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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

or

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

For the transition period from _____ to _____

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(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	ZSAN	The Nasdaq Stock Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

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 Exchange Act) Yes ☐ No x

As of November 5, 2021, the registrant had a total of 118,346,993 shares of its common stock, $0.0001 par value per share, outstanding.

Zosano Pharma Corporation
Quarterly Report on Form 10-Q

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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, strategy for, and the anticipated timing with respect to the resubmission of our 505(b)(2) New Drug Application ("NDA") for M207 to the U.S. Food and Drug Administration (the "FDA");
- 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) ("CMOs") 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 Part II, 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 Quarterly Report on Form 10-Q 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 Quarterly Report.

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 Part II, Item 1A, “Risk Factors.” This summary should be read in conjunction with 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 (successor to Trinity Capital Fund III, L.P.) (“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 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 M207, and based on feedback from the FDA, we conducted an additional pharmacokinetic ("PK") 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.
- If the FDA does not agree with our M207 NDA resubmission strategy to submit PK data primarily comparing Zomig® nasal spray and patches produced on manufacturing equipment at our Fremont, California facility that produced patches for our long-term safety study, then the approval pathway for M207 will likely take significantly longer than expected, cost significantly more than anticipated, and may not be successful.
- If M207 is approved utilizing our current NDA resubmission strategy, we will only be able to produce limited quantities of M207 at our Fremont, CA location and we will not be able to produce M207 drug product on our manufacturing equipment at our third-party CMOs without FDA approval, which may require us to conduct additional clinical studies and incur significant time and cost, and we may not be successful. If we are unable to manufacture M207 on our manufacturing lines at our CMOs, it will limit our product availability and materially adversely impact our business.
- 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 M207 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 manufacture, 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 on third-party suppliers for manufacture of certain components 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 M207 or any other product candidates we may develop.
- 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 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 currently have no internal capabilities to do so, and will rely on Eversana and other third parties for the commercialization of M207 or may need to develop an internal sales organization, and we and they may not be able to effectively market, sell and distribute M207, if approved. In addition, Eversana may terminate our master services agreement under certain circumstances, including if FDA approval of M207 is not received by December 31, 2021. Also, we and Eversana have agreed that if the NDA is approved, the deferral mechanism, payment terms and loan terms in the master services agreement will be adjusted as mutually agreed by both parties. There is no guarantee that we and Eversana will reach an agreement on the deferral mechanism, payment terms and loan terms.
- If we fail to comply with our obligations to our licensor in our intellectual property license, we could lose license rights that are important to our business.
- Our failure to obtain and maintain patent protection for our technology and our product candidates could permit our competitors to develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected.
- We are highly dependent on key executive officers and the research and development, clinical, manufacturing, financial and business development expertise of our executive officers and other employees at our Fremont, CA facility with extensive knowledge of our technology and manufacturing processes. If we are not able to adequately retain our officers or train and retain staff at our Fremont, CA facility, our ability to resubmit our NDA, obtain FDA approval and commercialize M207, if approved, would be impacted and our business would be materially 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 - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,147	$ 35,263
Prepaid expenses and other current assets	983	453
Total current assets	18,130	35,716
Restricted cash	455	455
Property and equipment, net	32,337	30,909
Operating lease right-of-use assets	4,073	4,928
Other long-term assets	—	3
Total assets	$ 54,995	$ 72,011
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,551	$ 1,884
Accrued compensation	1,916	2,294
Build-to-suit obligation, current portion, net of debt issuance costs and discount	4,528	4,779
Operating lease liabilities, current portion	1,552	1,378
Paycheck Protection Program loan, current portion	—	809
Other accrued liabilities	2,092	3,367
Total current liabilities	11,639	14,511
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	1,424	4,359
Operating lease liabilities, long-term portion	3,502	4,687
Paycheck Protection Program loan, long-term portion	—	812
Other long-term liabilities	226	127
Total liabilities	16,791	24,496
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 September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.0001 par value; 250,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 118,114,793 and 102,066,218 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	12	10
Additional paid-in capital	393,336	379,695
Accumulated deficit	(355,144)	(332,190)
Total stockholders' equity	38,204	47,515
Total liabilities and stockholders' equity	$ 54,995	$ 72,011

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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Service revenue	$ 252	$ —	$ 698	$ —
Operating expenses:				
Cost of service revenue	340	—	704	—
Research and development	5,985	5,824	16,315	16,270
General and administrative	2,522	2,704	8,294	8,552
Total operating expenses	8,847	8,528	25,313	24,822
Loss from operations	(8,595)	(8,528)	(24,615)	(24,822)
Other income (expense):				
Interest income	1	2	2	17
Interest expense	(17)	(165)	(136)	(561)
Other income (expense), net	(57)	4	1,795	95
Loss before provision for income taxes	(8,668)	(8,687)	(22,954)	(25,271)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	$ (8,668)	$ (8,687)	$ (22,954)	$ (25,271)
Net loss per common share – basic and diluted	$ (0.07)	$ (0.11)	$ (0.21)	$ (0.45)
Weighted-average common shares used in computing net loss per common share – basic and diluted	115,765	77,883	109,730	56,437

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2021	102,066,218	$ 10	$ 379,695	$ (332,190)	$ 47,515
Issuance of common stock upon exercise of Series E warrants	4,078,667	1	3,273	—	3,274
Issuance of common stock upon exercise of Series C warrants	145,000	—	94	—	94
Issuance of common stock in connection with at-the-market offering, net	82,935	—	—	—	—
Stock-based compensation	—	—	410	—	410
Net loss	—	—	—	(8,142)	(8,142)
Balance at March 31, 2021	106,372,820	11	383,472	(340,332)	43,151
Issuance of common stock in connection with at-the-market offering, net	6,848,672	—	5,531	—	5,531
Release of restricted stock units	107,799	—	—	—	—
Stock-based compensation	—	—	528	—	528
Net loss	—	—	—	(6,144)	(6,144)
Balance at June 30, 2021	113,329,291	11	389,531	(346,476)	43,066
Issuance of common stock in connection with at-the-market offering, net	4,785,502	1	3,308	—	3,309
Stock-based compensation	—	—	497	—	497
Net loss	—	—	—	(8,668)	(8,668)
Balance at September 30, 2021	118,114,793	$ 12	$ 393,336	$ (355,144)	$ 38,204

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2020	23,503,214	$ 2	$ 308,211	$ (298,821)	$ 9,392
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 and 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	2,649,723	—	1,722	—	1,722
Issuance of common stock in connection with at-the-market offering, net	2,151,346	—	2,706	—	2,706
Stock-based compensation	—	—	364	—	364
Net loss	—	—	—	(8,689)	(8,689)
Balance at March 31, 2020	54,361,635	5	331,475	(307,510)	23,970
Issuance of common stock in connection with at-the-market offering, net	1,550,231	1	1,160	—	1,161
Issuance of common stock upon exercise of Series C warrants	1,333,385	—	867	—	867
Stock-based compensation	—	—	361	—	361
Net loss	—	—	—	(7,895)	(7,895)
Balance at June 30, 2020	57,245,251	6	333,863	(315,405)	18,464
Issuance of common stock in connection with public offering, net	15,937,130	1	20,386	—	20,387
Issuance of common stock in connection with at-the-market offering, net	11,686,795	1	12,365	—	12,366
Issuance of common stock upon exercise of Series C warrants	10,003,038	1	6,501	—	6,502
Issuance of common stock upon exercise of Series E warrants	7,194,004	1	5,772	—	5,773
Stock-based compensation	—	—	439	—	439
Net loss	—	—	—	(8,687)	(8,687)
Balance at September 30, 2020	102,066,218	$ 10	$ 379,326	$ (324,092)	$ 55,244

