Zosano Pharma Corp
Form 10-Q
November 15, 2018
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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, 2018

or

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

Commission File Number 001-36570

ZOSANO PHARMA CORPORATION

(Exact name of registrant as specified in its charter)

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

34790 Ardentech Court

Fremont, CA 94555

(Address of principal executive offices) (Zip Code)

(510) 745-1200

(Registrant s telephone number, including area code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

As of November 12, 2018, the registrant had a total of 11,973,039 shares of its common stock, $0.0001 par value per share, outstanding.

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Quarterly Report on Form 10-Q

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ZOSANO PHARMA CORPORATION

CONDENSED BALANCE SHEETS

(in thousands, except par value and share amounts)

	September 30, 2018 *(unaudited)*	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,962	$ 11,651
Short-term investments in marketable securities	17,514	
Prepaid expenses and other current assets	1,069	1,742
Total current assets	30,545	13,393
Restricted cash	35	35
Property and equipment, net	7,620	4,152
Other long-term assets	655	420
Total assets	$ 38,855	$ 18,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,205	$ 1,511
Accrued compensation	1,733	1,571
Secured promissory note (including accrued interest), net of issuance costs, current portion		6,687
Build-to-suit obligation, current portion	1,336	
Other accrued liabilities	1,388	688
Total current liabilities	5,662	10,457
Deferred rent	1,428	495
Build-to-suit obligation, long-term portion, net of debt discount	3,265	
Total liabilities	10,355	10,952
Commitments and contingencies (note 6)		
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; none issued and outstanding as of September 30, 2018 and December 31, 2017		
Common stock, $0.0001 par value; 250,000,000 and 100,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively; 11,973,039 and 1,973,039 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	1	
Additional paid-in capital	279,584	232,922

Accumulated deficit		(251,085)		(225,874)
Stockholders equity		28,500		7,048
Total liabilities and stockholders equity	$	38,855	$	18,000

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

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ZOSANO PHARMA CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(unaudited; in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	$	$	$	$
Operating expenses:				
Research and development	5,899	5,683	18,238	14,672
General and administrative	2,353	2,036	6,887	6,346
Total operating expenses	8,252	7,719	25,125	21,018
Loss from operations	(8,252)	(7,719)	(25,125)	(21,018)
Other income (expense):				
Interest income (expense), net	74	(154)	(99)	(608)
Other income, net	9		13	10
Loss before provision for income taxes	(8,169)	(7,873)	(25,211)	(21,616)
Provision for income taxes				
Net loss	(8,169)	(7,873)	(25,211)	(21,616)
Net loss per common share basic and diluted	$ (0.68)	$ (0.20)	$ (2.93)	$ (0.66)
Weighted-average shares used in computing net loss per common share basic and diluted	11,973	39,228	8,603	32,991

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

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ZOSANO PHARMA CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited; in thousands)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (25,211)	$ (21,616)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	614	1,902
Stock-based compensation	815	562
Gain on sale of equipment		(13)
Amortization of debt discount/accretion of premium	4	
Accretion of interest	(535)	44
Deferred rent	1,026	271
Change in operating assets and liabilities:		
Interest receivable	55	
Prepaid expenses and other assets	307	(1,325)
Accounts payable	(306)	(370)
Accrued compensation and other accrued liabilities	861	(410)
Net cash used in operating activities	(22,370)	(20,955)
Cash flows from investing activities:		
Purchases of property and equipment	(4,082)	(709)
Proceeds from sales of property and equipment		22
Purchases of marketable securities	(46,700)	(8,280)
Proceeds from maturities of marketable securities	29,255	1,720
Net cash used in investing activities	(21,527)	(7,247)
Cash flows from financing activities:		
Proceeds from public offering of securities, net of offering costs	45,604	26,623
Proceeds from exercise of warrants and issuance of common stock		4,041
Payment of loan principal	(6,316)	(4,310)
Proceeds from exercise of stock options and issuance of common stock		137
Proceeds from build-to-suit obligation	5,000	
Payment of build-to-suit obligation	(80)	
Net cash provided by financing activities	44,208	26,491
Net increase (decrease) in cash and cash equivalents	311	(1,711)
Cash, cash equivalents and restricted cash at beginning of period	11,686	15,038

