letter ("CRL") from the FDA with respect to the NDA. The CRL cited inconsistent zolmitriptan exposure levels observed across clinical pharmacology studies, which had been previously identified in the FDA's discipline review letter that we received on September 29, 2020. Specifically, the CRL noted differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in our clinical trials and inadequate pharmacokinetic bridging between the lots that made interpretation of some safety data unclear. The CRL referenced unexpected high plasma concentrations of zolmitriptan observed in five study subjects enrolled in our pharmacokinetic studies. The FDA recommended that we conduct a repeat bioequivalence study comparing lots manufactured with the equipment used during development. The CRL noted that additional product quality validation data, which were planned to be submitted following approval, if received, were required to be submitted with the application. In addition, the CRL mentioned that due to U.S. Government and/or Agency-wide restrictions on travel, inspections of our contract manufacturing facilities were not able to be conducted but would be required before the application may be approved.

On January 29, 2021, we held a Type A meeting with the FDA Division of Neurology II (the “Division”) regarding the requirements for resubmission of the Qtrypta NDA. Based on feedback from the Type A meeting held with the Division, we plan to conduct an additional pharmacokinetic (“PK”) study for inclusion in an NDA resubmission package. During the meeting, the Division did not request that we conduct any further clinical efficacy studies to support the resubmission. On February 19, 2021, we received the official Type A meeting minutes from the FDA. The Type A meeting minutes were generally consistent with our expectations to conduct an additional PK study for inclusion in an NDA resubmission package. In a post-meeting comment, the FDA recommended a skin assessment on patients in the planned PK study to generate additional safety information. This assessment is included in the proposed study protocol, which has been submitted to the FDA. The Division indicated willingness to review the study protocol and provide comments prior to the initiation of the study. Our plans for resubmitting the NDA are based on our discussions with the FDA and may be subject to change upon receipt of the FDA’s comments to the proposed study protocol. We will incur additional costs and delays in our previously anticipated timeline for potential commercialization due to the additional PK study, and our plan to resubmit the NDA may be further delayed and we may incur higher than anticipated additional costs depending on the feedback we receive from the FDA on the study protocol and the time it takes to complete the PK study, or any additional studies or other requirements of the FDA. In addition, there is no guarantee that we will be able to adequately address the issues raised to the FDA’s satisfaction.

We do not anticipate realizing product revenues unless and until the FDA approves our Qtrypta NDA and we begin commercializing Qtrypta, which may never occur.

If approved, we plan to use contract manufacturing organizations ("CMOs") for the commercial production of Qtrypta. These CMOs include companies that will produce the various components that comprise our patch, our applicator, as well as the final packaging of the finished product. If approved, our CMOs will be required to produce commercial supply of Qtrypta in accordance with the FDA’s current good manufacturing practices ("cGMP") regulations. These companies are located in the United States and have expertise and experience in contract manufacturing.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the FDA, or equivalent foreign regulatory bodies, to market and sell our product candidates. Accordingly, our success depends not only on the development, but also on our ability to finance the development of each of our product candidates. We will require substantial additional funding to complete development and seek regulatory approval for these products.

On August 6, 2020, we entered into a master services agreement (the “Eversana Agreement”) with Eversana Life Science Services, LLC (“Eversana”) for the commercialization of Qtrypta in the United States, if approved by the FDA. Under the terms of the Eversana Agreement, Eversana and we will cooperate to conduct activities over the term of the Eversana Agreement pursuant to a commercialization budget estimated at approximately $250.0 million. We maintain ownership of the Qtrypta NDA as well as all legal, regulatory and manufacturing responsibilities for Qtrypta. Eversana receives an exclusive right to conduct agreed commercialization activities and will utilize its internal sales organization along with its other commercial capabilities for market access, marketing, distribution and patient support services for Qtrypta. Eversana will receive reimbursement of certain commercialization costs and a low double digit to mid-teen percentage of product profits if and when our net sales for Qtrypta surpass certain costs incurred by the parties pursuant to the commercialization budget.

The term of the Eversana Agreement is five years following the date, if any, that the FDA approves the NDA. Upon expiration or termination of the Eversana Agreement, we will retain all profits from product sales consummated after expiration or termination and assume all future corresponding commercialization responsibilities. We may terminate the Eversana Agreement if Eversana fails to provide pre-commercial or commercial plans and budgets by specified dates, if we decide to discontinue development or commercialization efforts for Qtrypta in the United States (subject to a termination payment if such termination occurs within a specified time period), or upon a change of control. Either party may terminate the Eversana Agreement if FDA approval is not received by July 31, 2021, if net profits are not realized within a specified time period following commercial launch, for material breach of the Eversana Agreement by the other party that is not cured within a defined time period, for insolvency of the other party, if Qtrypta is subject to a safety recall in the United States or if Qtrypta is not commercially launched within a specified time period after FDA approval of the NDA (other than by reason of the terminating party’s failure to perform its obligations under the Eversana Agreement). Due to the CRL and additional PK study, we do not expect that FDA approval of the NDA will be received by July 31, 2021.

We currently have no internal sales, marketing or distribution capabilities and we plan to rely on Eversana and other third parties for the commercialization of Qtrypta, if approved.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported results of operations during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the accounting policies discussed below are those that are most critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Leases

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. If the interest rate implicit in our lease contracts is not readily determinable, we utilize our incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Stock-Based Compensation

We have equity incentive plans under which various types of equity-based awards including, but not limited to, non-qualified stock options and restricted stock awards, may be granted to employees, non-employee directors, and non-employee consultants. Our equity incentive plans also allow incentive stock options to be awarded to employees. We have also awarded inducement grants to purchase common stock to new employees outside the existing equity incentive plans in accordance with Nasdaq listing rule 5635(c)(4).

We account for stock-based compensation, based on the fair value of the stock-based awards on the date that the grants are ultimately expected to vest. The fair value of employee stock option grants is estimated on the date of grant using the Black-Scholes option pricing model and is recognized as expense on a straight-line basis over the grantee's requisite service period. Prior to 2020, we did not have sufficient historical stock price information to meet the expected life of the stock option grants, and therefore, we used a blended volatility rate that included our common stock trading history supplemented with the trading history from the common stock of a set of comparable publicly-traded biopharmaceutical companies. During 2020, we determined that a sufficient amount of historical information was available regarding the volatility of our stock price and that it was no longer necessary to utilize a blended volatility rate. Due to the lack of historical exercise data to provide a reasonable basis upon which to estimate an expected term, we have opted to use the simplified method, which is the use of the midpoint of the vesting term and the contractual term of the award to estimate the expected term. We recognize the impact of stock option forfeitures on stock-based compensation expense in the period the award is forfeited.

Financial Operations Overview

General

As of December 31, 2020, we had an accumulated deficit of approximately $332.2 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our Qtrypta product candidate into later stages of development and, if approved, commercialization. We cannot assure you that we will receive additional capital or collaboration revenue in the future, as a result of any partnership that we might pursue.

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

We will require additional capital to undertake our planned pre-commercialization activities, research and development activities and to meet our operating requirements in and beyond 2021. We intend to raise such capital through the issuance of additional equity through public or private offerings, debt financing, strategic alliances with pharmaceutical partners, or any

combination of the above. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to further reduce our operating expenses and suspend, delay or reduce the scope of our Qtrypta development program, out-license intellectual property rights to our transdermal delivery technology, or a combination of the above, which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all.

We are actively seeking opportunities to evaluate collaborations with strategic partners to further the clinical and commercial development of our technology. We cannot forecast with any degree of certainty if we will enter into collaborations for Qtrypta or any other potential future use of our technology or how such arrangements would affect our development plans or capital requirements. As a result of these uncertainties, we are unable to determine the duration and completion of costs of our research and development projects or if, when and to what extent we will generate revenue from their commercialization and sale. Additionally, a future collaborative partner may only be interested in applying our technology in the development and advancement of their own product candidates.

The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time consuming. We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be affected by a variety of factors, including, but not limited to: the quality of the product candidate, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. In situations in which third parties have control over the clinical development of a product candidate, the estimated completion dates are largely under the control of such third parties and not under our control.

Service revenue

Service revenue is related to feasibility studies in which we provide research and development services to customers to determine the feasibility of using our System in connection with the customers' pharmaceutical agents. In 2020, we recognized revenue on agreements with two pharmaceutical companies for such studies. We expect these studies to continue in 2021 and for service revenue to fluctuate based on the volume and activity of the feasibility studies.

Cost of service revenue

Cost of service revenue consists of personnel and material costs associated with feasibility studies. In 2020, we incurred costs related to two such studies. We expect these studies to continue in 2021 and expect cost of service revenue to fluctuate in 2021 based on the volume and activity of the feasibility studies.

Research and development expenses

Research and development expenses consist primarily of:

- Salaries and related expenses for personnel in research and development functions, including stock-based compensation;
- Expenses related to the production of our System, including the purchase of active pharmaceutical ingredients and raw materials as well as fees paid to contract manufacturing organizations;
- Expenses related to the performance of drug formulation and clinical trials and studies, including fees paid to CROs, clinical consultants, clinical trial sites and vendors, including IRBs, in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis; and
- Allocation of certain shared costs, such as depreciation and facilities-related costs.

For the year ended December 31, 2020, our research and development efforts and resources focused primarily on advancing the development of Qtrypta.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services and other general operating expenses not otherwise included in research and development. We expect that our general and administrative expenses will increase as we move toward commercialization of our product candidate, Qtrypta, if approved.

Other income and expense

Interest income. Interest income consists primarily of interest and amortization of purchase premiums and accretion of purchase discounts related to our investments in marketable securities.

Interest expense. Interest expense consists primarily of interest costs and associated amortization of debt discounts and issuance costs, if any, related to debt financing and an equity line of credit.

Other income (expense). Other income (expense), net consists of miscellaneous income and expenses that are not included in other categories of the statement of operations.

Results of Operations

Comparison of the year ended December 31, 2020 and 2019

	Year Ended December 31,		Change	
	2020	2019	Amount	%
	(In thousands)			
Service revenue	$ 224	$ —	$ 224	N/A
Operating expenses:				
Cost of service revenue	$ 171	$ —	$ 171	N/A
Research and development	$ 21,622	$ 25,385	$ (3,763)	(15)%
General and administrative	$ 11,189	$ 11,812	$ (623)	(5)%
Other income (expense):				
Interest income	$ 18	$ 207	$ (189)	(91)%
Interest expense	$ (719)	$ (523)	$ (196)	37 %
Other income (expense), net	$ 90	$ (76)	$ 166	*

* Not meaningful.

Service revenue

In 2020, service revenue related to agreements with two pharmaceutical companies for feasibility studies. We expect these studies to continue in 2021 and for service revenue to fluctuate based on the volume and activity of the feasibility studies.

Cost of service revenue

In 2020, cost of service revenue related to two feasibility studies. We expect these studies to continue in 2021 and expect cost of service revenue to fluctuate in 2021 based on the volume and activity of the feasibility studies.

Research and development expenses

Research and development expenses decreased approximately $3.8 million, or 15%, for the year ended December 31, 2020, as compared to the year ended December 31, 2019. The decrease was primarily due to lower clinical expenses of $3.5 million resulting from the completion of the Qtrypta LTSS and PK study, lower employee costs of $0.9 million and $1.1 million in lower travel and general business expenses. These decreases were offset by increases of $0.9 million in production and manufacturing costs due to the scale up and technology transfer to our commercial manufacturing organizations and $0.8 million of additional depreciation related to assets placed into service at our contract manufacturing organizations.

General and administrative expenses

General and administrative expenses decreased approximately $0.6 million, or 5%, for the year ended December 31, 2020, as compared to the year ended December 31, 2019. The decrease was primarily due to a decrease of $0.9 million in compensation costs due to lower headcount and a $0.5 million decrease in professional service costs related to reduced strategic and pre-commercial activities. These decreases were partially offset by approximately $0.8 million increase in legal and professional services costs related to corporate and intellectual property matters.

Other income and expense

Interest income. For the years ended December 31, 2020 and 2019, interest income resulted primarily from interest recognized related to investments in marketable securities. The decrease for the year ended December 31, 2020 as compared to the same period in 2019 resulted from lower investment balances due to maturities of investments during the year and lower interest rates.

Interest expense. For the years ended December 31, 2020 and 2019, interest expense consisted primarily of interest and amortization of debt discount. The increase in interest expense resulted from a higher outstanding balance on our build-to-suit obligation with Trinity Funding 1, LLC (successor to Trinity Capital Fund III, L.P.) ("Trinity"). In 2019 and 2020, we capitalized a portion of interest paid to Trinity as construction-in-progress.

Other income (expense). Other income (expense), net consists of miscellaneous income and expenses that are not included in other categories of the statement of operations.

Income Taxes

As of December 31, 2020, we had deferred tax assets of $31.4 million and deferred tax liabilities of $1.1 million. The deferred tax assets primarily consisted of federal and state tax net operating losses and research and development tax credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these tax assets, a full valuation allowance has been established to offset our net deferred tax assets. As of December 31, 2020, we had federal net operating loss carryforwards of approximately $106.5 million and state net operating loss carryforwards of approximately $25.8 million. As of December 31, 2019, we had federal net operating loss carryforwards of approximately $76.0 million and state net operating loss carryforwards of approximately $68.2 million. If not utilized, certain federal net operating loss carryforwards incurred before January 1, 2018, will expire beginning in 2026, and state net operating loss carryforwards will expire beginning in 2028. The federal net operating losses incurred in 2018 and beyond do not expire.

As of December 31, 2020, we had federal and state research and development credit carryforwards of approximately $0.5 million and $6.0 million, respectively. As of December 31, 2019, we had federal and state research and development credit carryforwards of approximately $1.6 million and $5.6 million, respectively. If not utilized, the federal tax credits will begin to expire in 2040 and state tax credits currently do not expire.

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

On March 27, 2020 and December 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and the Consolidated Appropriation Act ("CAA"), respectively, as a result of the COVID-19 pandemic, which contain among other things, numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. We have evaluated the current legislation and at this time, do not anticipate that the tax provisions in the CARES Act or CCA will have a material impact on our financial statements.