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

ZOSANO PHARMA CORPORATION
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (22,954)	$ (25,271)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,435	1,164
Change in operating lease right-of-use assets	855	712
Depreciation and amortization	1,323	993
Effective interest on financing obligations	363	560
Capitalized effective interest	(306)	(353)
Gain on forgiveness of Paycheck Protection Program loan	(1,629)	—
Loss on disposal of fixed assets	62	—
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(527)	(179)
Accounts payable	198	(1,915)
Accrued compensation and other accrued liabilities	432	(312)
Operating lease liabilities	(1,011)	(835)
Net cash used in operating activities	(21,759)	(25,436)
Cash flows from investing activities:		
Purchases of property and equipment	(5,015)	(7,711)
Net cash used in investing activities	(5,015)	(7,711)
Cash flows from financing activities:		
Proceeds from offering of securities, net of commissions and offering costs	—	20,728
Proceeds from issuance of securities in connection with at-the-market offering program, net of commissions and offering costs	8,840	16,266
Proceeds from exercise of Series E warrants	3,274	5,773
Proceeds from exercise of Series C warrants	94	9,091
Proceeds from registered direct offering of securities, net of commissions and offering costs	—	10,135
Proceeds from public offering of securities and exercise of pre-funded Series D warrants, net of commissions and offering costs	—	8,264
Proceeds from Paycheck Protection Program loan	—	1,610
Principal payments on financing obligations	(3,550)	(1,482)
Net cash provided by financing activities	8,658	70,385
Net (decrease) increase in cash, cash equivalents and restricted cash	(18,116)	37,238
Cash, cash equivalents and restricted cash at beginning of period	35,718	6,771
Cash, cash equivalents and restricted cash at end of period	$ 17,602	$ 44,009
Supplemental cash flow information:		
Cash paid for interest	$ 509	$ 738
Non-cash investing and financing activities:		
Forgiveness of Paycheck Protection Program loan	$ 1,629	$ —
Acquisition of property and equipment under accounts payable and other accrued liabilities	$ 914	$ 3,237
Accrued offering costs	$ —	$ 425
Asset retirement obligation	$ 89	$ 97

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

Zosano Pharma Corporation
Notes to Financial Statements
(unaudited)

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 M207 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 M207 in the Company's trials and inadequate pharmacokinetic ("PK") 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 PK 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 M207 NDA and, on February 19, 2021, the Company received the final 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 PK study to generate additional safety information which was included in the proposed study protocol submitted to the FDA for review.

On April 12, 2021, the Company received FDA comments and recommendations to the Company's proposed PK study protocol for M207. The Company made the recommended changes to the study protocol and established an agreement with a contract research organization to conduct the PK study required to support the resubmission of the M207 505(b)(2) NDA.

On October 4, 2021, the Company announced that it had received preliminary top-line results from the PK study and had been granted a Type C written response-only meeting with the FDA regarding the resubmission of the M207 NDA.

On October 25, 2021, the Company received full data tables from its PK study, which were consistent with the preliminary top-line results announced on October 4, 2021.

On October 27, 2021, the Company submitted a briefing package to the FDA in advance of the Type C written-response-only meeting previously granted by the FDA to obtain feedback on the Company's strategy for resubmitting the M207 505(b)(2) NDA.

If FDA approval is received, the Company expects that commercialization of M207 would initially occur using drug product produced in the Fremont, California facility, on a timeline yet to be determined. The Company does not anticipate realizing product revenues unless and until the FDA approves the M207 NDA and the Company begins commercializing M207, which events may never occur.

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 September 30, 2021, had an accumulated deficit of approximately $355.1 million. As of September 30, 2021, the Company had approximately $17.1 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 filing of this Quarterly Report on Form 10-Q. 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.

2021 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 July 14, 2021 ("2021 Shelf Registration Statement"). The 2021 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 $150.0 million.

2020 Shelf Registration

The Company 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"). 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 $3.7 million was available at September 30, 2021.

At-the-Market Offering Program - 2021

On June 28, 2021, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (together, the "Sales Agents") to establish an at-the-market offering program ("2021 ATM"), under which the Company may sell from time to time, at its option, up to an aggregate of $30.0 million of shares of its common stock. Shares sold under the 2021 ATM are issued pursuant to the Company's 2020 Shelf Registration Statement and a prospectus supplement dated June 28, 2021. The Company is required to pay the Sales Agents a commission of 3% of the gross proceeds from the sale of shares and has also agreed to provide the Sales Agents with customary indemnification rights. During the three and nine months ended September 30, 2021, the Company issued and sold 4,785,502 shares of its common stock at an average price of $0.76 per share under the 2021 ATM for aggregate net proceeds of $3.3 million after deducting commissions and offering expenses payable by the Company. From October 1, 2021 through November 5, 2021, the Company issued and sold 232,200 shares of its common stock at an average price of $0.67 per share under the 2021 ATM for aggregate proceeds of $0.2 million after deducting commissions. As of the date of this Quarterly Report on Form 10-Q, the Company has approximately $26.2 million available to be offered and sold under the 2021 ATM.

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 was 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 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 nine months ended September 30, 2021, the Company issued and sold 6,931,607 shares of its common stock at an average price of $0.84 per share under the 2020 ATM for aggregate net proceeds of $5.5 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. As of June 30, 2021, no shares remained available for sale under the 2020 ATM.

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. During the nine months ended September 30, 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. No Series E Warrants were exercised during the three months ended September 30, 2021. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated March 4, 2020. As of the date of this Quarterly Report on Form 10-Q, the Company has Series E Warrants to purchase 630,835 shares of common stock outstanding.

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 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. During the nine months ended September 30, 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. No Series C Warrants were exercised during the three months ended September 30, 2021. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated February 12, 2020. As of the date of this Quarterly Report on Form 10-Q, the Company has Series C Warrants to purchase 22,700 shares of common stock outstanding.

The Company intends to raise additional capital through the issuance of additional equity through public or private offerings, debt financings or strategic alliances with pharmaceutical partners, or any combination of the above. However, there can be no assurances 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. 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 its operations.

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. The Company will continue to evaluate its timelines, strategic needs and working capital requirements.

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. The pandemic did appear to negatively impact enrollment and conduct of the Company's cluster headache study. 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 Quarterly Report on Form 10-Q, 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.

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") for interim financial information, the instructions to Form 10-Q and Regulation S-X. They do not include all the information and notes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal and recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or any other subsequent period. These financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2020, included in the Company's annual report on Form 10-K and filed with the United States Securities and Exchange Commission ("SEC") on March 11, 2021. 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 and 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 or assumptions.

Significant Accounting Policies

There have been no significant changes to the Company's accounting policies during the nine months ended September 30, 2021, as compared to the significant accounting policies described in Note 2 of the "Notes to the Financial Statements" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

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 September 30, 2021 and December 31, 2020, the Company had restricted cash of approximately $0.5 million consisting primarily 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:

	September 30, 2021	September 30, 2020
	(unaudited; in thousands)	
Cash and cash equivalents	$ 17,147	$ 43,554
Restricted cash	455	455
Total	$ 17,602	$ 44,009

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.

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:

	September 30, 2021	September 30, 2020
	(unaudited; shares)	
Options to purchase common stock	4,613,658	2,673,444
RSUs	872,236	342,317
Warrants to purchase common stock	728,535	5,148,108
Total	6,214,429	8,163,869

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board issued Accounting Standards Update 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 Company adopted the guidance beginning January 1, 2021 using a prospective approach. The adoption of the guidance did not 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 M207 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 M207 NDA as well as all legal, regulatory and manufacturing responsibilities for M207. 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 M207. 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 M207 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 M207 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 M207 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. Under the original terms, either party could terminate the Eversana Agreement if FDA approval was 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 M207 is subject to a safety recall in the United States or if M207 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 M207 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.