Cash, cash equivalents and restricted cash at end of period	$	11,997	$	13,327
Supplemental cash flow information:				
Interest paid	$	257	$	718
Acquisition of property and equipment under accounts payable	$		$	45

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

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Zosano Pharma Corporation

Notes to Condensed Financial Statements

September 30, 2018

(unaudited)

1. Organization and Basis of Presentation

The Company

Zosano Pharma Corporation (the Company) is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM , technology. In February 2017, the Company announced positive results from its ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated M207, which is its proprietary formulation of zolmitriptan delivered via the Company s ADAM technology, as an acute treatment for migraine. The Company is focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, for markets where patients remain underserved by existing therapies. The Company anticipates that many of our current and future development programs may enable the Company to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards commercialization.

Basis of Presentation

The condensed 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 recurring accruals) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018, 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, 2017, included in the Company s annual report on Form 10-K and filed with the United States Securities and Exchange Commission (SEC) on March 12, 2018.

On January 23, 2018, the Company s stockholders approved an increase to the number of authorized shares of the Company s common stock from 100,000,000 to 250,000,000 shares. On January 23, 2018, the board of directors approved a 1-for-20 reverse stock split of our outstanding common stock, which was effected on January 25, 2018. At the effective time, every twenty shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock. The par value of the Company s stock remained unchanged at $0.0001 per share. No fractional shares of our common stock were issued in the reverse stock split, but in lieu thereof, each holder of common stock who would otherwise have been entitled to a fraction of a share in the reverse stock split received a cash payment. In addition, by reducing the number of the Company s outstanding shares, its loss per share in all prior periods increased by a factor of twenty. A proportionate adjustment was also made to the per share exercise price and the number of shares issuable upon the exercise of its outstanding equity awards, options and warrants to purchase shares of its common stock and to the number of shares reserved for issuance pursuant to its equity incentive compensation plans. The reverse stock split affected all stockholders uniformly. As a result of the reverse stock split, the number of the Company s outstanding shares of common stock as of January 25, 2018 decreased from 39,460,931

(pre-split) shares to 1,973,039 (post-split) shares. Unless otherwise noted, all share and per share information included in the financial statements have been retroactively adjusted to give effect to the reverse stock split.

Liquidity and Substantial Doubt in Going Concern

Since inception, the Company has incurred recurring operating losses and negative cash flows from operating activities, and as of September 30, 2018, had an accumulated deficit of $251.1 million. As of September 30, 2018, the Company had approximately $29.5 million in cash, cash equivalents and short-term investments. Presently, the Company does not have sufficient cash, cash equivalents and short-term investments to enable it to fund the anticipated level of operations and meet its obligations as they become due within twelve months following the date of issuance 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.

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

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In October 2017, the Company entered into a purchase agreement (the Lincoln Park Purchase Agreement) with Lincoln Park Capital, LLC (Lincoln Park). Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $35.0 million worth of shares of our common stock. Such future sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company s option, over a 30-month period that commenced on November 21, 2017. No sales of common stock have been made under the Lincoln Park Purchase Agreement as of September 30, 2018. See Note 7 to the accompanying condensed financial statements for additional information on the Lincoln Park Purchase Agreement.

In April 2018, the Company closed a public offering of 10,000,000 shares of common stock at a public offering price of $5.00 per share. The Company received gross proceeds of $50.0 million and approximately $45.6 million of net proceeds from the offering and is using the net proceeds from the offering to fund the long-term safety study of M207 and for working capital and general corporate purposes.

In September 2018, the Company entered into an build-to-suit obligation with Trinity Capital Fund III, L.P. (Trinity) that provides the Company access to funds in the aggregate principal amount of up to $14 million. The Company drew the first advance of $5 million and may draw up to an additional $9 million, at any time prior to March 30, 2020. See Note 5 for discussion of Trinity Note.

As of September 30, 2018, the Company has an outstanding equipment purchase commitment aggregating approximately $9.2 million. Commitments to other third-party manufacturers and suppliers to conduct pre-commercialization manufacturing activities totaled approximately $4.8 million, which is due in the current fiscal year, and $23.3 million, which is due thereafter. See Note 6.