Liquidity and Capital Resources

Our liquidity and capital resources are summarized as follows:

	Year Ended December 31,	
	2020	2019
	(In thousands)	
Cash and cash equivalents	$ 35,263	$ 6,316
Working capital*	$ 21,205	$ (9,424)
Accumulated deficit	$ (332,190)	$ (298,821)

* We define working capital as current assets less current liabilities. See our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K for further details regarding our current assets and current liabilities.

Our cash and cash equivalents totaled $35.3 million as of December 31, 2020 compared to $6.3 million as of December 31, 2019, representing an increase of $29.0 million, which was primarily due to the proceeds from the issuance of common stock and warrants, net of commissions and discounts, of $38.7 million in connection with our offerings in 2020, and $14.9 million from the exercise of the related warrants, the proceeds from the issuance of common stock in connection with at-the-market offerings, net of commissions of $16.2 million, and $1.6 million from a PPP loan. These increases were primarily offset by cash used in other operating activities of $31.7 million, purchases of property and equipment of $8.5 million and payments to Trinity on our build-to-suit obligation of $2.2 million.

Presently, we do not have sufficient cash and cash equivalents to enable us to fund our anticipated level of operations and meet our obligations as they become due during the twelve months following the date of issuance of this Annual Report on Form 10-K, and we will need to obtain additional capital resources through an equity offering, a debt financing, a license or collaboration agreement, or through a combination of such sources of capital. The aforementioned factors raise substantial doubt about our ability to continue as a going concern.

We filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on April 16, 2020 ("2020 Shelf Registration Statement"). This shelf registration statement provides us with the ability to issue common stock and other securities as described in the registration statement from time to time up to an aggregate amount of $74.5 million. As of December 31, 2020, we have approximately $33.7 million remaining on this shelf registration statement.

Our ability to complete the sale of equity securities and access the market as a source of liquidity is dependent on investor demand, market conditions and other factors. Therefore, we can provide no assurance that any such offering will be on terms favorable to us or our stockholders, or that such offering will be successful at all. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

We expect to incur additional losses in the future and will require additional financing to develop our Qtrypta product candidate, conduct pre-commercialization manufacturing activities and fund our operations. If we are unable to raise additional funds when needed, we may be required to suspend, delay, reduce or terminate our development programs and clinical trials. We may also be required to sell or license our technologies, clinical product candidates, or programs, if any, that we would prefer to develop and commercialize ourselves.

We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the economic and global financial market uncertainty resulting from the COVID-19 pandemic;
- the scope, progress, expansion and costs of manufacturing our product candidates;
- the timing of and costs involved in obtaining regulatory approvals;
- the scope, progress, expansion, costs and results of our clinical trials;
- the type, number, costs and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- our ability to establish and maintain development partnering arrangements;
- the timing, receipt and amount of contingent, royalty and other payments from any of our future development partners;
- the emergence of competing technologies and other adverse market developments;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the resources we devote to marketing and, if approved, commercializing our product candidates; and
- the costs associated with being a public company.

The COVID-19 pandemic has caused volatility in the global financial markets and threatened a slowdown in the global economy, which may adversely affect our ability to raise additional capital on attractive terms or at all. A recession, depression or other sustained adverse market event resulting from the spread of COVID-19 may also limit our ability to obtain financing for our operations.

Cash Flows

	Year Ended December 31,	
	2020	2019
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (31,718)	$ (34,817)
Investing activities	(8,487)	2,164
Financing activities	69,152	29,829
Increase (decrease) in cash, cash equivalents, and restricted cash	$ 28,947	$ (2,824)

Operating Cash Flow: Net cash used in both 2020 and 2019 was primarily related to personnel, manufacturing, facility and technology transfer and development costs in conjunction with services performed by our contract manufacturers, clinical development and trial costs, other pre-commercial activities and other administrative expenses incurred in the course of our continuing operations. The changes in net cash used in operating activities are primarily related to our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable.

Net cash used in operating activities for 2020 of $31.7 million was primarily due to our net loss of $33.4 million adjusted for non-cash stock-based compensation of $1.6 million, depreciation and amortization of $1.4 million and a decrease in our accounts payable of $1.5 million. Net cash used in operating activities for 2019 of $34.8 million was primarily due to our net loss of $37.6 million, adjusted for non-cash stock-based compensation of $1.6 million, depreciation and amortization of $0.7 million and an increase in our accounts payable and accrued liabilities of $0.5 million.

Investing Cash Flow: Net cash used in investing activities of $8.5 million for 2020 was the result of property and equipment purchases to support our pre-commercialization activities. Net cash provided by investing activities of $2.2 million for 2019 was primarily the result of $13.9 million of net proceeds from maturities of marketable securities, partially offset by $11.8 million of property and equipment purchases to support our pre-commercialization activities.

Financing Cash Flow: Net cash provided by financing activities of $69.2 million for 2020 was primarily due to the proceeds from the issuance of common stock and warrants, net of commissions and discounts, of $38.7 million in connection with our offerings in 2020, and $14.9 million from the exercise of the related warrants, the proceeds from issuance of common stock in connection with at-the-market offerings, net of commissions of $16.2 million, and $1.6 million from a PPP loan. These proceeds were offset by repayments on the Trinity build-to-suit obligation of $2.2 million. See below for a further discussion of our equity and debt activity in 2020. Net cash provided by financing activities of $29.8 million in 2019 was primarily due to proceeds from various common stock offerings throughout the year amounting to $26.8 million, proceeds from additional Trinity drawdowns of $6.1 million, offset by repayments on the Trinity build-to-suit obligation of $3.1 million.

2020 Offerings

On August 31, 2020, we entered into an underwriting agreement with BTIG, LLC (“BTIG”), pursuant to which we issued and sold 15,937,130 shares of our common stock to BTIG at a price of $1.304 per share. The offering closed on September 3, 2020. We received net proceeds of approximately $20.3 million after deducting expenses payable by us in connection with the offering. The shares were sold pursuant to the 2020 Shelf Registration Statement and the prospectus supplement dated August 31, 2020.

On March 4, 2020, we entered into a securities purchase agreement with certain institutional investors for the issuance and sale in a registered direct offering of (i) 11,903,506 shares of our common stock and (ii) Series E Warrants to purchase up to a total of 11,903,506 shares of common stock at an offering price of $0.9275 per share and accompanying warrant. The Series E Warrants have an exercise price of $0.8025 per share, were immediately exercisable and expire five years from the date of issuance. The aggregate net proceeds from the offering were approximately $10.2 million, after deducting the placement agent fees and other offering expenses. During the year ended December 31, 2020, Series E Warrants to purchase 7,194,004 shares of common stock were exercised at an exercise price of $0.8025 per share for aggregate proceeds of approximately $5.8 million. During the period from January 1, 2021 to March 11, 2021, Series E Warrants to purchase 4,078,667 shares of common stock were exercised at an exercise price of $0.8025 per share for aggregate proceeds of approximately $3.3 million. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated March 4, 2020.

On February 14, 2020, we closed an underwritten offering for the issuance and sale of (i) 10,146,154 Class A Units, each consisting of one share of common stock and one Series C Warrant to purchase one share of common stock, at a public offering

price of $0.65 per Class A Unit, and (ii) 2,161,539 Class B Units, each consisting of one Series D Pre-Funded Warrant to purchase one share of common stock and one Series C Warrant to purchase one share of common stock, at a public offering price of $0.6499 per Class B Unit. The Series C Warrants have an exercise price of $0.65 per share, were immediately exercisable and will expire five years from the date of issuance. The Series D Pre-Funded Warrants had an exercise price of $0.0001 per share and were fully exercised in connection with the closing of the offering. We granted the underwriter a 30-day option to purchase up to an additional 1,846,153 shares of common stock and/or additional Series C Warrants to purchase up to 1,846,153 shares of common stock. The underwriter fully exercised its option to purchase the shares and the Series C Warrants. The aggregate net proceeds from the offering were $8.3 million after deducting underwriting commissions and other offering expenses. During the year ended December 31, 2020, Series C Warrants to purchase 13,986,146 shares of common stock were exercised at an exercise price of $0.65 per share for aggregate proceeds of approximately $9.1 million. During the period from January 1, 2021 to March 11, 2021, Series C Warrants to purchase 145,000 shares of common stock were exercised at an exercise price of $0.65 per share for aggregate proceeds of approximately $0.1 million. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated February 12, 2020.

At-the-Market Offerings

On June 8, 2020, we entered into a sales agreement with BTIG, as sales agent, to establish an at-the-market offering program (“2020 ATM”), under which we are permitted to offer and sell, from time to time, shares of common stock having a maximum aggregate offering price of up to $20.0 million. We are required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares and has also agreed to provide BTIG with customary indemnification rights. No shares were sold under the 2020 ATM during the quarter ended December 31, 2020. During the year ended December 31, 2020, we issued and sold 13,237,026 shares of our common stock at an average price of $1.07 per share under the 2020 ATM with aggregate net proceeds of approximately $13.5 million after deducting commission and offering expenses. The shares were sold pursuant to the 2020 Shelf Registration Statement and a prospectus supplement dated June 8, 2020.

On August 19, 2019, we entered into a sales agreement with BTIG, as sales agent, to establish an at-the-market offering program ("2019 ATM"), under which we were permitted to offer and sell, from time to time, shares of common stock having a maximum aggregate offering price of up to $15.0 million. We were required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares and also agreed to provide BTIG with customary indemnification rights. During the year ended December 31, 2020, we issued and sold 2,151,346 shares of our common stock at an average price of $1.30 per share under the 2019 ATM. The aggregate net proceeds were approximately $2.7 million after BTIG's commission and other offering expenses. On March 4, 2020, we delivered notice of termination of the sales agreement to BTIG. We did not incur any termination penalties as a result of our termination of the sales agreement.

Trinity Build-to-Suit Obligation

On May 27, 2020, we entered into the First Amendment to Lease Documents (the “Trinity Amendment”) with Trinity, which, among other things, extended the term of each lease schedule from a 36-month term to a 42-month term by providing for an interest-only period from May 2020 through October 2020. Principal payments recommenced November 1, 2020. Additionally, the Trinity Amendment removed all end-of-term options other than the option to purchase the equipment at 12% of equipment cost at the end of each 42-month-term.

PPP Loan

On April 21, 2020, we executed a promissory note (the “PPP Note”) evidencing an unsecured loan in the amount of $1.6 million under the Paycheck Protection Program (the “PPP Loan”). The Paycheck Protection Program (“PPP”) was established under the CARES Act and is administered by the U.S. Small Business Administration (“SBA”). Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and the maintenance of our payroll levels. We applied for forgiveness of the $1.6 million loan amount and accrued interest on October 4, 2020, however, no assurance is provided that we will obtain forgiveness of the PPP Loan in whole or in part.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020:

	Operating Lease Obligations (1)	Build-to-suit Obligation (2)	Paycheck Protection Program Loan Obligation (3)	Equipment Purchase Commitments (4)	Contract Manufacturing Commitments (5)	Total
2021	$ 1,976	$ 5,397	$ 814	$ 3,989	$ 2,028	$ 14,204
2022	2,043	4,104	813	—	1,978	8,938
2023	2,017	1,024	—	—	—	3,041
2024	1,371	—	—	—	—	1,371
Total	$ 7,407	$ 10,525	$ 1,627	$ 3,989	$ 4,006	$ 27,554

(1) **Operating leases**

Our operating lease obligations primarily consist of a lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings, for our office, research and development, and manufacturing facilities in Fremont, California. In addition to the minimum rental commitments, our leases may require us to pay additional amounts for taxes, insurance, maintenance and other operating expenses. See Note 6. *Leases*, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(2) **Build-to-suit obligation**

The build-to-suit obligation consists of principal and interest payments and purchase option fees related to our build-to-suit obligation with Trinity. See Note 7. *Debt Financing*, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(3) **Paycheck Protection Program loan obligation**

The Paycheck Protection Program loan obligation consists of principal and interest payments under the PPP Note. We applied for forgiveness of the loan amount and accrued interest on October 4, 2020, however, we can provide no assurance that we will be granted forgiveness of the PPP Loan in whole or in part. See Note 7. *Debt Financing* of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(4) **Equipment purchase commitments**

Equipment purchase commitments relate to a purchase commitment with a manufacturer to build a commercial coating and primary packaging system for the production of our product candidate, Qtrypta. The terms of the purchase commitment is generally contingent upon performance of certain milestones. See Note 10. *Commitments and Contingencies*, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(5) **Contract manufacturing commitments**

Our contract manufacturing commitments consist of non-cancelable commitments with our contract manufacturing organizations for the construction of dedicated manufacturing space and technology transfer fees. See Note 10. *Commitments and Contingencies*, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

See Note 2. *Summary of Significant Accounting Policies*, of the Notes to Financial Statements included in Item 8 of this Annual Report on Form 10-K for a summary of Recent Accounting Pronouncements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Some of the securities that we invest in have market risk where a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, as well as investments in marketable securities. We had cash and cash equivalents of $35.3 million as of December 31, 2020, which consisted of bank deposits. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Our cash and cash equivalents are held for working capital purposes. Cash balances are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits, and we are exposed to credit risk when our cash balances exceed FDIC insurance limits. Our total cash and cash equivalent balances exceed the maximum amounts insured by the FDIC.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. We hold interest-earning instruments, which carry a degree of interest rate risk. To date, fluctuations in interest income and expense have not been significant. However, fluctuations in market interest rates in the future could have a material impact on our financial condition and results of operations.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Zosano Pharma Corporation
Financial Statements
December 31, 2020 and 2019
Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Zosano Pharma Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Zosano Pharma Corporation (the "Company") as of December 31, 2020 and 2019, the related statement of operations and comprehensive loss, changes in stockholders' equity and statement of cash flow, for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring operating losses and negative cash flows from operating activities since inception and has an accumulated deficit, which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Deloitte & Touche LLP
San Francisco, California
March 11, 2021

We have served as the Company's auditor since 2019.