On September 28, 2021, the Company entered into Amendment No. 1, effective as of September 29, 2021 (the "Eversana Amendment"), to the Eversana Agreement, which modified the provision in the Eversana Agreement that provided for termination by either party of the Eversana Agreement if FDA approval was not received by July 31, 2021 to December 31, 2021, with written notice within sixty days of such date. In addition, the Eversana Amendment provides that if the NDA is approved, the deferral mechanism, payment terms and loan terms in the Eversana Agreement will be adjusted as mutually agreed by both parties.

The Company is accounting for the Eversana Agreement as a collaborative arrangement. As of September 30, 2021, 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 September 30, 2021:	Total	Fair Value Measurements: Quoted prices in active market Level 1	Significant other observable inputs Level 2	Significant unobservable inputs Level 3
	(unaudited; in thousands)			
Money market funds classified as cash equivalents	$ 15,420	$ 15,420	$ —	$ —

As of December 31, 2020:	Total	Fair Value Measurements: 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	$ —	$ —

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:

	September 30, 2021	December 31, 2020
	(unaudited; in thousands)	*(in thousands)*
Prepaid insurance	$ 315	$ 66
Prepaid software and subscriptions	159	118
Prepaid services	142	97
Other receivables	115	—
Unbilled revenue	81	124
Deferred offering costs	75	48
Other	96	—
Total	$ 983	$ 453

Property and Equipment

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

	September 30, 2021	December 31, 2020
	(unaudited; in thousands)	*(in thousands)*
Leasehold improvements	$ 24,301	$ 24,212
Manufacturing equipment	15,013	14,893
Laboratory and office equipment	1,641	1,641
Computer equipment and software	181	172
Construction-in-progress	20,750	18,239
Property and equipment at cost	61,886	59,157
Less: accumulated depreciation	(29,549)	(28,248)
Total	$ 32,337	$ 30,909

Depreciation expense was approximately $0.4 million and $0.5 million for the three months ended September 30, 2021 and 2020, respectively. Depreciation expense was approximately $1.3 million and $1.0 million for the nine months ended September 30, 2021 and 2020, respectively.

Construction-in-progress ("CIP") included $16.4 million and $14.6 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 September 30, 2021 and December 31, 2020, respectively, of which capitalized construction period interest was $3.2 million and $2.4 million as of September 30, 2021 and December 31, 2020, 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:

	September 30, 2021	December 31, 2020
	(unaudited; in thousands)	*(in thousands)*
Contract manufacturing services	$ 655	$ 71
Professional service fees	575	175
Pre-clinical and clinical studies	326	22
Construction-in-progress obligations	305	2,993
Deferred revenue	47	—
Other	184	106
Total	$ 2,092	$ 3,367

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 Company also has operating leases for manufacturing space at two of its contract manufacturing organizations ("CMOs"). The operating leases are embedded in agreements with these CMOs that include lease and non-lease components.

The following table summarizes the impact of the Company's operating leases on its financial statements for each of the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited; in thousands)			
Statements of Operations and Comprehensive Loss				
Operating lease costs	$ 439	$ 422	$ 1,317	$ 1,266

	Nine Months Ended September 30,	
	2021	2020
	(Unaudited; in thousands)	
Statements of Cash Flows		
Operating cash flows from operating leases - cash paid for operating leases	$ 1,473	$ 1,388

The following table summarizes the lease terms and discount rates for the Company's leases as of September 30, 2021:

	(unaudited)
Weighted-average remaining lease term (in years)	2.89
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 September 30, 2021:

	(unaudited; in thousands)
2021	$ 502
2022	2,043
2023	2,017
2024	1,371
Total undiscounted cash flows	5,933
Less: amount representing interest	(879)
Present value of lease liabilities	$ 5,054
Current portion	$ 1,552
Long-term portion	3,502
Total	$ 5,054

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”), which was delivered in the first quarter of 2021 and is currently being installed and qualified at the Company's CMO. 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 September 30, 2021, the Company had an aggregate commercial coating and primary packaging system CIP balance of $16.4 million, that included $3.2 million 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 September 30, 2021.

The following table summarizes the debt obligations as of September 30, 2021:

Drawdown Date	Drawdown Amount	Principal Balance	Purchase Option Fee	Discount on Purchase Option Fee	Unamortized Discounts and Issuance Costs	Monthly Payment	Stated Interest Rate	Amended Effective Interest Rate	Maturity Date
			(unaudited; in thousands)						
09/25/2018	$ 5,000	$ 775	$ 600	$ (4)	$ (24)	$ 160	9.43 %	24.38 %	04/01/2022
12/11/2018	2,800	689	336	(5)	(15)	90	9.68 %	18.25 %	07/01/2022
06/06/2019	2,300	968	276	(11)	(35)	74	9.93 %	18.08 %	01/01/2023
09/13/2019	2,300	1,162	276	(15)	(51)	74	9.93 %	18.04 %	04/01/2023
11/27/2019	1,600	896	192	(13)	(45)	52	9.93 %	18.16 %	06/01/2023
Total	$ 14,000	$ 4,490	$ 1,680	$ (48)	$ (170)	$ 450			

The following table summarizes the Company's build-to-suit obligation as of September 30, 2021 *(unaudited; in thousands)*:

Build-to-suit obligation principal amount	$	4,490
Build-to-suit obligation Purchase Option Fees at present value		1,632
Less: unamortized Purchase Option Fees		(140)
unamortized warrants, discounts and issuance costs		(30)
Build-to-suit obligation, net of debt issuance costs and discount	$	5,952
Build-to-suit obligation, current portion, net of debt issuance costs and discount	$	4,528
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount		1,424
Build-to-suit obligation, net of debt issuance costs and discount	$	5,952

The following table summarizes future minimum payments on the Company's build-to-suit obligation, including payments of principal and interest and Purchase Option Fees for each year ending December 31 as of September 30, 2021:

	Principal	Interest	Purchase Option Fees	Total
	(unaudited; in thousands)			
2021	$ 1,239	$ 111	$ —	$ 1,350
2022	2,979	189	936	4,104
2023	272	8	744	1,024
Total	$ 4,490	$ 308	$ 1,680	$ 6,478

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited; in thousands)			
Build-to-suit obligation, cash interest expense	$ 140	$ 225	$ 507	$ 705
Build-to-suit obligation, effective interest expense	99	147	355	560
Less: build-to-suit obligation, interest capitalized	(223)	(217)	(735)	(746)
Build-to-suit obligation interest expense	$ 16	$ 155	$ 127	$ 519

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"). On June 10, 2021, the Company was notified by its lender, Silicon Valley Bank, that its PPP Loan, in the amount of $1,610,000 in principal and $18,515 in accrued interest, was forgiven in its entirety by the SBA. The forgiveness of the PPP Loan and accrued interest was recorded as a gain in other income (expense), net in the Company's statement of operations in the second quarter of 2021.

8. Common Stock Warrants

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

	Warrants Outstanding as of December 31, 2020	Issued	Exercised	Expired	Warrants Outstanding as of September 30, 2021	Exercise Price per Share	Expiration Date
			unaudited				
Series E - March 2020	4,709,502	—	(4,078,667)	—	630,835	$ 0.8025	03/06/25
Series C - February 2020	167,700	—	(145,000)	—	22,700	$ 0.6500	02/14/25
Trinity - September 2018	75,000	—	—	—	75,000	$ 3.5928	09/25/25
Series B - August 2016	195,906	—	—	(195,906)	—		
Total	5,148,108	—	(4,223,667)	(195,906)	728,535		

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.