Historically, the Company s major sources of cash have comprised of proceeds from various public and private offerings of our common stock, warrant exercises, and debt financings. To date, none of its product candidates have been approved by the United States Food and Drug Administration (FDA), for sale. The Company will continue to require additional financing to develop M207 and any additional product candidates that it develops. Management intends to seek capital to support the Company s initiatives through equity or debt financing, collaboration or other arrangements with corporate partners, and/or other sources of financing. Management s plans to meet its operating cash flow requirements include financing activities such as public or private offerings of its common stock, and/or preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate partners. However, if such financing is not available at adequate levels or on acceptable terms, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of or eliminate some of its development programs, out-license intellectual property rights, or a combination of the above, which may have a material adverse effect on the Company s business, results of operations, financial condition and/or its ability to meet its scheduled obligations on a timely basis, if at all.

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

2. Summary of Significant Accounting Policies

Significant Accounting Policies

There have been no material changes to the Company s significant accounting policies during the nine months ended September 30, 2018, as compared to the significant accounting policies described in Note 2 of the Notes to Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2017.

Use of Estimates

The preparation of the accompanying condensed 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 condensed financial statements, and the reported amounts of revenue and expenses during the periods reported. Actual results could differ from those estimates.

Cash and Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash to amounts shown in the statement of cash flows (in thousands):

	September 30,	
	2018	**2017**
Cash and cash equivalents	$ 11,962	$ 13,292
Restricted cash	35	35
	$ 11,997	$ 13,327

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Cash and Cash Equivalents

All highly liquid investments with maturities of three months or less at the date of purchase are classified as cash equivalents.

Restricted Cash

The Company s restricted cash consists of funds set aside by a contractual pledge and security agreement with a bank whereby $35,000 is held as a security for corporate purchasing cards.

Marketable Securities

The Company classifies its investments in marketable securities as available-for sale. Investments with original maturities between three and twelve (12) months are considered short-term investments. Investments with original maturities greater than 12 months are considered long-term investments. The Company s investments that are classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses are recorded in earnings. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

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, accounts receivable, and accounts payable, approximate fair value due to their relatively short maturities. The carrying value of the Company s short-term notes payable approximates their fair value as the terms of the borrowing are consistent with current market rates and the duration to maturity is short.

Revenue

Effective January 1, 2018, the Company adopted Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers. In accordance with ASC Topic 606, the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive

in exchange for those goods and services. To determine revenue recognition for arrangements that the Company deems are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) calculate transfer price; (iv) allocate the transaction price to the performance obligation in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Research and Development Expenses

Research and development costs are charged to expense as incurred and consist of costs related to (i) furthering the Company s research and development efforts, and (ii) designing and manufacturing products that incorporate the Company s ADAM technology for the Company s clinical and nonclinical studies.

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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 common stock equivalents. Diluted earnings per common share is computed by giving effect to all potentially dilutive common stock equivalents outstanding for the period. For purposes of this calculation, warrants and options to purchase common stock are considered potentially dilutive common stock equivalents. For the nine months ended September 30, 2018 and 2017, diluted net loss per common share was the same as basic net loss per common share since the effect of inclusion of potentially dilutive common stock equivalents would have an antidilutive effect due to the loss reported. 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,	
	2018	**2017**
Warrants to purchase common stock	274,524	199,524
Options to purchase common stock	1,189,317	90,358
	1,463,841	289,882

Recent Accounting Pronouncements

In August 2018, the U.S Securities and Exchange Commission, (the SEC), adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification* , amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance for each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company plans to apply the new guidance to its condensed financial statements during the first quarter of 2019.