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,263	$ 6,316
Prepaid expenses and other current assets	453	497
Total current assets	35,716	6,813
Restricted cash	455	455
Property and equipment, net	30,909	24,636
Operating lease right-of-use assets	4,928	5,763
Other long-term assets	3	3
Total assets	$ 72,011	$ 37,670
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,884	$ 4,356
Accrued compensation	2,294	2,015
Build-to-suit obligation, current portion	4,779	4,554
Operating lease liabilities, current portion	1,378	1,140
Paycheck Protection Program loan, current portion	809	—
Other accrued liabilities	3,367	4,172
Total current liabilities	14,511	16,237
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	4,359	6,095
Operating lease liabilities, long-term portion	4,687	5,931
Paycheck Protection Program loan, long-term portion	812	—
Other long-term liabilities	127	15
Total liabilities	24,496	28,278
Commitments and contingencies (see note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; none issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 250,000,000 shares authorized as of December 31, 2020 and 2019, respectively; 102,066,218 and 23,503,214 shares issued and outstanding as of December 31, 2020 and 2019, respectively	10	2
Additional paid-in capital	379,695	308,211
Accumulated deficit	(332,190)	(298,821)
Total stockholders' equity	47,515	9,392
Total liabilities and stockholders' equity	$ 72,011	$ 37,670

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

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

	Year Ended December 31,	
	2020	2019
Service revenue	$ 224	$ —
Operating expenses:		
Cost of service revenue	171	—
Research and development	21,622	25,385
General and administrative	11,189	11,812
Total operating expenses	32,982	37,197
Loss from operations	(32,758)	(37,197)
Other income (expense):		
Interest income	18	207
Interest expense	(719)	(523)
Other income (expense), net	90	(76)
Loss before provision for income taxes	(33,369)	(37,589)
Provision for income taxes	—	—
Net loss	$ (33,369)	$ (37,589)
Unrealized gain on marketable securities, net of tax	—	5
Comprehensive loss	$ (33,369)	$ (37,584)
Net loss per common share – basic and diluted	$ (0.49)	$ (2.29)
Weighted-average common shares used in computing net loss per common share – basic and diluted	67,907	16,384

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

ZOSANO PHARMA CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share amount)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2019	11,973,039	$ 1	$ 279,946	$ (261,232)	$ (5)	$ 18,710
Issuance of common stock in connection with offering, net	5,750,000	1	18,330	—	—	18,331
Issuance of common stock in connection with at-the-market offering program, net	3,599,141	—	5,233	—	—	5,233
Issuance of common stock in connection with registered direct offering, net	2,181,034	—	3,090	—	—	3,090
Stock-based compensation	—	—	1,612	—	—	1,612
Unrealized gain on marketable securities	—	—	—	—	5	5
Net loss	—	—	—	(37,589)	—	(37,589)
Balance at December 31, 2019	23,503,214	2	308,211	(298,821)	—	9,392
Issuance of common stock in connection with offering, net	15,937,130	1	20,335	—	—	20,336
Issuance of common stock in connection with at-the-market offering program, net	15,388,372	2	16,232	—	—	16,234
Issuance of common stock and Series E warrants in connection with registered direct offering, net	11,903,506	1	10,210	—	—	10,211
Issuance of common stock, Series C and Series D pre-funded warrants, in connection with public offering, net	11,992,307	2	8,262	—	—	8,264
Issuance of common stock upon exercise of Series D pre-funded warrants	2,161,539	—	—	—	—	—
Issuance of common stock upon exercise of Series C warrants	13,986,146	1	9,090	—	—	9,091
Issuance of common stock upon exercise of Series E warrants	7,194,004	1	5,772	—	—	5,773
Stock-based compensation	—	—	1,583	—	—	1,583
Net loss	—	—	—	(33,369)	—	(33,369)
Balance at December 31, 2020	102,066,218	$ 10	$ 379,695	$ (332,190)	$ —	$ 47,515

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

ZOSANO PHARMA CORPORATION
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (33,369)	$ (37,589)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,583	1,612
Change in operating lease right-of-use assets	980	841
Depreciation and amortization	1,426	683
Effective interest on financing obligations	722	860
Capitalized effective interest	(447)	(582)
Accretion of interest on marketable securities	—	(55)
Other	7	93
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(17)	(193)
Accounts payable	(1,472)	1,764
Accrued compensation and other accrued liabilities	21	(1,288)
Operating lease liabilities	(1,152)	(963)
Net cash used in operating activities	(31,718)	(34,817)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	—	17,400
Purchases of marketable securities	—	(3,476)
Purchases of property and equipment	(8,487)	(11,760)
Net cash (used in) provided by investing activities	(8,487)	2,164
Cash flows from financing activities:		
Proceeds from offering of securities, net of commissions and offering costs	20,336	18,331
Proceeds from issuance of securities in connection with at-the-market offering program, net of commissions and offering costs	16,183	5,289
Proceeds from registered direct offering of securities, net of commissions and offering costs	10,135	3,162
Proceeds from exercise of Series C warrants	9,091	—
Proceeds from public offering of securities and exercise of pre-funded Series D warrants, net of commissions and offering costs	8,264	—
Proceeds from exercise of Series E warrants	5,773	—
Proceeds from Paycheck Protection Program loan	1,610	—
Proceeds from build-to-suit obligation, net of issuance costs	—	6,126
Principal payments on financing obligations	(2,240)	(3,079)
Net cash provided by financing activities	69,152	29,829
Net increase (decrease) in cash, cash equivalents and restricted cash	28,947	(2,824)
Cash, cash equivalents and restricted cash at beginning of year	6,771	9,595
Cash, cash equivalents and restricted cash at end of year	$ 35,718	$ 6,771
Supplemental cash flow information:		
Cash paid for interest	$ 961	$ 834
Cash paid for income taxes	$ 13	$ 3
Non-cash investing and financing activities:		
Acquisition of property and equipment under accounts payable and other accrued liabilities	$ 3,088	$ 4,420
Asset retirement obligation	$ 97	$ —
Accrued offering costs	$ —	$ 188

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

Zosano Pharma Corporation
Notes to Financial Statements
For the Years Ended December 31, 2020 and 2019

1. Organization

The Company

Zosano Pharma Corporation (the “Company”) is a clinical-stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics and other bioactive molecules to patients using its proprietary transdermal microneedle system ("System").

The Company submitted a 505(b)(2) New Drug Application (“NDA”) for Qtrypta™ (M207) (“Qtrypta”) to the U.S. Food and Drug Administration (the “FDA”) on December 20, 2019, and on October 20, 2020, the Company received a Complete Response Letter (“CRL”) from the FDA with respect to the NDA. The CRL cited inconsistent zolmitriptan exposure levels observed across clinical pharmacology studies, which had been previously identified in the FDA’s discipline review letter received by the Company on September 29, 2020. Specifically, the CRL noted differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in the Company’s trials and inadequate pharmacokinetic bridging between the lots that made interpretation of some safety data unclear. The CRL referenced unexpected high plasma concentrations of zolmitriptan observed in five study subjects enrolled in the Company’s pharmacokinetic studies. The FDA recommended that the Company conduct a repeat bioequivalence study comparing lots manufactured with the equipment used during development. The CRL noted that additional product quality validation data, which were planned to be submitted following approval, if received, were required to be submitted with the application. In addition, the CRL mentioned that due to U.S. Government and/or Agency-wide restrictions on travel, inspections of the Company’s contract manufacturing facilities were not able to be conducted but would be required before the application may be approved.

On January 29, 2021, the Company held a Type A meeting with the FDA Division of Neurology II (the “Division”) regarding the requirements for resubmission of the Qtrypta NDA. Based on feedback from the Type A meeting held with the Division, the Company plans to conduct an additional pharmacokinetic (“PK”) study for inclusion in an NDA resubmission package. During the meeting, the Division did not request that the Company conduct any further clinical efficacy studies to support the resubmission. On February 19, 2021, the Company received the official Type A meeting minutes from the FDA. The Type A meeting minutes were generally consistent with the Company's expectations to conduct an additional PK study for inclusion in an NDA resubmission package. In a post-meeting comment, the FDA recommended a skin assessment on patients in the planned PK study to generate additional safety information. This assessment is included in the proposed study protocol, which has been submitted to the FDA. The Division indicated willingness to review the study protocol and provide comments prior to the initiation of the study. The Company's plans for resubmitting the NDA are based on discussions with the FDA and may be subject to change upon receipt of the FDA’s comments to the proposed study protocol.

The Company does not anticipate realizing product revenues unless and until the FDA approves the NDA and the Company begins commercializing Qtrypta, which may never occur.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of the accompanying financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of expenses during the periods reported. Actual results could differ from those estimates. Assets and liabilities reported in the Company’s balance sheet and expenses and income reported for each of the periods presented are affected by estimates and assumptions, which are used for, but are not limited to, determining the fair value of assets and liabilities, income tax uncertainties, and measurement of stock-based compensation. Actual results could differ from such estimates or assumptions.

Liquidity and Substantial Doubt about Going Concern

Since inception, the Company has incurred recurring operating losses and negative cash flows from operating activities, and as of December 31, 2020, had an accumulated deficit of $332.2 million. As of December 31, 2020, the Company had approximately $35.3 million in cash and cash equivalents. Presently, the Company does not have sufficient cash and cash equivalents to enable it to fund its anticipated level of operations and meet its obligations as they become due within twelve months following the date of issuance of this Annual Report on Form 10-K. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Shelf Registration

The Company filed a shelf registration statement on Form S-3 with the U.S. Securities and Exchange Commission (the "SEC"), which was declared effective by the SEC on April 16, 2020 ("2020 Shelf Registration Statement"). The 2020 Shelf Registration Statement provides the Company with the ability to issue common stock and other securities as described in the registration statement from time to time up to an aggregate amount of $74.5 million, of which approximately $33.7 million is available at December 31, 2020.

At-the-Market Offering Program - 2020

On June 8, 2020, the Company entered into a sales agreement with BTIG, LLC ("BTIG") as sales agent, to establish an at-the-market offering program ("2020 ATM"), under which the Company is permitted to offer and sell, from time to time, shares of common stock having a maximum aggregate offering price of up to $20.0 million. The Company is required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares and has also agreed to provide BTIG with customary indemnification rights. During the year ended December 31, 2020, the Company issued and sold 13,237,026 shares of its common stock at an average price of $1.07 per share under the 2020 ATM with aggregate net proceeds of approximately $13.5 million after deducting commissions and offering expenses payable by the Company. The shares were sold pursuant to the Company's 2020 Shelf Registration Statement and a prospectus supplement dated June 8, 2020.

Offering - September 2020

On August 31, 2020, the Company entered into an underwriting agreement with BTIG, pursuant to which the Company issued and sold 15,937,130 shares of its common stock to BTIG at a price of $1.304 per share. The offering closed on September 3, 2020. The Company received net proceeds of approximately $20.3 million after deducting expenses payable by the Company in connection with the offering. The shares were sold pursuant to the 2020 Shelf Registration Statement and the prospectus supplement dated August 31, 2020.

Registered Direct Offering - March 2020

On March 4, 2020, the Company entered into a securities purchase agreement with certain institutional investors for the issuance and sale in a registered direct offering (the "March 2020 Offering") of (i) 11,903,506 shares of the Company's common stock and (ii) Series E Warrants to purchase up to a total of 11,903,506 shares of common stock at an offering price of $0.9275 per share and accompanying warrant. The Series E Warrants have an exercise price of $0.8025 per share, were immediately exercisable and expire five years from the date of issuance. The aggregate net proceeds from the offering were approximately $10.2 million, after deducting the placement agent fees and other offering expenses. During the year ended December 31, 2020, Series E Warrants to purchase 7,194,004 shares of common stock were exercised at an exercise price of $0.8025 per share for aggregate proceeds of approximately $5.8 million. During the period from January 1, 2021 to March 11, 2021, Series E Warrants to purchase 4,078,667 shares of common stock were exercised at an exercise price of $0.8025 per share for aggregate proceeds of approximately $3.3 million. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated March 4, 2020.

Public Offering - February 2020

On February 14, 2020, the Company closed an underwritten offering (the "February 2020 Offering") for the issuance and sale of (i) 10,146,154 Class A Units, each consisting of one share of common stock and one Series C Warrant to purchase one share of common stock, at a public offering price of $0.65 per Class A Unit, and (ii) 2,161,539 Class B Units, each consisting of one Series D Pre-Funded Warrant to purchase one share of common stock and one Series C Warrant to purchase one share of common stock, at a public offering price of $0.6499 per Class B Unit. The Series C Warrants have an exercise price of $0.65 per share, were immediately exercisable and will expire five years from the date of issuance. The Series D Pre-Funded Warrants had an exercise price of $0.0001 per share and were fully exercised in connection with the closing of the offering. The Company granted the underwriter a 30-day option to purchase up to an additional 1,846,153 shares of common stock and/or additional Series C Warrants to purchase up to 1,846,153 shares of common stock. The underwriter fully exercised its option to

purchase the shares and the Series C Warrants. The aggregate net proceeds from the offering were $8.3 million after deducting underwriting commissions and other offering expenses. During the year ended December 31, 2020, Series C Warrants to purchase 13,986,146 shares of common stock were exercised at an exercise price of $0.65 per share for aggregate proceeds of approximately $9.1 million. During the period from January 1, 2021 to March 11, 2021, Series C Warrants to purchase 145,000 shares of common stock were exercised at an exercise price of $0.65 per share for aggregate proceeds of approximately $0.1 million. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated February 12, 2020.

The Company plans to raise additional funding through equity or debt financings, licensing or collaboration agreements, or strategic alliances with pharmaceutical partners, or any combination of the above. However, there are no assurances that additional funding will be obtained and that the Company will succeed in its future operations. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and it may have to cease operations.

The Company will continue to evaluate its timelines, strategic needs, and working capital requirements. There can be no assurance that if the Company attempts to raise additional capital, it will be successful in doing so on terms acceptable to the Company, or at all. Further, there can be no assurance that it will be able to gain access and/or be able to execute on securing new sources of funding, new development opportunities, successfully obtain regulatory approvals for and commercialize new products, achieve significant product revenues from its products (if approved), or achieve or sustain profitability in the future.

COVID-19 Pandemic

On March 11, 2020, the World Health Organization designated COVID-19 as a global pandemic. Due to the COVID-19 pandemic, there has been uncertainty in the global financial markets and economic conditions. The Company is closely monitoring the impact of the COVID-19 pandemic on its business, including how it will impact its employees, clinical trials and third-party service providers who perform critical services for the Company's business. In addition, the impact of the COVID-19 pandemic on the global financial markets and economic conditions could impact the Company's ability to raise capital through an equity financing, debt financing, a license or collaboration or a combination of such sources of capital, and as a result, its ability to continue as a going concern. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it. As of the date of issuance of this Annual Report on Form 10-K, management is not aware of any specific event or circumstances that would require an update to its estimates or a revision of the carrying value of its assets or liabilities. These estimates may change, as new events occur, and additional information is obtained.