9. Stock-Based Compensation

The following table summarizes activity under the Amended and Restated 2014 Equity and Incentive Plan ("2014 Plan"), the 2012 Stock Incentive Plan and inducement grants issued to new employees outside of the 2014 Plan in accordance with Nasdaq Listing Rule 5635(c)(4) for the nine months ended September 30, 2021 (unaudited):

	Number of Shares Subject to Outstanding Stock Options	Weighted-Average Exercise Price per Share	Number of RSUs Outstanding	Weighted-Average Grant Date Fair Value per Share
Outstanding at January 1, 2021	2,724,537	$ 3.31	335,004	$ 0.84
Granted	2,112,500	$ 1.17	670,250	$ 1.17
Released	—	$ —	(107,799)	$ 0.84
Canceled/forfeited/expired	(223,379)	$ 3.46	(25,219)	$ 1.04
Outstanding at September 30, 2021	4,613,658	$ 2.32	872,236	$ 1.09

On January 1, 2021, the number of shares of common stock authorized for issuance under the 2014 Plan was increased by 3,572,317 shares pursuant to the automatic annual increase provisions of the 2014 Plan. As of September 30, 2021, 1,129,087 shares of common stock were available for issuance under the 2014 Plan.

Stock-Based Compensation Expense

The following table summarizes the Company's stock compensation expense for each of the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited; in thousands)			
Research and development	$ 185	$ 177	$ 505	$ 507
General and administrative	312	262	930	657
Total	$ 497	$ 439	$ 1,435	$ 1,164

10. Commitments and Contingencies

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 M207. During the term of the agreement, the CMO will provide services related to processing, packaging, labeling and storing M207, 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 transfer of technology in 2021 and other operating expenses. 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 NDA approval of M207 in the United States.

The Company may terminate the agreements upon denial of regulatory approvals or if regulatory approvals are withdrawn under certain circumstances for the cost to remove the Company's equipment and restore the CMO's facility, which is recorded as a liability on the balance sheet. 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 $3.0 million, of which $0.6 million was a current liability on the balance sheet as of September 30, 2021.

The Company has additional agreements with CMOs to provide services related to the manufacture and assembly of component parts of M207. Under these agreements, the Company may be required to pay up to an aggregate of $7.4 million in various fees and minimum purchase requirements; however, significant portions of these payments will not be required if the FDA does not approve M207, and no such payment will be required in the event of a material breach by a CMO.

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 September 30, 2021.

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 "Class Period"). The complaints alleged 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 sought 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 "Securities Action"). The Co-Lead Plaintiffs filed their consolidated amended complaint on March 30, 2021, which alleged the same claims as the previous complaints and extended the Class Period through October 20, 2020. The Company filed a motion to dismiss the consolidated amended complaint on May 14, 2021; the Co-Lead Plaintiffs filed their opposition brief on June 14, 2021; and the Company filed a reply brief by July 6, 2021. The hearing on the motion was held on July 22, 2021 and the Court took the motion under submission. On September 1, 2021, the Court issued an order granting the Company's motion and dismissing in full the Securities Action ("Dismissal Order"), but granting the Co-Lead Plaintiffs in the Securities Action leave to file an amended complaint within 30 days. The Co-Lead Plaintiffs in the Securities Action elected not to file an amended complaint and, on October 8, 2021, the parties to the Securities Action filed a Joint Stipulation of Dismissal dismissing the Securities Action with prejudice and waiving Co-Lead Plaintiffs' right to appeal the Dismissal Order. The Joint Stipulation was approved by the Court the same day, ending the Securities Action.

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 “Derivative Action”). The complaint alleged 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 sought damages, restitution, interest, attorneys’ fees and costs, and other unspecified relief. Pursuant to stipulation of the parties, on March 24, 2021, the Court entered an order staying the Derivative Action, including all deadlines, conferences and hearings, until the final resolution of the Company's motion to dismiss in the Securities Action, including through any amendments and/or appeals. On October 18, 2021, the plaintiff elected to voluntarily dismiss the Derivative Action without prejudice, with each side bearing their own costs and fees. The dismissal was approved by the Court on October 19, 2021, ending the Derivative Action.

Although both the Securities Action and Derivative Action have ended, 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 the Company's 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.

Item 2. 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 Quarterly Report on Form 10-Q. 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 ("PK") profile compared to original dosage forms. The System consists of a 3cm2 to 6cm2 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, M207, our proprietary formulation of zolmitriptan delivered utilizing our System. We are currently in the process of identifying an alternative proprietary name for M207. 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. M207 was developed with the intent of providing faster onset of efficacy and sustained freedom from migraine symptoms. M207 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 M207 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 M207 in our trials and inadequate PK 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 PK 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 M207 NDA and, on February 19, 2021, we received the final 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 PK study to generate additional safety information which was included in the proposed study protocol submitted to the FDA for review.

On April 12, 2021, we received FDA comments and recommendations to our proposed PK study protocol for M207. We made the recommended changes to the study protocol and established an agreement with a contract research organization to conduct the PK study required to support the resubmission of the M207 505(b)(2) NDA.

On October 4, 2021, we announced that we had received preliminary top-line results from the PK study and had been granted a Type C written response-only meeting with the FDA regarding the resubmission of the M207 NDA. The study included 48 healthy volunteers and evaluated approximately 2,500 samples utilizing lots of M207 produced with two different pieces of manufacturing equipment. The study was designed to evaluate safety and the pharmacokinetics of M207 compared to a control of two 5 mg doses of intranasal zolmitriptan. The safety assessment showed that M207 was generally well tolerated, consistent with previous studies. The PK study data showed that there were no outliers with unexpected high plasma concentrations of zolmitriptan, which was a focus of the FDA as identified in the Complete Response Letter for the original M207 NDA.

The FDA had also raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of M207 in our clinical trials. The PK study data showed that drug plasma concentration levels of M207 produced on manufacturing equipment at our Fremont, California facility, which produced M207 patches for our long-term safety study, were lower compared to control and to M207 produced by alternative equipment, that was the basis for our Phase 2/3 clinical efficacy data in our original NDA submission, but within ranges consistent with approved therapeutic dose levels of zolmitriptan.

Based upon the data from our PK study and pending the receipt of Type C written responses from the FDA, which we expect to receive by mid-December, we plan to resubmit our M207 NDA with PK data primarily comparing Zomig® nasal spray and patches produced on the manufacturing equipment at our Fremont, California facility. Our long-term safety study, which used patches produced on this equipment, also collected open-label efficacy data, which we believe may provide supportive safety and efficacy evidence for M207. In contrast, our initial NDA submission relied on data and results from our published pivotal Phase 2/3 clinical efficacy study as well as data and results from our long-term safety study.

On October 25, 2021, we received full data tables from our PK study, which were consistent with the preliminary top-line results announced on October 4, 2021.

On October 27, 2021, we submitted a briefing package to the FDA in advance of the Type C written-response-only meeting previously granted by the FDA, to obtain feedback on our strategy for resubmitting the M207 505(b)(2) NDA.

If FDA approval is received, we expect that commercialization of M207 would initially occur using drug product produced in the Fremont, California facility, on a timeline yet to be determined. We do not anticipate realizing product revenues unless and until the FDA approves the M207 NDA and we begin commercializing M207, which events may never occur.