In August 2018, the FASB issued ASU 2018-15, *Intangible Goodwill and Other Internal-Use Software (Subtopic 350-40)*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating ASU 2018-15 to determine the impact to its condensed financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*. The new guidance modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating ASU 2018-13 to determine the impact to its condensed financial statements and disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation Stock Compensation (Topic 718); Improvements to Nonemployee Share-Based Payment Accounting* which aligned certain aspects of share-based payments accounting between employees and non-employees. Specifically, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied and an entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. ASU No. 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity s adoption date of Topic 606. The Company is currently evaluating ASU 2018-07 to determine the impact to its condensed financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815), (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*, which allows for the exclusion of a down round feature, when evaluating whether or not an instrument or embedded feature requires derivative classification. ASU No. 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2017-11 to determine the impact to its condensed financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* This new guidance is intended to present credit losses on available for sale debt securities as an allowance rather than as a write-down. ASU 2016-13 is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2019, with early adoption permitted for those fiscal years beginning after December 15, 2018. Adoption of ASU 2016-13 is not expected to have a significant impact in the Company s financial statements and disclosures.

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In February 2016, the FASB issued authoritative guidance under ASU 2016-02, *Leases* (Topic 842). ASU 2016-02 requires lessees to recognize lease assets and lease liabilities on the balance sheet and requires expanded disclosures about leasing arrangements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 and interim periods in fiscal years beginning after December 15, 2018, with early adoption permitted. While the Company continues to evaluate the effect of adoption on its financial statements, the Company expects the adoption will result in the recognition of right-of-use assets and lease liabilities that were not previously recognized, which will increase total assets and liabilities on the balance sheet.

3. Cash, Cash Equivalents and Investments in Marketable Securities

As September 30, 2018 and December 31, 2017, cash, cash equivalent, and investments in marketable securities, comprised of funds in depository, money market accounts, U.S. treasury securities, commercial paper, and corporate bonds. The Company classifies all highly liquid investments with maturities of three months or less at the date of purchase as cash equivalents. The following table presents cash equivalents and investments carried at fair value as of September 30, 2018 and December 31, 2017 in accordance with the fair value hierarchy defined in Note 2.

		Fair Value Measurements		
		Quoted prices in active market Level I	Significant other observable inputs Level II	Significant unobservable inputs Level III
		(unaudited; in thousands)		
As of September 30, 2018:				
Cash and restricted cash	$ 3,238			
	Total			
Money market funds, included in cash equivalents	8,759	8,759		
Commercial paper	3,237		3,237	
Corporate notes and bonds	6,491		6,491	
U.S. treasuries	7,786	7,786		
Total	$ 26,273	$ 16,545	$ 9,728	$

		Quoted prices in active market Level I	Significant other observable inputs Level II	Significant unobservable inputs Level III
As of December 31, 2017:				
Cash and restricted cash	$ 4,587			
	Total			

Money market funds, included in cash equivalents	6,414	6,414	
U.S. government agencies, included in cash equivalents	650		650
Total	$ 7,064	$ 6,414	$ 650

	September 30, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(unaudited; in thousands)			
Commercial paper	$ 3,237	$	$	$ 3,237
Corporate notes and bonds	6,494		(3)	6,491
U.S. Treasuries	7,787		(1)	7,786
	$ 17,518	$	$ (4)	$ 17,514

	December 31, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
U.S. government agency bonds	$ 650	$	$	$ 650
	$ 650	$	$	$ 650

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4. Property and Equipment

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

	September 30, 2018 *(unaudited; in thousands)*	December 31, 2017 *(in thousands)*
Laboratory and office equipment	$ 1,379	$ 1,159
Manufacturing equipment	10,423	10,387
Computer equipment and software	223	209
Leasehold improvements	16,460	15,660
Construction in progress	5,312	2,351
	33,797	29,766
Less: accumulated depreciation	(26,177)	(25,614)
	$ 7,620	$ 4,152

Depreciation and amortization expense was approximately $0.2 million and $0.6 million for the three months ended September 30, 2018 and 2017, respectively. Depreciation and amortization expense was $0.6 million and $1.9 million for the nine months ended September 30, 2018 and 2017, respectively.