Segment Reporting

The Company operates in one reportable segment: the development of human pharmaceutical products. All long-lived assets are maintained in the United States.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents.

As of December 31, 2020 and 2019, the Company had restricted cash of approximately $0.5 million primarily consisting of deposits of $0.3 million to secure its building lease until the end of the lease term and a deposit of approximately $0.1 million to a utility provider.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets and as presented as cash, cash equivalents and restricted cash in the statements of cash flows.

	December 31, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 35,263	$ 6,316
Restricted cash	455	455
Total	$ 35,718	$ 6,771

Marketable Securities

Marketable securities generally consist of debt securities with original maturities greater than 90 days and remaining maturities of less than one year. Marketable securities with an original maturity greater than one year, if any, would be considered long-term investments. All of the Company's investments are classified as available-for-sale and carried at fair value based upon quoted market price. The change in unrealized gains and losses related to fixed maturity debt securities is reported as a separate component of comprehensive loss in the statements of operations and comprehensive loss and as a separate component of stockholders' equity on the balance sheets. Interest income includes interest, dividends, amortization and accretion of purchase premiums and discounts and realized gains and losses on sales of securities, if any. The cost of securities sold is based on the specific-identification method.

The Company monitors its investment portfolio for potential impairment on a quarterly basis. If the carrying amount of an investment in available-for-sale debt securities exceeds its fair value and the decline in value is determined to be other-than-temporary, an allowance is recorded in the amount that the carrying amount of the security exceeds its fair value and a loss is recognized in operating results for the amount of such decline. If the carrying amount of an investment in marketable securities, other than available-for-sale debt securities, exceeds its fair value and the decline in value is determined to be other-than-temporary, the carrying amount of the security is reduced to fair value and a loss is recognized in operating results for the amount of such decline. In order to determine whether a decline in value is other-than-temporary, the Company evaluates, among other factors, the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, and its intent and ability to hold the security to maturity or expected recovery.

Fair Value Instruments

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

Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.

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

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

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

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company invests its excess cash in money market funds, U.S. treasuries, corporate notes and commercial paper. The Company’s investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. Other than for obligations of the U.S. government, the Company’s policy is that no single issuer in the portfolio shall exceed 10% or $1 million, whichever is greater, of the total portfolio at the time of purchase. Bank deposits are held by a single financial institution having a strong credit rating and these deposits may at times be in excess of FDIC insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the balance sheets.

Property and Equipment

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

The Company records as construction-in-progress (“CIP”) property and equipment that has not yet been placed in service for its intended use. All costs prior to a project becoming probable of being constructed are expensed as incurred. After the construction is considered probable, all directly identifiable costs related to an asset are capitalized.

Interest related to construction of assets is capitalized when the financial statement effect of capitalization is material, construction of the asset has begun, and interest is being incurred. Interest capitalization ends at the earlier of the asset being substantially complete and ready for its intended use or when interest costs are no longer being incurred.

When assets are retired or otherwise disposed of, the costs and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statement of operations and comprehensive loss in the period realized.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for indications of possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets is measured by a comparison of the carrying amount of the asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

There was no impairment of long-lived assets during the years ended December 31, 2020 and December 31, 2019.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. If the interest rate implicit in the Company's lease contracts is not readily determinable, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Finance leases are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under finance leases are recorded in property and equipment, net on the balance sheets and depreciated in a manner similar to other property and equipment.

Deferred Financing Costs

Deferred financing costs represent legal, accounting and other direct costs related to the Company’s efforts to raise capital through a public or private sale of the Company’s common stock. These costs are generally deferred until the completion of the applicable offering, at which time such costs are reclassified to additional paid-in-capital as a reduction of the proceeds. In the instance where costs are incurred for a canceled or delayed offering, the deferred financing costs are recorded as expense in the period the offering is canceled or delayed beyond 90 days. The financing costs and value of any commitment shares incurred to secure an equity line of credit are recorded as deferred financing costs and amortized as interest expense over the term of the equity line of credit.

Revenue

On October 1, 2020, the Company adopted Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (“Topic 606”). Topic 606 supersedes the revenue recognition requirements in Topic 605 *Revenue Recognition* (“Topic 605”) and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 using the modified retrospective transition method on October 1, 2020 as the Company did not have revenue from the required adoption date of Topic 606 until October 1, 2020.

For all revenue transactions, the Company evaluates its contracts with customers to determine revenue recognition using the following five-step model:

1. Identify the contract(s) with a customer;
2. Identify the performance obligations in the contract;
3. Determine the transaction price;
4. Allocate the transaction price to the identified performance obligations; and
5. Recognize revenue when (or as) the Company satisfies a performance obligation.

Currently, the Company's revenue is related to feasibility studies in which the Company provides research and development services to customers to determine the feasibility of using its System in connection with the customers' pharmaceuticals. All studies are evidenced by signed contracts delineating the terms of the services provided. Performance obligations generally consist of various phases of research and development activities and the agreements may also include provisions for exclusivity, future licensing negotiations options and most favored pricing. Such additional provisions are analyzed on an individual basis to determine whether they represent performance obligations. The transaction price is stipulated in the specific agreement and is allocated to research and development activities using the cost-plus-margin method and to any additional provisions using the residual value method. Revenue for research and development activities is typically recognized over time using a percentage of completion input method as there is open communication and transfer of understanding and know-how between the parties during the research and development activities. Revenue recognition for exclusivity agreements is recognized ratably over the duration of the exclusivity. The Company analyzes its agreements regularly to determine the need for any reserves for unexpected payment. As of December 31, 2020, the Company has not recorded any such reserves.

Research and Development Expenses

Research and development costs are charged to expense as incurred and consist of costs related to seeking regulatory approval of the Company's primary product candidate, Qtrypta, pre-commercialization efforts for Qtrypta, clinical trial costs and furthering its research and development efforts. Research and development costs include salaries and related employee benefits, fees paid to contract manufacturing organizations ("CMOs") that conduct manufacturing activities on behalf of the Company, costs associated with clinical trials, nonclinical research and development activities, regulatory activities, costs of active pharmaceutical ingredients and raw materials and research and development related overhead expenses.

For the year ended December 31, 2020, the Company incurred research and development costs of approximately $7.2 million in connection with the Company's research and development efforts and approximately $14.4 million in the manufacturing of the Company's System and facility set-up and technology transfer fees to its CMOs. For the year ended December 31, 2019, the Company incurred research and development costs of approximately $11.5 million in connection with the Company's research and development efforts and approximately $13.9 million in the manufacturing of the Company's System and facility set-up and technology transfer fees to its CMOs.

Clinical Trial Costs

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

Stock-Based Compensation

The Company has equity incentive plans under which various types of equity-based awards including, but not limited to, non-qualified stock options and restricted stock awards, may be granted to employees, non-employee directors, and non-employee consultants. The Company's equity incentive plans also allow incentive stock options to be awarded to employees. The Company has also awarded inducement grants to purchase common stock to new employees outside the existing equity compensation plans in accordance with Nasdaq listing rule 5635(c)(4).

The Company accounts for stock-based compensation, based on the fair value of the stock-based awards on the date of grant. The fair value of employee stock option grants is estimated on the date of grant using the Black-Scholes option pricing model and is recognized as expense on a straight-line basis over the awardee's requisite service period. Prior to 2020, the Company did not have sufficient historical stock price information to meet the expected life of the stock option grants, and therefore, it used a blended volatility rate that included its common stock trading history supplemented with the trading history from the common stock of a set of comparable publicly-traded biopharmaceutical companies. During 2020, the Company determined that a sufficient amount of historical information was available regarding the volatility of its stock price and that it was no longer necessary to utilize a blended volatility rate. Due to the lack of historical exercise data to provide a reasonable basis upon which to estimate an expected term, the Company has opted to use the simplified method, which is the use of the midpoint of the vesting term and the contractual term of the award to estimate the expected term. The Company recognizes the impact of stock option forfeitures on stock-based compensation expense in the period the award is forfeited.

Stock-based compensation expense related to stock options granted to non-employees, if any, is recognized based on the fair value of the stock options as determined using the Black-Scholes option pricing model, as earned.

Warrants

The Company has issued freestanding warrants to purchase shares of common stock in connection with equity offerings, debt agreements and a build-to-suit arrangement. The warrants are recorded at fair value using the Black-Scholes option pricing model.

Income Taxes

The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax basis. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Financial statement effects of uncertain tax positions are recognized when it is more-likely-than-not, based on the technical merits of the position, that they will be sustained upon examination. Interest and penalties related to unrecognized tax benefit, if any, would be included within the provision for income tax. As of December 31, 2020 and 2019, the Company has a full valuation allowance on its net deferred tax assets.

Interest Expense

Interest expense includes cash and non-cash components with the non-cash components consisting of (i) interest recognized from the amortization of debt discount and issuance costs that are generally derived from cash payments or warrants issued related to financing obligations, (ii) interest recognized from the amortization of purchase option and termination fees related to financing obligations, offset by (iii) interest capitalized for assets constructed for use in operations.

The capitalized amounts related to the debt issuance costs and debt discounts are generally amortized to interest expense over the term of the related debt instruments unless they are attributable to assets constructed for use in operations and are therefore capitalized as construction-in-progress until the asset is substantially complete and ready for its intended use.

Net Loss Per Common Share

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

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

	December 31, 2020	December 31, 2019
	(shares)	
Warrants to purchase common stock	5,148,108	274,524
Options to purchase common stock	2,724,537	2,260,307
RSUs	335,004	—
Total	8,207,649	2,534,831

Emerging Growth Company (EGC) Status

As of December 31, 2020, the Company is no longer an EGC as a result of its status as a public entity for five years. Because the aggregate worldwide market value of the voting and non-voting common equity of the Company held by non-affiliates as of June 30, 2020 was less than $700 million and the Company's revenues for the year ended December 31, 2020 were less than $100 million, the Company will continue as a smaller reporting company as designated by the SEC, and as such, it will be able to use the exemptions from certain reporting requirements available to smaller reporting companies.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* (Topic 606). Topic 606 supersedes the revenue recognition requirements in Topic 605 *Revenue Recognition* (Topic 605) and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 using the modified retrospective transition method on October 1, 2020 as the Company did not have revenue from the required adoption date of Topic 606 until October 1, 2020. The Company adopted Topic 606 effective October 1, 2020 using the modified retrospective transition method as the Company has had no revenue since the required adoption date.

In November 2018, the FASB issued ASU 2018-18 *Collaborative Arrangements* (Topic 808), Clarifying the Interaction between Topic 808 and Topic 606, which (1) clarifies that certain transactions between collaborative arrangement participants should be accounted for under ASC Topic 606, Revenue from Contracts with Customers (Topic 606), when the collaborative arrangement participant is a customer in the context of a unit of account, (2) adds unit-of-account guidance in Topic 808 to align with Topic 606 when an entity is assessing whether the collaborative arrangement, or a part of the arrangement, is within the scope of Topic 606, (3) precludes presenting transactions together with revenue when those transactions involve collaborative arrangement participants that are not directly related to third parties and are not customers. The Company adopted ASU 2018-18 in the third quarter of 2020. The adoption of ASU 2018-18 did not have a material impact on the Company's condensed financial statements.

The FASB issued ASU 2019-05, *Financial Instruments - Credit Losses, Targeted Transition Relief* in May 2019, ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments — Credit Losses*, Topic 815, *Derivatives and Hedging*, and Topic 825, *Financial Instruments* in April 2019, and ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses* in November 2018. This new guidance is intended to present credit losses on available-for-sale debt securities as an allowance rather than as a write-down. Entities are required to apply the standards' provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The Company adopted ASU 2019-05, ASU 2019-04 and ASU 2018-19 effective January 1, 2020. The adoption of this guidance did not have an impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangible - Goodwill and Other - Internal-Use Software* (Subtopic 350-40), which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The Company adopted ASU 2018-15, Subtopic 350-40 effective January 1, 2020 on a prospective basis. The adoption of this guidance did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (Topic 820). The new guidance modifies the disclosure requirements on fair value measurements. The Company adopted Topic 820 effective January 1, 2020 on a modified retrospective basis. The adoption of this guidance did not have a material impact on the Company's financial statement disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* This new guidance simplifies the accounting for income taxes by removing certain exceptions to general principles, clarifying requirements and including amendments to improve consistent application of the guidance. The guidance specifically removes the exception to the incremental approach for intra period tax allocation when there is a loss from continuing operations and income or a gain from other items, such as discontinued operations or other comprehensive income. The guidance also requires an entity to recognize a franchise tax that is partially based on income as an income-based tax and to account for any other amounts incurred as a non-income based tax. The guidance is effective for the Company beginning January 1, 2021 using a prospective approach. The Company has evaluated the new guidance and does not anticipate it to have a material impact on its financial statements.

3. Master Services Agreement with Eversana

On August 6, 2020, the Company entered into a master services agreement (the "Eversana Agreement") with Eversana Life Science Services, LLC ("Eversana") for the commercialization of Qtrypta in the United States, if approved by the FDA. Under the terms of the Eversana Agreement, Eversana and the Company will cooperate to conduct activities over the term of the Eversana Agreement. The Company maintains ownership of the Qtrypta NDA as well as all legal, regulatory and manufacturing responsibilities for Qtrypta. Eversana receives an exclusive right to conduct agreed commercialization activities and will utilize its internal sales organization along with its other commercial capabilities for market access, marketing, distribution and patient support services for Qtrypta. Eversana will receive reimbursement of certain commercialization costs pursuant to a commercialization budget estimated at approximately $250.0 million and a low double digit to mid-teen percentage of product profits if and when Company net sales of Qtrypta surpass certain costs incurred by the parties pursuant to the commercialization budget.