Recent Developments

On July 20, 2021, we were granted an additional patent covering method of use of M207 with the issuance of U.S. Patent No. 11,058,630 titled *Method of Rapidly Achieving Therapeutic Concentrations of Triptans for the Treatment of Migraines*. The newly issued patent covers methods for the release of active drug from our microneedle system in about one minute and reaching potentially therapeutic levels as quickly as 30 minutes upon application. This latest patent adds to our M207 patent portfolio, which now includes two U.S. patents with claims covering composition of matter and method of use for M207 with expirations in 2037.

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 M207 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 proprietary transdermal microneedle system. Due to the 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. Subjects enrolled in the Phase 2/3 trial 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. Of the subjects randomized, 23 subjects treated a cluster attack with C213 and of those who treated, 22 had post-treatment self-reported diary data. Of the treated subjects, eight received placebo, nine received 1.9 mg of C213 and five received 3.8 mg of C213. The percentage of subjects who were positive for both co-primary endpoints (pain relief at 15 minutes and pain relief at 15 minutes sustained to 60 minutes) were 37.5% placebo, 44.4% C213 1.9 mg and 100% C213 3.8 mg. There were five adverse events, all mild in intensity, reported by one placebo subject and three C213 1.9 mg subjects. The number of subjects who treated a cluster attack was not sufficient to perform pre-planned statistical comparisons.

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 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.

There have been no significant changes to our critical accounting policies which are included in Note 2. Summary of Significant Accounting Policies to the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the U.S. Securities and Exchange Commission (the "SEC") on March 11, 2021.

Financial Operations Overview

General

As of September 30, 2021, we had an accumulated deficit of approximately $355.1 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our M207 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 M207 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 do not anticipate realizing product revenues unless and until the FDA approves our M207 NDA and we begin commercializing M207, which may never occur.

We will require additional capital to undertake our planned research and development activities, pre-commercialization 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 financings, strategic alliances, 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 M207 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 M207 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 the three and nine months ended September 30, 2021, we recognized revenue on agreements with three pharmaceutical companies for such studies. Subsequent to the successful completion of all of our development responsibilities, one such agreement, with Mitsubishi Tanabe Pharma Corporation, ended in the third quarter of 2021 as Mitsubishi Tanabe Pharma Corporation determined that they would not continue with the in vivo portion of the study. We expect 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 the three and nine months ended September 30, 2021, we incurred costs related to three such studies. We 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 Institutional Review Boards, 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 facilities-related costs.

In the three and nine months ended September 30, 2021, our research and development efforts and resources focused primarily on advancing the development of M207.

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, M207, if approved.

Other income and expense

Interest income. Interest income consists primarily of interest, amortization of purchase premiums and accretion of purchase discounts, if any, 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.

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 three months ended September 30, 2021 and 2020

	Three Months Ended September 30,		Change	
	2021	2020	Amount	%
	(unaudited; in thousands, except percentages)			
Service revenue	$ 252	$ —	$ 252	N/A
Operating expenses:				
Cost of service revenue	$ 340	$ —	$ 340	N/A
Research and development	$ 5,985	$ 5,824	$ 161	3 %
General and administrative	$ 2,522	$ 2,704	$ (182)	(7)%
Other income (expense):				
Interest income	$ 1	$ 2	$ (1)	(50)%
Interest expense	$ (17)	$ (165)	$ 148	(90)%
Other income (expense), net	$ (57)	$ 4	$ (61)	*

* Not meaningful.

Service revenue

For the three months ended September 30, 2021, service revenue related to agreements with two pharmaceutical companies for feasibility studies. We expect service revenue to fluctuate based on the volume and activity of feasibility studies.

Cost of service revenue

For the three months ended September 30, 2021, cost of service revenue related to two feasibility studies. We expect cost of service revenue to fluctuate in 2021 based on the volume and activity of feasibility studies.

Research and development expenses

Research and development expenses increased approximately $0.2 million, or 3%, for the three months ended September 30, 2021, as compared to the same period in 2020. The increase was primarily due to an increase of $0.7 million in spending for clinical trials, partially offset by decreases of $0.4 million in employee and consulting costs and employee costs recorded as cost of service for work performed on our feasibility agreements, and $0.1 million in other costs.

General and administrative expenses

General and administrative expenses decreased approximately $0.2 million, or 7%, for the three months ended September 30, 2021, as compared to the same period in 2020. The change was primarily due to a decrease of $0.2 million in consulting and professional services expenses.

Other income and expense

Interest income. For the three months ended September 30, 2021 and 2020, interest income resulted primarily from interest recognized related to investments in marketable securities. The decrease for the three months ended September 30, 2021 as compared to the same period in 2020 resulted primarily from lower interest rates.

Interest expense. For the three months ended September 30, 2021 and 2020, interest expense consisted primarily of interest and amortization of debt discount. The decrease in interest expense resulted from a lower outstanding balance on our build-to-suit obligation with Trinity Funding 1, LLC (successor to Trinity Capital Fund III, L.P.) (“Trinity”) during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. For the three months ended September 30, 2021 and 2020, we capitalized a portion of interest paid to Trinity as construction-in-progress.

Other income (expense), net. Other income (expense), net consists of miscellaneous income and expenses that are not included in other categories of the statement of operations. For the three months ended September 30, 2021, other income (expense), net consisted primarily of a loss on disposal of fixed assets.

Comparison of the nine months ended September 30, 2021 and 2020

	Nine Months Ended September 30,		Change	
	2021	2020	Amount	%
	(unaudited; in thousands, except percentages)			
Service revenue	$ 698	$ —	$ 698	N/A
Operating expenses:				
Cost of service revenue	$ 704	$ —	$ 704	N/A
Research and development	$ 16,315	$ 16,270	$ 45	— %
General and administrative	$ 8,294	$ 8,552	$ (258)	(3)%
Other income (expense):				
Interest income	$ 2	$ 17	$ (15)	(88)%
Interest expense	$ (136)	$ (561)	$ 425	(76)%
Other income (expense), net	$ 1,795	$ 95	$ 1,700	*

* Not meaningful.

Service revenue

For the nine months ended September 30, 2021, service revenue related to agreements with three pharmaceutical companies for feasibility studies. We expect service revenue to fluctuate based on the volume and activity of feasibility studies.

Cost of service revenue

For the nine months ended September 30, 2021, cost of service revenue related to three feasibility studies. We 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 were substantially the same for the nine months ended September 30, 2021 and 2020. Increases of $0.8 million in clinical trial costs, $0.3 million of additional depreciation related to assets placed into service at our contract manufacturing organizations, and $0.2 million in production and manufacturing costs due to the scale up and technology transfer to our commercial manufacturing organizations, were primarily offset by a reduction of $1.3 million in employee and temporary employee costs due to lower employee and consulting costs and employee costs recorded as cost of service for work performed on our feasibility agreements.

General and administrative expenses

General and administrative expenses decreased approximately $0.3 million, or 3%, for the nine months ended September 30, 2021, as compared to the same period in 2020. The decrease was primarily due to a decrease of $0.4 million in professional service fees, offset by an increase of $0.1 million in insurance costs.

Other income and expense

Interest income. For the nine months ended September 30, 2021 and 2020, interest income resulted primarily from interest recognized related to investments in marketable securities. The decrease for the nine months ended September 30, 2021 as compared to the same period in 2020 resulted from lower interest rates.

Interest expense. For the nine months ended September 30, 2021 and 2020, interest expense consisted primarily of interest and amortization of debt discount. The decrease in interest expense resulted from a lower outstanding balance on our build-to-suit obligation with Trinity during the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. For the nine months ended September 30, 2021 and 2020, we capitalized a portion of interest paid to Trinity as construction-in-progress.