5. Debt Financing

Build-to-Suit Obligation with Trinity

In September 2018, the Company entered into a build-to-suit arrangement with, Trinity Capital Fund III, L.P., (Trinity) with a maximum funding from Trinity of $14 million. The Company is considered the deemed owner of the asset under construction, and as a result, the Company recorded the cost of the asset under construction as construction in progress which is included as a component of Property and Equipment and a corresponding payable to Trinity on the accompanying unaudited condensed balance sheet for the amount of approximately $2 million as of September 30, 2018. Upon completion of construction, the Company will apply sale-and-leaseback accounting to determine whether it can derecognize the project.

As of September 30, 2018, the Company had taken a single drawdown of $5 million on the build-to-suit arrangement, of which approximately $2 million was incurred for the cost of asset under construction and approximately $2 million to pay off an existing loan with Hercules loan (see below). Each drawdown is accounted for as a separate funding under the build-to-suit arrangement, with each drawdown having a term of thirty-six months. In September 2018, the Company paid interim rent of $80,000 and a security deposit of $160,000. Under the terms of the master lease agreement, the Company will pay subsequent monthly rent payments of $160,000 starting October 2018.

Additional drawdowns, up to an additional $9 million, can be drawn at the Company s option at any time, subject to Trinity s approval, until expiration of the build-to-suit arrangement on March 30, 2020. Upon expiration of the build-to-suit arrangement in March 2020, title to the manufacturing equipment system will transfer to Trinity Capital. The Company has the option, as of the end of the thirty-six month term of the Company s final drawdown (which could be up to 36 months after March 30, 2020 if the final drawdown is taken on March 30, 2020), to (i) extend the lease term for an additional three months, with the option to purchase the equipment at 4% of equipment cost

following the end of such extended term, or (ii) purchase the equipment at 12% of equipment cost. It is the Company s intention to exercise one of the aforementioned options in order to take title to the equipment.

Upon expiration of the agreement on March 30, 2020, the Company must pay Trinity a non-utilization fee equal to 3% of any unused portion of the $14 million. The Company has granted Trinity first priority liens and security interests in substantially all of the Company s assets as collateral.

In connection with the build-to-suit arrangement, the Company issued a warrant (Trinity Warrant) for a total of 75,000 shares of common stock at an exercise price of $3.5928 per share. The Trinity Warrant will expire on September 25, 2025. Proceeds allocated to the Trinity Warrant based on its relative fair value approximated $244,000 was recorded as a discount and will amortize over 36 months. There has been no amortization expense recorded for the period ending September 30, 2018 on the build-to-suit arrangement. In addition, the Company incurred debt issuance costs of $75,400 in connection with the build-to-suit arrangement with Trinity. These deferred financing fees are being amortized as interest expense using the effective interest method.

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Senior Secured Term Loan with Hercules

In June 2014, the Company entered into a loan and security agreement with Hercules Capital Inc. (Hercules). Hercules provided the Company a $15 million loan (Hercules Term Loan) of which equal installment payments of principal and interest were due monthly, with the schedule maturity date of December 1, 2018. The Hercules Term Loan bore interest at a variable rate equal to the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. The interest rate on the Hercules Term Loan was 7.95% as of December 31, 2017. On June 1, 2017, the Company paid a $100,000 legacy end of term charge. On September 25, 2018, the Company paid all its outstanding obligations under the Hercules Term Loan, including an end of term charge of $351,135.

For the three and nine months ended September 30, 2018, the Company recorded total interest expense of $0.1 million and $0.3 million, respectively. For the three and nine months ended September 30, 2017, the Company recorded interest expense of $0.2 million and $0.7 million, respectively, related to the Hercules Term Loan. The outstanding obligation under the Hercules Term Loan was paid in full in September 2018.

6. Commitments and Contingencies

Litigation

The Company is not party to any material pending legal proceedings. However, the Company may from time to time become involved in litigation relating to claims arising in the ordinary course of business.

Operating lease

The Company has an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings and related party, for its office, research and development, and manufacturing facilities in Fremont, California. On June 6, 2017, the Company entered into the seventh amendment to the existing lease (Seventh Amendment), effective as of May 30, 2017. The Company entered into the eighth amendment to the existing lease (Eight Amendment), effective as of May 30, 2018.