The term of the Eversana Agreement is five years following the date, if any, that the FDA approves the NDA. Upon expiration or termination of the Eversana Agreement, the Company will retain all profits from product sales consummated after expiration or termination and assume all future corresponding commercialization responsibilities. The Company may terminate the Eversana Agreement if Eversana fails to provide pre-commercial or commercial plans and budgets by specified dates, if the Company decides to discontinue development or commercialization efforts for Qtrypta in the United States (subject to a termination payment if such termination occurs within a specified time period), or upon a change of control of the Company. Either party may terminate the Eversana Agreement if FDA approval is not received by July 31, 2021, if net profits are not realized within a specified time period following commercial launch, for material breach of the Eversana Agreement by the other party that is not cured within a defined time period, for insolvency of the other party, if Qtrypta is subject to a safety recall in the United States or if Qtrypta is not commercially launched within a specified time period after FDA approval of the NDA (other than by reason of the terminating party's failure to perform its obligations under the Eversana Agreement).

In addition, under the Eversana Agreement, following FDA approval of the NDA, Eversana has agreed to provide a revolving credit facility of up to $5.0 million (the "Credit Facility") to the Company pursuant to a loan agreement to be entered into between Eversana and the Company on a subsequent date. The loan will bear interest at an annual rate equal to 10.0%, to be paid monthly, and the Company will be able to prepay any amounts borrowed under the Credit Facility at any time without penalty or premium. The Credit Facility will be secured by substantially all of the Company's assets, subject to prior liens and security interests.

The Company is accounting for the Eversana Agreement as a collaborative arrangement. As of December 31, 2020, no material accruals, expenses, payments, or revenues were recorded by the Company in connection with the Eversana Agreement.

4. Cash Equivalents and Investments in Marketable Securities

The following table summarizes the Company's cash equivalents and investments in marketable securities at fair value on a recurring basis as of December 31, 2020:

		Fair Value Measurements		
	Total	Quoted prices in active market Level 1	Significant other observable inputs Level 2	Significant unobservable inputs Level 3
	(in thousands)			
Money market funds classified as cash equivalents	$ 33,918	$ 33,918	$ —	$ —

The Company did not hold any cash equivalents and investments in marketable securities as of December 31, 2019.

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

The following table summarizes the Company's prepaid expenses and other current assets for each of the periods presented:

	December 31, 2020	December 31, 2019
	(in thousands)	
Unbilled revenue	$ 124	$ —
Prepaid software and subscriptions	118	61
Prepaid services	97	316
Prepaid insurance	66	49
Deferred offering costs	48	65
Other	—	6
Total	$ 453	$ 497

Property and Equipment

The following table summarizes the Company's property and equipment for each of the periods presented:

	December 31, 2020	December 31, 2019
	(in thousands)	
Leasehold improvements	$ 24,212	$ 16,932
Manufacturing equipment	14,893	12,173
Laboratory and office equipment	1,641	1,610
Computer equipment and software	172	167
Construction-in-progress	18,239	20,602
Property and equipment at cost	59,157	51,484
Less: accumulated depreciation property and equipment	(28,248)	(26,848)
Total	$ 30,909	$ 24,636

Depreciation expense was approximately $1.4 million and $0.7 million for the years ended December 31, 2020 and 2019, respectively.

Construction-in-progress included $14.6 million and $12.4 million of an asset relating to the build-to-suit arrangement for construction of the Company's commercial coating and primary packaging system as of December 31, 2020 and 2019, respectively, of which capitalized construction period interest was $2.4 million and $1.5 million as of December 31, 2020 and 2019, respectively (See Note 7. *Debt Financing*).

Other Accrued Liabilities

The following table summarizes the Company's other accrued liabilities for each of the periods presented:

	December 31, 2020	December 31, 2019
	(in thousands)	
Construction-in-progress obligations	$ 2,993	$ 3,422
Professional service fees	175	206
Contract manufacturing	71	250
Pre-clinical and clinical studies	22	43
Accrued taxes	—	27
Other	106	224
Total	$ 3,367	$ 4,172

6. Leases

Operating Leases

The Company has a non-cancelable operating lease for office, research and development, and manufacturing facilities in Fremont, California through August 31, 2024, with an option to further extend the lease for an additional 60 months subject to certain terms and conditions. The operating lease right-of-use asset and associated lease liability do not consider the option to extend the term after August 31, 2024, as the Company is not reasonably certain of exercising the extension option. Per the terms of the agreement, the Company does not have any residual value guarantees, restrictions or covenants. In calculating the present value of the lease payments, the Company utilized its incremental borrowing rate, as the rates implicit in the lease were not readily determinable. The Company estimates its incremental borrowing rate based on qualitative factors including company specific credit offers, lease term, general economics and the interest rate environment. The Company accounts for lease and non-lease components separately. The building lease includes non-lease components (i.e. common area maintenance) which are charged and paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability but reflected in operating expense in the period incurred.

As of December 31, 2020, the Company had operating leases for manufacturing space at two of its CMOs. The operating leases are embedded in agreements with these CMOs that include lease and non-lease components. The Company accounts for lease and non-lease components separately and determined the value of the lease and non-lease components of the agreements based upon estimates of relative standalone prices and a residual estimation approach for components that are highly variable or uncertain and where standalone prices were not readily available or estimable. These agreements have initial terms and options to extend that are dependent upon FDA approval of the Company's NDA for Qtrypta. Both agreements have cancellation clauses if the FDA does not approve the NDA for Qtrypta. As the Company does not currently have an intention to cancel the agreements prior to an FDA approval decision, the Company has recorded right-of-use assets and lease liabilities at the present value of the amount in each CMO agreement that was identified as an embedded operating lease. The lease term does not extend past the estimated date of an FDA approval decision, as it is not reasonably certain that the Company would not exercise the cancellation options in the event that Qtrypta was not approved. Pursuant to the terms of the agreements, the Company does not have any residual value guarantees, restrictions or covenants. In calculating the present value of the lease payments, the Company utilized its incremental borrowing rate, as the rates implicit in the leases were not readily determinable. The Company estimates its incremental borrowing rate based on qualitative factors including company specific credit offers, lease term, general economics and the interest rate environment. Prior to the receipt of a discipline review letter from the FDA on September 29, 2020, which indicated that an approval was unlikely, any embedded leases within these agreements were not considered long-term and were not separately disclosed as lease commitments, but included as commitments to CMOs in the commitments and contingencies footnote of the financial statements. The establishment of the embedded leases resulted in $146,000 of right-of-use assets and associated lease liabilities and was reflected as a non-cash operating activity in the statement of cash flows for the year ended December 31, 2020.

The following table summarizes the components of lease costs for each of the periods presented:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Operating lease costs	$ 1,706	$ 1,671

The following table summarizes cash payments for leases for each of the periods presented:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Operating cash flows from operating leases - cash paid for operating leases	$ 1,877	$ 1,793

The following table summarizes the lease terms and discount rates for the Company's leases as of December 31, 2020:

	Operating leases
Weighted-average remaining lease term (in years)	3.63
Weighted average discount rate	11 %

The following table summarizes the maturities of the Company's lease liabilities for each year ending December 31, as of December 31, 2020:

	Operating leases
	(in thousands)
2021	$ 1,976
2022	2,043
2023	2,017
2024	1,371
Total undiscounted cash flows	7,407
Less: amount representing interest	(1,342)
Present value of lease liabilities	$ 6,065
Current portion	$ 1,378
Long-term portion	4,687
Total	$ 6,065

7. Debt Financing

Build-to-Suit Obligation with Trinity

The Company has a build-to-suit arrangement (the "Agreement") with Trinity Funding 1, LLC (successor to Trinity Capital Fund III, L.P.) ("Trinity") to finance the third-party construction of the Company's commercial coating and primary packaging system (the "Equipment"), expected to be completed in 2021. Under the Agreement, Trinity provided the Company $14.0 million for equipment costs and associated soft costs ("Total Cost"), with an initial drawdown of $5.0 million and additional drawdowns in increments of not less than $0.5 million. Under the Agreement, each individual drawdown represents a separate financing arrangement with its own term and stated interest rate. Each drawdown is non-cancelable, with no prepayment options. In consideration of the financing arrangement, as collateral, the Company granted Trinity a first-priority lien and security interest in substantially all of the Company's assets.

On May 27, 2020, the Company entered into the First Amendment to Lease Documents (the “Trinity Amendment”). The Trinity Amendment, among other things, extended each individual drawdown term from 36 months to 42 months by providing for an interest-only period from May 2020 through October 2020. Principal payments recommenced November 1, 2020. Additionally, the Trinity Amendment removed all end-of-term options other than the option to purchase the equipment at 12% of the Total Cost, which is equal to the drawdown amount (“Purchase Option Fee”), which the Company intends to exercise at the end of each 42-month-term. The transfer of title from Trinity to the Company will occur at the end of the final 42-month-term, provided that the purchase option was executed, and the Purchase Option Fee was paid in full at the end of each 42-month-term. The security interest will terminate on the earlier to occur of (i) the date that falls six (6) months after the delivery and installation of the Equipment or (ii) payment in full of all amounts owed. The Company accounted for the Trinity Amendment as a debt modification under ASC 470-50, as the amended terms were not substantially different from the terms of the Agreement.

The Company determined that it controls the Equipment during the construction period due to its involvement in and its obligations related to the construction of the Equipment. Accordingly, construction costs incurred were recorded as construction-in-progress, a component of property and equipment on the balance sheet, and the Trinity financing obligation was recorded as a build-to-suit obligation on the balance sheet. As of December 31, 2020 and 2019, the Company had an aggregate commercial coating and primary packaging system CIP balance of $14.6 million and $12.4 million, respectively, that included $2.4 million and $1.5 million, respectively, of interest related to its build-to-suit obligation.

In connection with the build-to-suit arrangement, the Company issued common stock warrants ("Trinity Warrants") for a total of 75,000 shares of common stock at an exercise price of $3.5928 per share. The Trinity Warrants expire on September 25, 2025. Proceeds allocated to the Trinity Warrants based on their relative fair value approximated $243,000 and were recorded as a discount to the initial $5.0 million drawdown under the Trinity financing arrangement and are being amortized as interest over the term of the September 2018 drawdown.

The Trinity build-to-suit arrangement requires compliance with various affirmative and restrictive covenants in regard to making certain investments and other restricted payments, engaging in mergers or consolidations, and the sale or transfer of certain assets. Failure to comply with any of these covenants, or pay principal, interest or other amounts when due, would constitute an event of default under the applicable agreement. The Company was in compliance with its covenants with respect to the Trinity build-to-suit arrangement as of December 31, 2020.

The following table summarizes the debt obligations as of December 31, 2020:

Drawdown Date	Drawdown Amount	Principal Balance	Purchase Option Fee	Discount on Purchase Option Fee	Unamortized Discounts and Issuance Costs	Monthly Payment	Monthly Payment (interest only period)	Stated Interest Rate	Amended Effective Interest Rate	Maturity Date
				(in thousands)						
09/25/2018	$ 5,000	$ 2,097	$ 600	$ (20)	$ (123)	$ 160	$ 20	9.43 %	24.38 %	04/01/2022
12/11/2018	2,800	1,412	336	(17)	(55)	90	13	9.68 %	18.25 %	07/01/2022
06/06/2019	2,300	1,534	276	(25)	(81)	74	14	9.93 %	18.08 %	01/01/2023
09/13/2019	2,300	1,714	276	(32)	(105)	74	16	9.93 %	18.04 %	04/01/2023
11/27/2019	1,600	1,273	192	(26)	(88)	52	12	9.93 %	18.16 %	06/01/2023
Total	$ 14,000	$ 8,030	$ 1,680	$ (120)	$ (452)	$ 450	$ 75			

The following table summarizes of the Company's build-to-suit obligation as of December 31, 2020 *(in thousands)*:

Build-to-suit obligation principal amount	$	8,030
Build-to-suit obligation Purchase Option Fees at present value		1,560
Less: unamortized Purchase Option Fees		(352)
unamortized fair value of free-standing warrants		(33)
unamortized debt discount		(63)
unamortized debt issuance costs		(4)
Build-to-suit obligation, net of debt issuance costs and discount	$	9,138
Build-to-suit obligation, current portion		4,779
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount		4,359
Build-to-suit obligation, net of debt issuance costs and discount	$	9,138

Future minimum payments on the Company’s build-to-suit obligation, including payment of principal and interest and Purchase Option Fees for each year ending December 31 were as follows:

	Principal	Interest	Purchase Option Fees	Total
		(in thousands)		
2021	$ 4,779	$ 618	$ —	$ 5,397
2022	2,979	189	936	4,104
2023	272	8	744	1,024
Total	$ 8,030	$ 815	$ 1,680	$ 10,525

The following table summarizes interest incurred on the Company's build-to-suit obligation for each of the periods presented:

	Year ended December 31,	
	2020	2019
	(in thousands)	
Build-to-suit obligation, cash interest expense	$ 926	$ 782
Build-to-suit obligation, effective interest expense	711	812
Less: build-to-suit obligation, interest capitalized	(965)	(1,170)
Build-to-suit obligation interest expense	$ 672	$ 424

PPP Loan

On April 21, 2020, the Company executed a promissory note (the “PPP Note”) evidencing an unsecured loan in the amount of $1.6 million under the Paycheck Protection Program (the “PPP Loan”). The Paycheck Protection Program (“PPP”) was established under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”) and is administered by the U.S. Small Business Administration (“SBA”). The Loan was made through Silicon Valley Bank (the "Lender"). Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and the maintenance of the Company's payroll levels.

The PPP Loan has a two-year term and bears interest at a rate of 1.0% per annum. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and the maintenance of the Company's payroll levels. The Company applied for forgiveness of the entire $1.6 million loan amount and accrued interest on October 4, 2020. The Lender reviewed the application and submitted it to the SBA on October 7, 2020. No assurance is provided that forgiveness for any portion of the PPP Loan or accrued interest will be obtained.

The Paycheck Protection Flexibility Act of 2020, P.L. 116-142, extended the deferral period for loan payments to either (1) the date that the SBA remits the borrower's loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, ten months after the end of the borrower's loan forgiveness covered period. The Lender has modified the Company's first payment from November 21, 2020 to September 21, 2021 and if the loan is fully forgiven, the Company is not responsible for any payments. If only a portion of the loan is forgiven, or if the forgiveness application is denied, any remaining balance due on the loan must be repaid by the Company on or before April 21, 2022, the maturity date of the loan. Interest accrues during the time between the disbursement of the loan and SBA remittance of the forgiveness amount. The Company is responsible for paying the accrued interest on any amount of the loan that is not forgiven.