Other income (expense), net. Other income (expense), net consists of miscellaneous income and expenses that are not included in other categories of the statement of operations. For the nine months ended September 30, 2021, other income (expense), net consisted primarily of a gain on the forgiveness of our Paycheck Protection Program loan.

Liquidity and Capital Resources

Our liquidity and capital resources are summarized as follows:

	September 30, 2021	December 31, 2020
	(unaudited; in thousands)	*(in thousands)*
Cash and cash equivalents	$ 17,147	$ 35,263
Working capital*	$ 6,491	$ 21,205
Accumulated deficit	$ (355,144)	$ (332,190)

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

As of September 30, 2021, we had approximately $17.1 million in cash and cash equivalents, $6.5 million of working capital and an accumulated deficit of $355.1 million. The decrease in cash and cash equivalents and working capital as of September 30, 2021 as compared to December 31, 2020 was primarily the result of our loss from operations, investments made in property and equipment and our payments to Trinity, offset primarily by cash received from the sale of shares of our common stock through our at-the-market offering programs and warrant exercises. 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 filing of this Quarterly Report on Form 10-Q, and we will need to obtain additional capital resources through equity offerings, debt financings, 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 (the "2020 Shelf Registration Statement"). The 2020 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, of which approximately $3.7 million was available at September 30, 2021.

Additionally, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on July 14, 2021 ("2021 Shelf Registration Statement"). The 2021 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 $150.0 million.

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 M207 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 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 economic and global financial market uncertainty resulting from the COVID-19 pandemic;
- the resources we devote to marketing and commercializing our product candidates, if approved; 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

	Nine Months Ended September 30,	
	2021	2020
	(unaudited; in thousands)	
Net cash provided by (used in):		
Operating activities	$ (21,759)	$ (25,436)
Investing activities	(5,015)	(7,711)
Financing activities	8,658	70,385
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (18,116)	$ 37,238

Operating Cash Flow: Net cash used in operating activities for the nine months ended September 30 in both 2021 and 2020 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 were 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 the nine months ended September 30, 2021 of $21.8 million was primarily due to our net loss of $23.0 million, adjusted for non-cash items of $2.1 million, consisting primarily of $1.4 million of stock-based compensation, $1.3 million of depreciation and amortization and $0.9 million of change in operating lease right-of-use assets, offset by $1.6 million of a gain on forgiveness of debt. Additionally, we used cash of $1.0 million for changes in operating lease liabilities. Net cash used in operating activities for the nine months ended September 30, 2020 of $25.4 million was primarily due to our net loss of $25.3 million, adjusted for non-cash items of $3.1 million consisting primarily of $1.2 million of stock-based compensation, $1.0 million of depreciation and amortization and $0.7 million of change in operating lease right-of-use assets. Additionally, we used cash of approximately $2.2 million for changes in accounts payable and accrued compensation and other accrued liabilities and $0.8 million for changes in operating lease liabilities.

Investing Cash Flow: Net cash used in investing activities of $5.0 million and $7.7 million for the nine months ended September 30, 2021 and 2020, respectively, was the result of property and equipment purchases to support our pre-commercialization activities.

Financing Cash Flow: Net cash provided by financing activities of $8.7 million for the nine months ended September 30, 2021 was primarily due to the proceeds from the issuance of common stock under our 2020 and 2021 at-the-market offering programs of $8.8 million and from the exercise of warrants of $3.4 million. These proceeds were offset by repayments on the Trinity build-to-suit obligation of $3.6 million. See below for a further discussion of our equity activity during the first nine months of 2021. Net cash provided by financing activities for the first nine months of 2020 was primarily due to $29.0 million of net proceeds from public underwritten offerings, $16.3 million of net proceeds from ATM offerings, $14.9 million from the exercise of warrants, $10.1 million of net proceeds from a registered direct offering, and $1.6 million of proceeds from a PPP loan, offset by $1.5 million in principal payments on our build-to-suit obligation with Trinity.

2021 Issuance of Shares

At-the-Market Offering Program - 2021

On June 28, 2021, we entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (together, the "Sales Agents") to establish an at-the-market offering program ("2021 ATM"), under which we may sell from time to time, at our option, up to an aggregate of $30.0 million of shares of our common stock. Shares sold under the 2021 ATM are issued pursuant to our 2020 Shelf Registration Statement and a prospectus supplement dated June 28, 2021. We are required to pay the Sales Agents a commission of 3% of the gross proceeds from the sale of shares and have also agreed to provide the Sales Agents with customary indemnification rights. During the three and nine months ended September 30, 2021, we issued and sold 4,785,502 shares of our common stock at an average price of $0.76 per share under the 2021 ATM for aggregate net proceeds of $3.3 million after deducting commissions and offering expenses payable by us. From October 1, 2021 through November 5, 2021, we issued and sold 232,200 shares of our common stock at an average price of $0.67 per share under the 2021 ATM for aggregate proceeds of $0.2 million after deducting commissions. As of the date of this Quarterly Report on Form 10-Q, we have approximately $26.2 million available to be offered and sold under the 2021 ATM.

At-the-Market Offering Program - 2020

On June 8, 2020, we entered into a sales agreement with BTIG, LLC ("BTIG") as sales agent to establish an at-the-market offering program ("2020 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 $20.0 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 nine months ended September 30, 2021, we issued and sold 6,931,607 shares of our common stock at an average price of $0.84 per share under the 2020 ATM for aggregate net proceeds of $5.5 million after deducting commissions and offering expenses payable by us. The shares were sold pursuant to our 2020 Shelf Registration Statement and a prospectus supplement dated June 8, 2020. As of June 30, 2021, no shares remained available for sale under the 2020 ATM.

Registered Direct Offering - March 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 (the "March 2020 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. During the nine months ended September 30, 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. No Series E Warrants were exercised during the three months ended September 30, 2021. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated March 4, 2020. As of the date of this Quarterly Report on Form 10-Q, we have Series E Warrants to purchase 630,835 shares of our common stock outstanding.

Public Offering - February 2020

On February 14, 2020, we 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. 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. During the nine months ended September 30, 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. No Series C Warrants were exercised during the three months ended September 30, 2021. The shares were sold pursuant to an effective shelf registration statement and a prospectus supplement dated February 12, 2020. As of the date of this Quarterly Report on Form 10-Q, we have Series C Warrants to purchase 22,700 shares of our common stock outstanding.

Contractual Obligations

During the nine months ended September 30, 2021, there were no material changes to our contractual obligations described under Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for our fiscal year ended December 31, 2020, filed with the SEC on March 11, 2021, other than the fulfillment of existing obligations in the ordinary course of business. See Note 10. *Commitments and Contingencies* of the Notes to Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for more information regarding our contractual obligations.

Recently Issued Accounting Pronouncements

See Note 2. *Summary of Significant Accounting Policies* of the Notes to Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for a summary of Recent Accounting Pronouncements.

Off-Balance Sheet Arrangements

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

Item 3. 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 $17.1 million as of September 30, 2021, which consisted of bank deposits and money market accounts. 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 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. 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 (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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Act of 1933, as amended, is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our Chief Executive Officer and 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 Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) during the quarter ended September 30, 2021, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. 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 "Class Period"). The complaints alleged 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 sought 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 "Securities Action"). The Co-Lead Plaintiffs filed their consolidated amended complaint on March 30, 2021, which alleged the same claims as the previous complaints and extended the Class Period through October 20, 2020. We filed a motion to dismiss the consolidated amended complaint on May 14, 2021; the Co-Lead Plaintiffs filed their opposition brief on June 14, 2021; and we filed a reply brief on July 6, 2021. The hearing on the motion was held on July 22, 2021 and the court took the motion under submission. On September 1, 2021, the Court issued an order granting our motion and dismissing in full the Securities Action ("Dismissal Order"), but granting the Co-Lead Plaintiffs in the Securities Action leave to file an amended complaint within 30 days. The Co-Lead Plaintiffs in the Securities Action elected not to file an amended complaint and, on October 8, 2021, the parties to the Securities Action filed a Joint Stipulation of Dismissal dismissing the Securities Action with prejudice and waiving Co-Lead Plaintiffs' right to appeal the Dismissal Order. The Joint Stipulation was approved by the Court the same day, ending the Securities Action.