The PPP Note contains customary events of default relating to, among other things, payment defaults, providing materially false and misleading representation to the SBA or Lender or breaching the terms of the PPP Note. The occurrence of an event of default may result in the immediate repayment of all amounts outstanding, collection of all amounts owing from the Company or filing suit and obtaining judgment against the Company.

8. Stockholders' Equity

Shelf Registration

The Company filed the 2020 Shelf Registration Statement with the SEC, which was declared effective by the SEC on April 16, 2020. The 2020 Shelf Registration Statement provides the Company with the ability to issue common stock and other securities as described in the registration statement from time to time up to an aggregate amount of $74.5 million, of which approximately $33.7 million is available at December 31, 2020.

Offerings

Offering - September 2020

On August 31, 2020, the Company entered into an underwriting agreement with BTIG, pursuant to which the Company issued and sold 15,937,130 shares of its common stock to BTIG at a price of $1.304 per share. The offering closed on September 3, 2020. The Company received net proceeds of approximately $20.3 million after deducting expenses payable by the Company in connection with the offering. The shares were sold pursuant to the 2020 Shelf Registration Statement and the prospectus supplement dated August 31, 2020.

Registered Direct Offering - March 2020

On March 4, 2020, the Company entered into a securities purchase agreement with certain institutional investors for the issuance and sale in a registered direct offering of (i) 11,903,506 shares of the Company's common stock and (ii) Series E Warrants to purchase up to a total of 11,903,506 shares of common stock at an offering price of $0.9275 per share and accompanying warrant. The Series E Warrants have an exercise price of $0.8025 per share, were immediately exercisable and expire five years from the date of issuance. The aggregate net proceeds from the offering were approximately $10.2 million, after deducting the placement agent fees and other offering expenses. During the year ended December 31, 2020, Series E Warrants to purchase 7,194,004 shares of common stock were exercised at an exercise price of $0.8025 per share for aggregate proceeds of approximately $5.8 million. During the period from January 1, 2021 to March 11, 2021, Series E Warrants to purchase 4,078,667 shares of common stock were exercised at an exercise price of $0.8025 per share for aggregate proceeds of approximately $3.3 million. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated March 4, 2020.

Public Offering - February 2020

On February 14, 2020, the Company closed the February 2020 Offering for the issuance and sale of (i) 10,146,154 Class A Units, each consisting of one share of common stock and one Series C Warrant to purchase one share of common stock, at a public offering price of $0.65 per Class A Unit, and (ii) 2,161,539 Class B Units, each consisting of one Series D Pre-Funded Warrant to purchase one share of common stock and one Series C Warrant to purchase one share of common stock, at a public offering price of $0.6499 per Class B Unit. The Series C Warrants have an exercise price of $0.65 per share, were immediately exercisable and will expire five years from the date of issuance. The Series D Pre-Funded Warrants had an exercise price of $0.0001 per share and were fully exercised in connection with the closing of the offering. The Company granted the underwriter a 30-day option to purchase up to an additional 1,846,153 shares of common stock and/or additional Series C Warrants to purchase up to 1,846,153 shares of common stock. The underwriter fully exercised its option to purchase the shares and the Series C Warrants. The aggregate net proceeds from the offering were $8.3 million after deducting underwriting commissions and other offering expenses. During the year ended December 31, 2020, Series C Warrants to purchase 13,986,146 shares of common stock were exercised at an exercise price of $0.65 per share for aggregate proceeds of approximately $9.1 million. During the period from January 1, 2021 to March 11, 2021, Series C Warrants to purchase 145,000

shares of common stock were exercised at an exercise price of $0.65 per share for aggregate proceeds of approximately $0.1 million. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated February 12, 2020.

Registered Direct Offering - December 2019

On November 27, 2019, the Company entered into a securities purchase agreement with several institutional investors providing for the issuance and sale of an aggregate of 2,181,034 shares of common stock at a price of $1.45 per share in a registered direct offering. The aggregate net proceeds from the offering were $3.1 million after deducting offering expenses, of which $0.1 million were accrued at December 31, 2019. An affiliate of one of the Company's directors, purchased 689,655 shares in this offering at the same price as other investors.

Offering - April 2019

On April 11, 2019, the Company closed an offering of 5,000,000 shares of common stock at a price to the underwriter of $3.29 per share. On May 8, 2019, the underwriter purchased an additional 750,000 shares at a price to the underwriter of $3.29 per share pursuant to the exercise of the underwriter's option to purchase additional shares. The aggregate net proceeds were approximately $18.3 million, after deducting underwriting costs and offering expenses. An affiliate of one of the Company's directors and an executive officer purchased an aggregate of 528,571 shares in this offering at the same price as other investors.

At-the-Market Offering Programs

At-the-Market Offering Program - 2020

On June 8, 2020, the Company entered into a sales agreement with BTIG, as sales agent, to establish the 2020 ATM, under which the Company is permitted to offer and sell, from time to time, shares of common stock having a maximum aggregate offering price of up to $20.0 million. The Company is required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares and has also agreed to provide BTIG with customary indemnification rights. During the year ended December 31, 2020, the Company issued and sold 13,237,026 shares of its common stock at an average price of $1.07 per share under the 2020 ATM with aggregate net proceeds of approximately $13.5 million after deducting commissions and offering expenses payable by the Company. The shares were sold pursuant to the Company's 2020 Shelf Registration Statement and a prospectus supplement dated June 8, 2020.

At-the-Market Offering Program - 2019

On August 19, 2019, the Company entered into a sales agreement with BTIG, as sales agent, to establish an at-the-market offering program ("2019 ATM"), under which the Company was permitted to offer and sell, from time to time, shares of common stock having a maximum aggregate offering price of up to $15.0 million. The Company was required to pay BTIG a commission of 3% of the gross proceeds from the sale of shares and also agreed to provide BTIG with customary indemnification rights. During the year ended December 31, 2020 the Company issued and sold 2,151,346 shares of its common stock at an average price of $1.30 per share under the 2019 ATM. The aggregate net proceeds were approximately $2.7 million after BTIG's commissions and other offering expenses. On March 4, 2020, the Company delivered notice of termination of the sales agreement to BTIG. The Company did not incur any termination penalties as a result of its termination of the sales agreement.

Equity Line of Credit

On October 20, 2017, the Company entered into a purchase agreement and a registration rights agreement with an accredited investor, Lincoln Park, providing for the purchase of up to $35.0 million worth of the Company’s common stock over a 30-month term that commenced on November 21, 2017 ("Equity Line of Credit"). On August 22, 2019, the Company terminated its purchase agreement with Lincoln Park. No sales of common stock were made under the agreement.

On October 20, 2017, the Company issued 11,375 shares of its common stock, as initial commitment shares, to Lincoln Park with a fair value of $15.30 per share. The value of the commitment shares and professional service fees to secure the Equity Line of Credit were recorded as deferred financing costs and were amortized as interest expense over the term of the Equity Line of Credit, as there was no guarantee that additional shares would be sold under the Equity Line of Credit. The remaining unamortized deferred financing costs at the date of termination were recorded as other expense in the statement of operations for the year ended December 31, 2019.

Warrants

The following table summarizes the Company's issued and outstanding common stock warrants:

	Warrants Outstanding as of December 31, 2019	Issued	Exercised	Expired	Warrants Outstanding as of December 31, 2020	Exercise Price	Expiration Date
Series E - March 2020	—	11,903,506	(7,194,004)	—	4,709,502	$ 0.8025	03/06/25
Series D - February 2020	—	2,161,539	(2,161,539)	—	—		
Series C - February 2020	—	14,153,846	(13,986,146)	—	167,700	$ 0.65	02/14/25
Trinity - September 2018	75,000	—	—	—	75,000	$ 3.5928	09/25/25
Series B - August 2016	195,906	—	—	—	195,906	$ 31.00	08/19/21
Hercules - June 2015	2,035	—	—	(2,035)	—		
Hercules - June 2014	1,583	—	—	(1,583)	—		
Total	274,524	28,218,891	(23,341,689)	(3,618)	5,148,108		

Each warrant grants the holder the right to purchase one share of common stock. Equity warrants are recorded at their relative fair market value in the stockholders' equity section of the balance sheet. The Company's equity warrants can only be settled through the issuance of shares and do not have any anti-dilution or price reset provision.

Series C, Pre-Funded D and E Warrants

The Company issued Series C Warrants and Series D Pre-funded Warrants in its February 2020 Offering and Series E Warrants in its March 2020 Offering. The Series D Pre-funded Warrants were exercised in full at the close of the February 2020 Offering. The Company evaluated the Series E and Series C Warrants under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and determined permanent equity treatment was appropriate for these freestanding financial instruments. The March 2020 Offering and the February 2020 Offering did not include any embedded features that would require bifurcation. Each Series E and Series C common stock warrant grants the holder the right to purchase one share of common stock, subject to proportional adjustments in the event of stock splits, combinations or similar events. The Series E and Series C Warrants do not have any dividend or liquidation preferences or participation rights. Subject to certain conditions, the warrants are exercisable on a cashless basis, and subject to certain beneficial ownership limitations, any unexercised Series E or Series C Warrants will be automatically exercised via cashless exercise on the expiration date pursuant to the terms of the respective warrant agreements.

Trinity Warrants

In connection with its build-to-suit arrangement, the Company issued the Trinity Warrants for a total of 75,000 shares of common stock at an exercise price of $3.5928 per share. The Trinity Warrants expire on September 25, 2025. Proceeds allocated to the Trinity Warrants based on their relative fair value approximated $0.2 million and were recorded as a discount to the initial $5.0 million drawdown under the Trinity financing arrangement and are being amortized as interest over the 36-month-term of the September 2018 drawdown.

Series B Warrants

On August 15, 2016, the Company entered into a Securities Purchase Agreement ("Purchase Agreement") between the Company and certain investors, including members of the Company's board of directors and executive management, pursuant to which the Company sold and issued shares of common stock and warrants to purchase shares of common stock for aggregate gross proceeds of $7.5 million. Costs related to the offering were $0.9 million. Pursuant to the Purchase Agreement, the Company sold 239,997 common shares at $26.40 per common share. Additionally, 480,000 warrants were sold, at a price of $2.50 per warrant. Each warrant grants the holder the right to purchase one share of the Company's common stock. The Company granted 239,997 Series A Warrants, which expired in August 2017. The Company granted 239,997 Series B Warrants, which have a per share exercise price of $31.00 and expire in August 2021. Certain of the Company's board of director and executive officers purchased an aggregate of 13,771 shares of common stock and an aggregate of 27,542 warrants in this offering at the same price as the other investors. As of December 31, 2020, 195,906 warrants, which were issued in conjunction with the PIPE, remain outstanding.

Hercules Warrants

In June 2014, the Company entered into a loan and security agreement ("Hercules Term Loan") with Hercules Capital, Inc. ("Hercules"), and in June 2015 the Company entered into the first amendment to the Hercules Term Loan. In June 2014, the Company issued Hercules warrants to purchase 1,583 shares of the Company's common stock at an exercise price of $176.80 per share in connection with the Hercules Term Loan, and in June 2015, the Company issued Hercules warrants to purchase 2,035 shares of the Company's common stock at an exercise price of $147.40 per share in conjunction with the first amendment to the Hercules Term Loan. These warrants expired in 2020.

9. Stock-Based Compensation

The 2012 Stock Incentive Plan

The 2012 Stock Incentive Plan ("2012 Plan") provided for the granting of stock options and restricted stock awards to employees, directors and consultants of the Company. Options granted under the 2012 Plan were either incentive stock options or nonqualified stock options. Incentive stock options were granted only to Company employees. Nonqualified stock options were granted to Company employees, outside directors and consultants. Options and awards under the 2012 Plan were granted for periods of up to ten years. Employee options granted by the Company generally vested over four years. In connection with the Company's initial public offering of its common stock, the Company's Board of Directors terminated the 2012 Plan effective as of January 27, 2015 and no further awards were issued under the 2012 Plan. However, any awards outstanding under the 2012 Plan at January 27, 2015 continue to be governed by the terms of the 2012 Plan.

The Amended and Restated 2014 Equity and Incentive Plan

The Amended and Restated 2014 Equity and Incentive Plan ("2014 Plan") provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company's common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. Options and awards under the 2014 Plan may be granted for periods of up to ten years. Employee options granted by the Company generally vest over four years.

During the second quarter of 2020, the Company granted RSUs to its employees and members of the Board of Directors. Upon vesting, each RSU is settled into one share of the Company's common stock. The value of an RSU award is based on the Company's closing stock price on the date of grant. The RSUs granted to employees vest annually over four years and are subject to the employee's continuing service to the Company. The RSUs granted to members of the Board of Directors vest fully after one year and are subject to the director's continuing service to the Company. Stock-based compensation expense is recognized straight-line over the vesting term.

On January 1, 2020, the shares of common stock authorized for issuance under the 2014 Plan were increased by 822,612 shares pursuant to the automatic annual increase provisions of the 2014 Plan. As of December 31, 2020, 84,402 shares of common stock were available for issuance under the 2014 Plan.

Inducement Grants

The Company has granted options to purchase common stock to new employees as inducement grants outside the existing equity compensation plans in accordance with Nasdaq listing rule 5635(c)(4). Such options vest at a rate of 25% of the shares on the first anniversary of the commencement of such employee's employment with the Company, and then one forty-eighth (1/48) of the shares monthly thereafter subject to such employee's continued service.

The following tables summarize activity under the 2014 Plan, the 2012 Plan and inducement grants issued to new employees for the years ended December 31, 2019 and 2020:

Options

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (In Years)
Balance at January 1, 2019	1,309,994	$ 5.91	7.41
Options granted	1,053,950	$ 2.55	
Options canceled/forfeited/expired	(103,637)	$ 7.14	
Balance at December 31, 2019	2,260,307	$ 4.29	7.20
Options granted	923,925	$ 0.97	
Options canceled/forfeited/expired	(459,695)	$ 3.40	
Balance at December 31, 2020	2,724,537	$ 3.31	8.19
Options exercisable at December 31, 2020	1,093,712	$ 5.08	7.45

The weighted-average grant-date fair value of options granted during the years ended December 31, 2020 and 2019 was $0.77 and $2.55, respectively. The aggregate intrinsic value of outstanding options at December 31, 2020 was $8,000. The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company's common stock for in-the-money options at December 31, 2020.

RSUs

	Number of Awards	Weighted Average Grant Date Fair Value
Balance at January 1, 2020	—	
Awards granted	343,442	$ 0.84
Awards canceled/forfeited/expired	(8,438)	$ 0.84
Balance at December 31, 2020	335,004	$ 0.84

The total fair value of options and awards that vested during the years ended December 31, 2020 and 2019 was $1.6 million and $1.3 million, respectively.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
	(in thousands)	
Research and development	$ 674	$ 742
General and administrative	909	870
Total	$ 1,583	$ 1,612

At December 31, 2020, the Company had $2.8 million of total unrecognized stock-based compensation related to outstanding stock options that will be recognized over a weighted-average period of 2.55 years.

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
Risk-free interest rate	0.37% - 0.95%	1.60% - 2.66%
Expected volatility	114.58%-120.42%	106.33%-107.76%
Expected term (years)	5.50 - 6.08	5.96 - 6.08
Dividend yield	—%	—%

10. Commitments and Contingencies

Equipment Purchase Commitments

The Company has a remaining commitment of $4.0 million, of which $2.9 million was recorded as a current liability at December 31, 2020, with an equipment manufacturer to purchase a commercial coating and primary packaging machine for the production of its product candidate, Qtrypta. The terms of the purchase commitment are contingent upon performance of certain milestones. The Company anticipates that the obligation will be paid within the next 6 months.

Contract Manufacturing Organizations

The Company has a technology transfer agreement and a manufacturing and supply agreement with a CMO to provide services related to the manufacture and commercialization of Qtrypta. During the term of the agreement, the CMO will provide services related to processing, packaging, labeling and storing Qtrypta, in addition to other services such as stability testing, quality control and assurance, and waste disposal.

The agreements call for annual fees of $2.8 million in 2021 escalating to $14.0 million in 2024, to be paid in equal monthly installments. The annual fee includes the production of a defined number of units with an option to purchase additional units at a defined price. The agreement contains negotiated representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the manufacturing and supply agreement continues until the seventh anniversary of the date on which the Company receives New Drug Application approval of Qtrypta in the United States. The Company had recorded a right-of-use asset and associated lease liability at the present value of the amount of the manufacturing and supply agreement identified as an embedded operating lease (See Note 6. Leases).

The Company may terminate the agreements upon denial of regulatory approvals or if regulatory approvals are withdrawn under certain circumstances. The Company may also elect to terminate the contracts for convenience, which would result in cancellation fees in the amount of 50% of the annual fee due in the year that the contract is terminated, and costs to remove the Company's equipment and restore the CMO's facility. The Company or the CMO may terminate the agreement for the other’s uncured material breach, uncured force majeure or bankruptcy or insolvency-related events.

The Company has non-cancelable commitments with this CMO for the construction of manufacturing space and technology transfer fees totaling $3.9 million, of which $0.4 million was a current liability on the balance sheet as of December 31, 2020.

On July 31, 2020, the Company entered into an amendment to a Business Understanding Agreement dated September 13, 2018 with a CMO (the “Amended Agreement”). Pursuant to the Amended Agreement, this CMO agreed to provide services related to the manufacture and assembly of a component (the “Product”) of Qtrypta. Under the Amended Agreement, the parties expressed their mutual intent to enter into a commercial supply agreement (“Supply Agreement”) addressing certain of the terms set forth in the Amended Agreement. The Amended Agreement provides that if the Company does not enter into a Supply Agreement with this CMO or ceases to purchase the Product from this CMO prior to reaching a minimum commitment level, then the Company would be required to pay the CMO up to $2.5 million; however, no such payment will be required in the event of this CMO’s material breach. The Company may be required to pay an additional payment of up to $4.6 million if the Company ceases to purchase the Product from this CMO and a Supply Agreement is not entered into, except that no such payment will be required in the event of this CMO’s material breach or if the FDA does not approve Qtrypta. As of December 31, 2020, the Company had recorded a right-of-use asset and associated lease liability at the present value of the amount of the agreement identified as an embedded operating lease (See Note 6. Leases).

The Company has a manufacturing and supply agreement through September 2023 with a supplier for a component part that includes an inactivity fee of up to $85,000 annually.

Indemnification and Guarantees

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2020.

Legal Proceedings

On October 29, 2020 and November 6, 2020, two stockholders filed alleged class action lawsuits against the Company and certain of its current and former executive officers in the United States District Court for the Northern District of California: Carr v. Zosano Pharma Corporation, et al., Case No. 3:20-cv-07625, and Becerra v. Zosano Pharma Corporation, et al., Case No. 3:20-cv-07850. The complaints were filed purportedly on behalf of all persons who purchased or otherwise acquired the Company's securities between February 13, 2017 and September 30, 2020. The complaints allege that the Company and certain of its current and former executive officers made false and/or misleading statements and failed to disclose material adverse facts about the Company's business, operations and prospects in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The plaintiffs seek damages, interest, costs, attorneys' fees and other unspecified relief. On February 4, 2021, the Carr and Becerra actions were consolidated and the court appointed two Co-Lead Plaintiffs and two law firms as Co-Lead Counsel in the consolidated action. The Co-Lead Plaintiffs' deadline to file a consolidated amended complaint is March 29, 2021. The Company anticipates filing a motion to dismiss. Pursuant to a stipulated court order, the Company expects to file the motion on May 13, 2021; the Co-Lead Plaintiffs are expected to file their opposition on June 14, 2021; and the Company expects to file a reply brief on July 6, 2021. The earliest date upon which the Court may hear the motion is July 20, 2021. These dates are subject to change upon court order or if the Co-Lead Plaintiffs file their consolidated amended complaint prior to the March 29, 2021 deadline.

On February 9, 2021, a stockholder filed a derivative action, purportedly on behalf of the Company (named as a nominal defendant), against certain of the Company's current and former executive officers and directors in the United States District Court for the District of Delaware: Gensemer v. Lo, et al., Case No. 1:21-cv-00168. The complaint alleges breaches of the defendants' fiduciary duties as the Company's directors and/or officers, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Exchange Act, and for contribution under Sections 10(b) and 21D of the Exchange Act. The plaintiff seeks damages, restitution, interest, attorneys' fees and costs, and other unspecified relief. The Company believes the cases are without merit and it intends to vigorously defend itself against the claims. Given the uncertainty of litigation and the preliminary stage of the cases, the Company cannot predict the outcome of or estimate the possible loss or range of loss that may result from these actions.

The Company, from time to time, may be involved in other lawsuits and legal proceedings, which arise, in the ordinary course of business. Lawsuits and legal proceedings are subject to inherent uncertainties and an adverse result in any lawsuit or legal proceeding may materially adversely affect our business, financial condition and results of operations. The Company accrues for contingencies when it believes that a loss is probable and that it can reasonably estimate the amount of any such loss. To the extent that there is a reasonable possibility that a loss exceeding amounts already recognized may be incurred and the amount of such additional loss would be material, the Company will either disclose the estimated additional loss or state that such an estimate cannot be made.

11. Income Taxes

The Company has incurred cumulative net operating losses ("NOLs") in the United States since inception and, consequently, has not recorded any income tax expense for the years ended December 31, 2020 and 2019 due to its net operating loss position.

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
Federal statutory tax rate	(21.0)%	(21.0)%
State statutory tax rate, net of federal benefit	(1.9)	(7.0)
Change in effective tax rate	1.0	—
Research and development credits, net of uncertain tax positions	(2.1)	(2.6)
Derecognition due to Section 382 and 383	15.2	0.9
Stock-based compensation	0.6	0.7
Permanent items	(0.4)	—
Change in valuation allowance	8.6	29.0
Total	— %	— %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately $2.9 million and $10.9 million during the years ended December 31, 2020 and 2019, respectively.

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
	(in thousands)	
Net operating loss carryforwards	$ 24,143	$ 20,717
Research and development credits	4,150	4,809
Depreciation and amortization	508	638
Accruals	517	558
Inventory	239	—
Lease liability	1,391	1,980
Stock-based compensation	459	331
Capital loss carryforwards	23	23
Other	4	8
Total gross deferred tax assets	31,434	29,064
Valuation allowance	(30,304)	(27,450)
	1,130	1,614
Right-of-use assets	(1,130)	(1,614)
Net deferred tax assets	$ —	$ —

As of December 31, 2020, the Company had federal net operating loss carryforwards of approximately $106.5 million and state net operating loss carryforwards of approximately $25.8 million. As of December 31, 2019, the Company had federal net operating loss carryforwards of approximately $76.0 million and state net operating loss carryforwards of approximately $68.2 million. If not utilized, certain federal net operating loss carryforwards incurred before January 1, 2018, will expire beginning in 2026, and state net operating loss carryforwards will expire beginning in 2028. The federal net operating losses incurred in 2018 and beyond do not expire.

If the Company experiences a greater than 50 percentage point aggregate change in ownership over a 3-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards is subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company's stock at the time of such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. As of December 31, 2020, the Company determined that ownership changes occurred on February 26, 2014, November 30, 2015, March 22, 2017, April 3, 2018, and March 4, 2020. As a result of the ownership changes, approximately $221.7 million and $248.8 million of the NOLs will expire unutilized for federal and California purposes, respectively. As of December 31, 2020, the Company has derecognized NOL related deferred tax assets in the tax effected amounts of $46.6 million and $17.4 million for federal and California purposes, respectively. The ability of the Company to use its remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

As of December 31, 2020, the Company had federal and state research credit carry forwards of approximately $0.5 million and $6.0 million, respectively. As of December 31, 2019, the Company had federal and state research credit carry forwards of approximately $1.6 million and $5.6 million, respectively. If not utilized, the federal tax credits will begin to expire in 2040 and the state tax credits do not expire. Research and development credits are subject to IRC section 383. In the event of a change in ownership as defined by this code section, the usage of the credits may be limited. As a result of the previously mentioned ownership changes, the Company has derecognized approximately $6.9 million of gross federal research and development credit-related deferred tax assets due to the Section 383 limitation as of December 31, 2020. The Company has not derecognized any of the California research and development credit-related deferred tax assets because the credits do not expire.

CARES Act and CAA

On March 27, 2020 and December 27, 2020, the United States enacted the CARES Act and the Consolidated Appropriation Act ("CAA"), respectively, as a result of the Coronavirus pandemic, which acts contain, among other things, numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. The Company has evaluated the current legislation and, at this time, does not anticipate that the tax provisions in the CARES Act or CCA will have a material impact on its financial statements.

Uncertain Income Tax Positions

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

The Company had approximately $1.3 million of unrecognized tax benefits as of December 31, 2020 and approximately $1.4 million of unrecognized tax benefits as of December 31, 2019. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits reduce the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months. A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
	(in thousands)	
Balance at the beginning of year	$ 1,439	$ 1,128
Increase (decrease) related to prior year tax positions	(312)	47
Increase related to current year tax positions	161	264
Balance at the end of year	$ 1,288	$ 1,439

As of December 31, 2020 and 2019, the Company had not recognized any tax-related interest or penalties in its financial statements. Any interest and penalties related to unrecognized tax benefits would be included as income tax expense in the Company’s statements of operations.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is not currently under audit by the Internal Revenue Service or any other similar state, local, or foreign authority. All tax years remain open to examination by major taxing jurisdictions to which the Company is subject.

12. Employee Benefit Plan

The Company has established a 401(k) tax-deferred savings plan (the "401(k) Plan"), which permits participants to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. The Company is responsible for administrative costs of the 401(k) Plan. The Company may, at its discretion, make matching contributions to the 401(k) Plan. No employer contributions have been made during the periods ended December 31, 2020 and 2019.

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

On May 28, 2019, we dismissed Marcum LLP ("Marcum") as our independent registered public accounting firm. The dismissal of Marcum was approved by the audit committee of our board of directors ("Audit Committee"). The audit reports of Marcum on our financial statements for the years ended December 31, 2018 and 2017, did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles, except that both of the reports included an explanatory paragraph with respect to our ability to continue as a going concern. The financial statements did not include any adjustments that might have resulted from the outcome of this uncertainty. During the fiscal years ended December 31, 2018 and 2017, and any subsequent interim period through the date of Marcum's dismissal, there were no: (1) disagreements with Marcum on any matters of accounting principles or practices, financial statement disclosure, or auditing scope and procedures which, if not resolved to the satisfaction of Marcum, would have caused Marcum to make reference to the subject matter of the disagreement in connection with their reports on our financial statements, or (2) there were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K of the rules and regulations of the SEC, during our years ended December 31, 2018 and 2017 or in any subsequent interim period through the date of Marcum's dismissal.

On May 28, 2019, the Audit Committee appointed Deloitte & Touche LLP ("Deloitte") as our new independent registered public accounting firm to audit our financial statements for the fiscal year ending December 31, 2019. During the fiscal years ended December 31, 2018 and 2017, in the interim period ended March 31, 2019, and in the subsequent interim period through May 28, 2019, neither we nor anyone acting on our behalf consulted with Deloitte regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided that Deloitte concluded was an important factor considered by us in reaching a decision as to the accounting, auditing, or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in paragraph 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) or a reportable event (as described in paragraph 304(a)(1)(v) of Regulation S-K).

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate controls over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the guidelines established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting includes policies and procedures that provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. GAAP.

Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2020. We reviewed the results of management's assessment with our audit committee.

Since we are a non-accelerated filer, this Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) during the quarter ended December 31, 2020, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

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

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in our proxy statement relating to our 2021 annual meeting of stockholders to be filed by us with the SEC no later than 120 days after the close of our fiscal year ended December 31, 2020 (the "Proxy Statement") and is incorporated herein by reference.

Code of Ethics

We have adopted a written code of ethics that applies to our officers, directors and employees, which is available on our website (www.zosanopharma.com) under "Investors — Corporate Governance." The code of ethics is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002, as amended, and Item 406 of Regulation S-K. In addition, we intend to promptly disclose on our website (1) the nature of any amendment to our code of ethics that applies to our directors or our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions that is required to be disclosed under Item 5.05 of Form 8-K and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to a director or one of these specified officers, the name of such person who is granted the waiver and the date of the waiver.

Item 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) FINANCIAL STATEMENTS

Financial Statements—See index on page 77 to Financial Statements on Item 8 of this Annual Report on Form 10-K.