On February 9, 2021, a stockholder filed a derivative action, purportedly on behalf of Zosano Pharma Corporation (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 "Derivative Action"). The complaint alleged 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 sought damages, restitution, interest, attorneys' fees and costs, and other unspecified relief. Pursuant to stipulation of the parties, on March 24, 2021, the Court entered an order staying the Derivative Action, including all deadlines, conferences and hearings, until the final resolution of our anticipated motion to dismiss in the Securities Action, including through any amendments and/or appeals. On October 18, 2021, the plaintiff elected to voluntarily dismiss the Derivative Action without prejudice, with each side bearing their own costs and fees. The dismissal was approved by the Court on October 19, 2021, ending the Derivative Action.

Although both the Securities Action and Derivative Action have ended, 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 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 our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, including our financial statements and related notes thereto, 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.

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 September 30, 2021, we had an accumulated deficit of $355.1 million and approximately $17.1 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 filing of this Quarterly Report on Form 10-Q. 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 and our unaudited financial statements included in this Quarterly Report on Form 10-Q 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 and the nine months ended September 30, 2021, we incurred a net loss of $33.4 million and $23.0 million, respectively, and, as of September 30, 2021, we had an accumulated deficit of $355.1 million. We expect to continue to incur additional significant operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue the development of our product candidate, M207, or any other product candidates. 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 M207 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 M207, if approved; and
- the costs associated with being a public company.

Our build-to-suit arrangement with Trinity Funding 1, LLC (successor to Trinity Capital Fund III, L.P.) ("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 and we are only able to manufacture our product candidates on a limited scale at the Fremont, California site. The successful commercialization of M207 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 marketing and sales activities.

Our operations continue to be focused on pre-commercialization efforts for M207, 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 provided us with 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"), provided for loans to qualifying businesses and is administered by the U.S. Small Business Administration ("SBA"). On June 10, 2021, we received notice from our lender that our PPP Loan and accrued interest was fully forgiven by the SBA. However, 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 M207, 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 M207. 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 ("PK") 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 M207 in our clinical trials.

On October 20, 2020, we received a complete response letter ("CRL") from the FDA in response to the M207 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 M207 in our clinical trials and inadequate PK 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 PK 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 M207 NDA and, on February 19, 2021, we received the final 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 PK study to generate additional safety information which was included in the proposed study protocol submitted to the FDA for review.

On April 12, 2021, we received FDA comments and recommendations to our proposed PK study protocol for M207. We made the recommended changes to the study protocol and established an agreement with a contract research organization to conduct the PK study required to support the resubmission of the M207 505(b)(2) NDA.

On October 4, 2021, we announced that we had received preliminary top-line results from the PK study and had been granted a Type C written response-only meeting with the FDA regarding the resubmission of the M207 NDA. The study included 48 healthy volunteers and evaluated approximately 2,500 samples utilizing lots of M207 produced with two different pieces of manufacturing equipment. The study was designed to evaluate safety and the pharmacokinetics of M207 compared to a control of two 5 mg doses of intranasal zolmitriptan. The safety assessment showed that M207 was generally well tolerated, consistent with previous studies. The PK study data showed that there were no outliers with unexpected high plasma

concentrations of zolmitriptan, which was a focus of the FDA as identified in the Complete Response Letter for the original M207 NDA.

The FDA had also raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of M207 in our clinical trials. The PK study data showed that drug plasma concentration levels of M207 produced on manufacturing equipment at our Fremont, California facility, which produced M207 patches for our long-term safety study, were lower compared to control and to M207 produced by alternative equipment, that was the basis for our Phase 2/3 clinical efficacy data in our original NDA submission, but within ranges consistent with approved therapeutic dose levels of zolmitriptan.

Based upon the data from our PK study and pending the receipt of Type C written responses from the FDA, which we expect to receive by mid-December, we plan to resubmit our M207 NDA with PK data primarily comparing Zomig® nasal spray and patches produced on the manufacturing equipment at our Fremont, California facility. Our long-term safety study, which used patches produced on this equipment, also collected open-label efficacy data, which we believe may provide supportive safety and efficacy evidence for M207. In contrast, our initial NDA submission relied on data and results from our published pivotal Phase 2/3 clinical efficacy study as well as data and results from our long-term safety study.

On October 25, 2021, we received full data tables from our PK study, which were consistent with the preliminary top-line results announced on October 4, 2021.

On October 27, 2021, we submitted a briefing package to the FDA in advance of the Type C written-response-only meeting previously granted by the FDA to obtain feedback on our strategy for resubmitting the M207 505(b)(2) NDA.

We have incurred and 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 should any additional studies or other requirements be required by the FDA.

There is no guarantee that we will be able to adequately address the issues raised to the FDA's satisfaction. In addition, if the FDA does not agree with our M207 NDA resubmission strategy to submit PK data primarily comparing Zomig® nasal spray and patches produced on manufacturing equipment at our Fremont, California facility that produced patches for our long-term safety study, then the approval pathway for M207 will likely take significantly longer than expected, cost significantly more than anticipated, and may not be successful.

In addition to the above factors, the development and commercialization of M207 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 may be required to undertake additional clinical trials of M207 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 components of our products;
- we depend on CROs to conduct our clinical trials;
- we may experience delays in the commencement of, enrollment of patients in and timing of our clinical trials;
- we may not be able to demonstrate that 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 may depend on Eversana or another third party to commercialize M207, 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 Long-term Safety Study ("LTSS") for M207 is an important step in the development of M207. If the results from the study do not establish the safety of M207 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 M207 for the acute treatment of migraine. If the results do not provide sufficient evidence for the FDA to determine the safety of M207, 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 M207. Also, even though we have discussed our development strategy with the FDA on our M207 program and received feedback from the FDA about the size and the length of the safety study, the FDA may require us to provide more data than we currently anticipate before approving M207, 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. 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 an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidates, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market 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 M207. In addition, we have limited experience in preparing and submitting regulatory filings, and other than the NDA for M207, we have not previously submitted an NDA for any product candidate. Consequently, the completion of our clinical trials for M207 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 M207 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 Institutional Review Board (“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 us or 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 have 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. 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 the discontinuation of 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 M207 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 their 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 M207 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 M207 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.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. 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. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards.

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. 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, for 35 days beginning on December 22, 2018, the U.S. government shut down and certain regulatory agencies, such as the FDA, 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. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. 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 or conduct necessary site inspections, including any such inspections that may be required for the FDA to review our planned NDA submission for M207, 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 M207.

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.

M207 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.

The manufacture of our product candidates is complex, and we may encounter difficulties in manufacturing sufficient quantities of our product candidates.

Any failure or delay in our internal manufacturing operations or those of our CMOs could delay the development, regulatory approval and commercialization, if approved, of M207. 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 M207, 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 and/or the potential commercialization of M207 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.

If M207 is approved utilizing our current NDA resubmission strategy, we will only be able to produce limited quantities of M207 at our Fremont, CA location and we will not be able to produce M207 drug product on our manufacturing equipment at our third-party CMOs without FDA approval, which may require us to conduct additional clinical studies and incur significant time and cost, and we may not be successful. If we are unable to manufacture M207 on our manufacturing lines at our CMOs, it will limit our product availability and materially adversely impact our business.

Difficulties in relevant manufacturing processes and facilities implicated could result in supply shortfalls of M207, 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 M207 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, M207, and other product candidates, and to date have only manufactured our product candidates for our clinical trials. If M207 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 certain components of M207 and have entered into agreements regarding the same, we may nevertheless not be able to successfully produce, develop and market M207 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, validation and PK 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 M207 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 all components of 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 material 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 components of 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 manufacturing capacity needed to support 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 M207 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 M207 for treatment of migraine. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and product 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 manufacture, 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 manufacture, 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 M207 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 on third-party suppliers for the manufacture of certain components 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 M207 or any other product candidates we may develop.

We have contracted with CMOs to produce, in collaboration with us, commercial supplies of certain materials utilized in the manufacture of M207, if approved, in the United States. We have not entered into any agreements with any alternate suppliers for M207 product or active pharmaceutical ingredients ("APIs"). 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 potential commercialization of M207. Additionally, if M207 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 M207 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 M207, 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 M207 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) that produce materials for M207 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 to manufacture M207 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 materials for any of our product candidates, which could delay or prevent us from obtaining approval for such product candidates. Additionally, a failure by any of our CMOs to establish and follow cGMPs or to document their adherence to such requirements 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 M207 will not occur in the future. Additionally, we or 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 M207 in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand for M207 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 M207 and could have a material adverse effect on our business, results of operations, financial conditions and prospects.

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 third party CROs 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 have limited influence over their actual performance, and we 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 will 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, in August 2020, we entered into a commercialization agreement with Eversana for the commercialization of M207, 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 currently have no internal capabilities to do so, and will rely on Eversana and other third parties for the commercialization of M207 or may need to develop an internal sales organization, and we and they may not be able to effectively market, sell and distribute M207, if approved.

We currently have no internal sales, marketing or distribution capabilities. Even if M207 is approved by the FDA, we may not be able to effectively market and distribute M207. 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 M207. 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 M207. Further, there can be no assurance that the capabilities of Eversana will be effective in marketing and selling M207, or that their personnel will be more effective than an internally developed sales organization. In addition, under the amended master services agreement, 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 M207 is not received by December 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 M207 is subject to a safety recall in the United States or if M207 is not commercially launched within a specified time period after FDA approval of the NDA. Also, in connection with the amendment of the master services agreement in September 2021, we and Eversana agreed that if the NDA is approved, the deferral mechanism, payment terms and loan terms in the master services agreement will be adjusted as mutually agreed by both parties. There is no guarantee that we and Eversana will reach an agreement on the deferral mechanism, payment terms and loan terms. 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 M207 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 M207 or any other product candidate, if approved, which would materially adversely affect our business, financial condition and results of operations.

If M207 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 M207 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 M207, 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 man-made 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 online 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 M207 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 M207 or any other product candidates under Section 505(b)(2).

We intend to pursue regulatory approval for M207 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. The FDA may also find that additional studies are necessary for the Section 505(b)(2) application, which could delay when our product candidates are commercialized, potentially increasing the amount of time and expense in the development of our product candidates.

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 M207 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 General Data Protection Regulation ("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. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK

adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision.

In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act ("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, the California Privacy Rights Act ("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, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the law 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 December 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, 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 rely on key executive officers and qualified personnel and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our key executive officers and the research and development, clinical, manufacturing, financial and business development expertise of our executive officers and other employees at our Fremont, CA facility with extensive knowledge of our technology and manufacturing processes. 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. For example, if we are not able to adequately retain our officers or train and retain staff at our Fremont, CA facility, our ability to resubmit our NDA, obtain FDA approval and commercialize M207, if approved, would be impacted and our business would be materially adversely affected.

On February 1, 2020, Gregory Kitchener resigned as our chief financial officer and, on October 22, 2021, Hayley Lewis resigned as our Senior Vice President, Operations. 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 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.

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.

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 November 5, 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 were named as defendants in a securities class action lawsuit, and a related shareholder derivative lawsuit was filed; defending against any future 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: 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 "Class Period"). The complaints alleged 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 sought 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 "Securities Action"). The Co-Lead Plaintiffs filed their consolidated amended complaint on March 30, 2021, which alleged the same claims as the previous complaints and extended the Class Period through October 20, 2020. We filed a motion to dismiss the consolidated amended complaint on May 14, 2021; the Co-Lead Plaintiffs filed their opposition brief on June 14, 2021; and we filed a reply brief by July 6, 2021. The hearing on the motion was held on July 22, 2021 and the court took the motion under submission. On September 1, 2021, the Court issued an order granting our motion and dismissing in full the Securities Action ("Dismissal Order"), but granting the Co-Lead Plaintiffs in the Securities Action leave to file an amended complaint within 30 days. The Co-Lead Plaintiffs in the Securities Action elected not to file an amended complaint and, on October 8, 2021, the parties to the Securities Action filed a Joint Stipulation of Dismissal dismissing the Securities Action with prejudice and waiving Co-Lead Plaintiffs' right to appeal the Dismissal Order. The Joint Stipulation was approved by the Court the same day, ending the Securities Action.

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 "Derivative Action"). The complaint alleged 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 sought damages, restitution, interest, attorneys' fees and costs, and other unspecified relief. Pursuant to stipulation of the parties, on March 24, 2021, the court entered an order staying the Derivative Action, including all deadlines, conferences and hearings, until the final resolution of our motion to dismiss in the Securities Action, including through any amendments and/or appeals. On October 18, 2021, the plaintiff elected to voluntarily dismiss the Derivative Action without prejudice, with each side bearing their own costs and fees. The dismissal was approved by the Court on October 19, 2021, ending the Derivative Action.

Although both the Securities Action and Derivative Action have ended, 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.

In the past, we have received written notices 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 June 1, 2021, 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 have a period of 180 calendar days, or until November 29, 2021, to regain compliance with the minimum bid price requirement. If we do not regain compliance by November 29, 2021, an additional 180 days may be granted to regain compliance if we (i) meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market (except for the bid price requirement) and (ii) provide written notice to Nasdaq of our intention to cure the deficiency during the second 180-day compliance period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 calendar days. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our common stock will be subject to delisting. At that time, we may appeal Nasdaq's delisting determination to a Hearings Panel. There is no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

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

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. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party service providers and vendors may or could have access to our confidential information. Our third-party service providers have experienced such attacks and we and our third-party service providers may experience attacks in the future. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage.

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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not Applicable.

Item 5. OTHER INFORMATION

None.

Item 6. 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 Quarterly Report on Form 10-Q filed with the Commission on August 10, 2021)
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)
10.1	Amendment No. 1 to Master Services Agreement, effective as of September 29, 2021, by and between Zosano Pharma Corporations and Eversana Life Science Services, LLC (incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on October 4, 2021)
31.1*	Certification of Principal 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 Principal 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(b) and 15d-14(b) 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.

\# Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

SIGNATURES

Pursuant to the requirements 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.

Dated: November 10, 2021

Zosano Pharma Corporation
(Registrant)

/s/ Steven Lo

Steven Lo
Chief Executive Officer
(Principal Executive Officer)

/s/ Christine Matthews

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

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 Quarterly Report on Form 10-Q 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: November 10, 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 Quarterly Report on Form 10-Q 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: November 10, 2021

By: /s/ Christine Matthews
Christine Matthews
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 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: November 10, 2021

By: /s/ Steven Lo

Steven Lo
Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2021

By: /s/ Christine Matthews

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