(2) FINANCIAL STATEMENT SCHEDULES

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

(3) INDEX TO EXHIBITS

EXHIBIT INDEX

Exhibit number	Description
3.1	Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Commission on February 3, 2015)
3.2	Amended and Restated Bylaws of Zosano Pharma Corporation (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed with the Commission on February 3, 2015)
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation, filed on January 24, 2018 (Authorized Share Increase) (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed with the Commission on January 25, 2018)
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Zosano Pharma Corporation, filed on January 24, 2018 (Reverse Stock Split) (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed with the Commission on January 25, 2018)
4.1	Specimen certificate evidencing shares of common stock of Zosano Pharma Corporation (incorporated by reference to Exhibit 4.1 to the registrant's Amendment No. 3 to Registration Statement on Form S-1 filed with the Commission on July 25, 2014)
4.2	Description of Registrant's Securities (incorporated by reference to Exhibit 4.2 to the registrant's Annual Report on Form 10-K filed with the Commission on March 13, 2020)
4.3	Warrant Agreement, dated as of June 23, 2015, between Zosano Pharma Corporation and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
4.4	Warrant to Purchase Stock, dated as of September 25, 2018 (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K filed with the SEC on September 26, 2018).
4.5	Form of Series C Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K filed with the Commission on February 13, 2020)
4.6	Amended Form of Series E Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the registrant's Quarterly Report of Form 10-Q filed with the Commission on May 14, 2020)
10.1	Letter Amendment to Intellectual Property License Agreement, dated February 22, 2011 between ALZA Corporation and Zosano Pharma, Inc. (incorporated by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.2**	Intellectual Property License Agreement, dated as of October 5, 2006, between ALZA Corporation and The Macroflux Corporation (incorporated by reference to Exhibit 10.4 to the registrant's Amendment No. 2 to Registration Statement on Form S-1 filed with the Commission on July 17, 2014)
10.3	Lease Agreement, dated May 1, 2007, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)

10.4	First Amendment to Lease, dated June 20, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.5	Second Amendment to Lease, dated October 16, 2008, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.6	Third Amendment to Lease, dated April 29, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.12 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.7	Fourth Amendment to Lease, dated July 31, 2011, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.13 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.8	Fifth Amendment to Lease, dated April 1, 2012, between Zosano Pharma, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.9	Sixth Amendment to Lease, dated as of June 24, 2015, between ZP Opco, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.5 to the registrant's Current Report on Form 8-K filed with the Commission on June 29, 2015)
10.10	Seventh Amendment to Lease, dated as of May 30, 2017, between ZP Opco, Inc. and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 9, 2017)
10.11	Eighth Amendment to Lease entered into as of May 30, 2018 by and between Zosano Pharma Corporation and BMR-34790 Ardentech Court LP (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on August 9, 2018)
10.12(a)#	ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.30 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.12(b)#	Form of Incentive Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.31 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.12(c)#	Form of Non-Statutory Stock Option under ZP Holdings, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.32 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.13(a)#	Zosano Pharma Corporation Amended and Restated 2014 Equity and Incentive Plan, as amended May 31, 2018 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 5, 2018)
10.13(b)#	Form of Zosano Pharma Corporation Incentive Stock Option Award Agreement (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on August 6, 2020)
10.13(c)#	Form of Zosano Pharma Corporation Nonstatutory Stock Option Award Agreement (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 6, 2020)
10.13(d)#	Form of Zosano Pharma Corporation Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on August 6, 2020)
10.14	Purchase Order by and between Zosano Pharma Corporation and Harro Hoflinger Packaging System (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August 6, 2018)
10.15	Purchase Order #9186, dated as of February 14, 2019 between Zosano Pharma Corporation and Harro Hofliger Packaging Systems (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2019)
10.16	Change Order by and between Zosano Pharma Corporation and Harro Hofliger Packaging System (incorporated by reference to Exhibit 10.17 to the registrant's Annual Report of Form 10-K filed with the SEC on March 13, 2020)
10.17**	Manufacturing and Supply Agreement, dated September 25, 2018 with Patheon Manufacturing Services LLC. (Incorporated by reference to Exhibit 10.7 to the registrant's current report on Form 10-Q filed with the SEC on November 15, 2018).

10.18	Business Understanding Agreement, dated September 13, 2018, by and between the Company and CSP Technologies, Inc. (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on August 6, 2020)
10.19	Amendment No. 1 to Business Understanding Agreement, dated July 31, 2020, by and between the Company and CSP Technologies, Inc. (incorporated by reference to Exhibit 10.2 to the registrant's Current Report on Form 8-K filed with the Commission on August 6, 2020)
10.20	Master Services Agreement, dated August 6, 2020, by and between the Company and Eversana Life Science Services, LLC (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q filed with the Commission on November 13, 2020)
10.21	Form of Securities Purchase Agreement, dated as of March 4, 2020, between Zosano Pharma corporation and certain investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on March 6, 2020)
10.22	Sales Agreement, dated as of June 8, 2020, by and between Zosano Pharma Corporation and BTIG, LLC (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on June 8, 2020)
10.23	Master Lease Agreement, dated September 25, 2018, with Trinity Capital Fund III, L.P., as amended, together with Equipment Schedule No. 1-1, dated September 25, 2018, Equipment Schedule No. 1-2, dated December 11, 2018, and Equipment Schedule No. 1-3, dated June 6, 2019 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2019)
10.24	Trinity Capital Fund III, L.P. Equipment Schedule No. 1-4, dated September 13, 2019. (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q filed with the SEC on November 14, 2019)
10.25	Trinity Capital Find III, L.P. Equipment Schedule No. 1-5, dated November 27, 2019 (incorporated by reference to Exhibit 10.23 to the registrant's Annual Report on Form 10-K filed with the SEC on March 13, 2020)
10.26	First Amendment to Lease Documents, dated May 27, 2020, by and between the Company and Trinity Funding 1, LLC (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on May 28, 2020)
10.27	Form of Indemnification Agreement for directors associated with an Investment Fund (incorporated by reference to Exhibit 10.15 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.28	Form of Indemnification Agreement for directors not associated with an Investment Fund (incorporated by reference to Exhibit 10.16 to the registrant's Registration Statement on Form S-1 filed with the Commission on June 24, 2014)
10.29#	Amended and Restated Employment Agreement dated September 18, 2018 with Donald Kellerman, Pharm D. (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed with the SEC on September 24, 2018)
10.30#	Amended Agreement dated October 15, 2018 with Donald Kellerman, Pharm D. (incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K filed with the SEC on October 16, 2018)
10.31#	Amended and Restated Employment Agreement dated September 18, 2018 with Hayley Lewis (Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K filed with the SEC on September 24, 2018)
10.32#	Amended Agreement dated October 15, 2018 with Hayley Lewis (incorporated by reference to Exhibit 10.3 to the registrant's current report on Form 8-K filed with the SEC on October 16, 2018)
10.33#	CEO Transition Letter Agreement dated October 7, 2019 with John Walker (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on October 8, 2019)
10.34#	Employment Letter Agreement dated October 5, 2019 with Steven Lo (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on October 8, 2019)
10.35#	Employment Letter Agreement dated April 30, 2020, with Christine Matthews (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on May 1, 2020)
10.36	Note dated April 21, 2020 (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on April 23, 2020)
10.37#*	Zosano Pharma Corporation Non-Employee Director Compensation Program

16.1	Letter to the U.S. Securities and Exchange Commission, dated May 31, 2019, from Marcum LLP (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed with the SEC on May 31, 2019)
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Chief Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1†	Certification of Chief Executive Officer and Chief Financial Officer, as required by rules 13a-14(a) and 15d-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

Management contract or compensatory plan or arrangement.

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

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

ZOSANO PHARMA CORPORATION

By:	/s/ Steven Lo
	Steven Lo
	Chief Executive Officer
Date:	March 11, 2021

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Steven Lo and Christine Matthews his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his or her name.

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

Signature	Title	Date
/s/ Steven Lo **Steven Lo**	Chief Executive Officer (Principal Executive Officer)	March 11, 2021
/s/ Christine Matthews **Christine Matthews**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 11, 2021
/s/ John Walker **John Walker**	Chairman of the Board of Directors	March 11, 2021
/s/ Steven A. Elms **Steven A. Elms**	Director	March 11, 2021
/s/ Linda S. Grais **Linda S. Grais**	Director	March 11, 2021
/s/ Kenneth R. Greathouse **Kenneth R. Greathouse**	Director	March 11, 2021
/s/ Joseph P. Hagan **Joseph P. Hagan**	Director	March 11, 2021
/s/ Kleanthis G. Xanthopoulos **Kleanthis G. Xanthopoulos**	Director	March 11, 2021

Zosano Pharma Corporation
Non-Employee Director Compensation Program

This Zosano Pharma Corporation (the "***Company***") Non-Employee Director Compensation Program (this "***Program***") has been adopted and shall be effective as of March 4, 2021 (the "***Effective Date***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board of Directors of the Company (the "***Board***"), to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company prior to the first day of the calendar year with respect to which such compensation is scheduled to be earned, or, in the case of a Non-Employee Director who first becomes eligible to participate in the Program, within the first 30 days of such eligibility. The notice shall be effective for such compensation and all subsequent compensation unless otherwise agreed in writing between the Company and the Non-Employee Director.

Cash Compensation

Annual retainers will be paid in the following amounts to Non-Employee Directors:

Non-Employee Director:	$45,000
Non-Executive Chair of the Board of Directors:	$30,000
Lead Independent Director:	$10,000
Audit Committee Chair:	$15,000
Compensation Committee Chair:	$11,000
Nominating and Corporate Governance Committee Chair:	$8,000
Audit Committee Member (non-Chair):	$7,500
Compensation Committee Member (non-Chair):	$5,500
Nominating and Corporate Governance Committee Member (non-Chair):	$4,000

All annual retainers will be paid in cash quarterly in arrears promptly following the end of the applicable calendar quarter, but in no event more than 30 days after the end of such quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described above, for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

Equity Compensation

Initial Equity Grant:	Each Non-Employee Director who is initially elected or appointed to serve on the Board shall be granted under the Company's Amended and Restated 2014 Equity and Incentive Plan or any other applicable Company equity incentive plan then-maintained by the Company (such plan, the "***Plan***") an option (the "***Initial Option***") to purchase 90,000 shares of the Company's common stock (the "***Common Stock***"). The Initial Option will be automatically granted on the date on which such Non-Employee Director commences service on the Board and will vest as to 25% of the shares subject thereto on the first anniversary of the date of grant and as to 1/48th of the shares subject thereto on each monthly anniversary thereafter, subject to the Non-Employee Director continuing in service to the Company and its subsidiaries through each vesting date.
Annual Equity Grant:	Each Non-Employee Director who will continue to serve on the Board as of the date of each annual meeting of the Company's stockholders (each, an "***Annual Meeting***") shall be granted under the Plan: (i) an option to purchase 30,000 shares of Common Stock (the "***Annual Option***") and (ii) 15,000 restricted stock units (the "***Annual RSUs***"). Notwithstanding the foregoing, the number of shares subject to each of the Annual Option and the Annual RSUs granted to any Non-Employee Director who commenced service during the 12 months preceding the Annual Meeting shall be multiplied by a fraction, the numerator of which is the number of whole months elapsed between the date of such Non-Employee Director's election or appointment and the date of the Annual Meeting and the denominator of which is 12, and rounded down to the nearest whole share. The Annual Option and the Annual RSUs will be automatically granted on the date of the applicable Annual Meeting, and will vest in full upon the earlier of (i) the first anniversary of the date of grant and (ii) immediately prior to the Annual Meeting that occurs following the date of grant, subject to the Non-Employee Director continuing in service to the Company and its subsidiaries through such vesting date.

The per share exercise price of each Initial Option and Annual Option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Plan) of a share of Common Stock on the date the option is granted.

The term of each option granted to a Non-Employee Director shall be ten years from the date the option is granted.

No portion of an Initial Option, Annual Option or Annual RSUs which is unvested or, as applicable, unexercisable at the time of a Non-Employee Director's termination of service with the Company (as determined by the Board) shall become vested and, as applicable, exercisable thereafter. Any Initial Option, Annual Option or Annual RSUs granted hereunder shall be subject to the Plan and the applicable standard form of award agreement thereunder, as modified to reflect the terms herein.

Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Options and Annual RSUs as described above.

Change in Control

Upon a Change in Control (as defined in the Plan), all outstanding equity awards that are held by a Non-Employee Director shall become fully vested and/or exercisable, irrespective of any other provisions of the Non-Employee Director's award agreement, subject to such Non-Employee Director's continued service as of immediately prior to such Change in Control.

Reimbursements

The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

Miscellaneous

The other provisions of the Plan shall apply to the options and restricted stock units granted automatically pursuant to this Program, except to the extent such other provisions are inconsistent with this Program. All applicable terms of the Plan apply to this Program as if fully set forth herein, and all grants of options and restricted stock units hereby are subject in all respects to the terms of the Plan. The grant of any option or award of restricted stock units under this Program shall be made solely by and subject to the terms set forth in a written agreement in a form approved by the Board and duly executed by an executive officer of the Company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-213567, 333-229686 and 333-237187) and Form S-8 (File Nos. 333-203039, 333-218502, 333-225527, 333-233284 and 333-239100) of our report (which includes an emphasis of matter paragraph as to the Company's ability to continue as a going concern) dated March 11, 2021, relating to the financial statements of Zosano Pharma Corporation as of December 31, 2020 appearing in the Annual Report on Form 10-K for the year ended December 31, 2020.

By: /s/ Deloitte & Touche LLP

Deloitte & Touche LLP

San Francisco, CA

March 11, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven Lo, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 11, 2021

By: /s/ Steven Lo

Steven Lo
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christine Matthews, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 11, 2021

By: /s/ Christine Matthews

Christine Matthews
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Steven Lo, the Chief Executive Officer of Zosano Pharma Corporation (the "Company"), and Christine Matthews, the Chief Financial Officer of the Company, hereby certify that, to their knowledge:

1. The Annual Report on Form 10-K for the year ended December 31, 2020 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 11, 2021

By: /s/ Steven Lo

Steven Lo
Chief Executive Officer
(Principal Executive Officer)

Date: March 11, 2021

By: /s/ Christine Matthews

Christine Matthews
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)