Under the Seventh Amendment, the Company extended the term of the lease for the Company s headquarters in Fremont, California through August 31, 2024, with an option to further extend the lease for an additional 65 months, subject to certain terms and conditions. The Company has agreed to pay a monthly base rent of $136,191 for the period commencing September 1, 2017, and ending on August 31, 2018, with an increase on September 1, 2018, and annual increases on September 1 of each subsequent year until the lease year beginning September 1, 2023. The Seventh Amendment also provides for rent abatements, subject to certain conditions, totaling $275,552 and certain tenant improvements to be completed at the Landlord s expense (not to exceed $975,000 or, under certain conditions, $1,100,000). The Company will incur additional expense of approximately $0.4 million under the lease in connection with roof repairs that will be treated as additional rent and paid over the term of the lease.

The Eighth Amendment extended the deadline for the Company to cause certain tenant improvements to be completed at the landlord s expense from May 30, 2018 to September 30, 2018. No change to the financial statements resulted from the terms of the Eighth Amendment. For the three and nine months ended September 30, 2018, the Company recorded rental expense under the related party operating lease of $0.4 million and $1.2 million, respectively. For the three and nine months ended September 30, 2017, the Company recorded rental expense under the related party operating lease of $0.4 million and $0.8 million, respectively.

As of September 30, 2018, future minimum payments under the Company s non-cancelable related party operating lease for each year ending December 31 are as follows:

		Total *(unaudited; in thousands)*
Remaining of 2018	$	434
2019		1,754
2020		1,807
2021		1,861
2022		1,914
2023 and thereafter		3,310
	$	11,080

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Severance obligations

The Company has entered into employment agreements with some of its executive officers. Generally, the terms of these agreements provide that, if the Company terminates the officer other than for cause, death, or disability, or if the officer terminates his or her employment with the Company for good cause, the officer shall be entitled to receive certain severance compensation and benefits as described in each such agreement.

On May 15, 2018, Georgia Erbez resigned as Chief Business Officer and Chief Financial Officer. Pursuant to the terms of a Separation Agreement entered into May 10, 2018, the Company agreed to pay severance totaling approximately $201,000, including base salary and benefit continuation coverage, for the six months following the separation date. Accordingly, as of September 30, 2018, the Company has approximately $55,000 of remaining severance related to this arrangement accrued and unpaid. In addition, 25% of the unvested portion of Ms. Erbez equity awards at the time of her resignation were accelerated. Her vested options remain exercisable for a period of eighteen months following her resignation.

On May 8, 2017, Konstantinos Alataris resigned as President and Chief Executive Officer. Pursuant to the terms of a Separation Agreement, the Company agreed to pay severance totaling approximately $252,000, including base salary and benefit continuation coverage, for six months following the separation date. As of September 30, 2018, the Company had no severance due to Dr. Alataris related to his separation agreement.

Equipment Purchase Commitment

In May 2018, the Company entered into a Purchase Order with Harro Hofliger Packaging Systems to purchase a commercial coating and primary packaging machine for the production of its product candidate, M207, for an aggregate purchase price of $12.2 million. The terms of the purchase commitment are contingent upon performance of certain milestones. The Company anticipates that the obligation will be paid over an eighteen-month period. As of September 30, 2018, the Company had made payments totaling $3.0 million which were recorded in construction-in-progress and the total remaining obligation on the equipment purchase commitment was $9.2 million.

Manufacturing and Supply Agreement with Patheon.

In September 2018, the Company entered into a manufacturing and supply agreement with Patheon Manufacturing Services LLC (Patheon), for Patheon to provide services related to the manufacture and commercialization of M207. During the term of the agreement, Patheon will provide manufacturing services to the Company for the manufacturing of M207, including, services related to processing, packaging, labelling and storing of M207, in addition to other services such as stability testing, quality control and assurance and waste disposal.

The Company is required to pay for commercial supply by Patheon in annual base fees in equal monthly installments in the amounts specified in the agreement. In addition, we are required to pay an additional product fee for units in excess of the number of units covered by the base fee at the price per unit provided for in the agreement. The agreement contains negotiated representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the agreement continues until the seventh anniversary of the date on which we receive NDA approval of M207 in the United States.

The Company may terminate the agreement if M207 is not granted certain regulatory approvals or if such regulatory approval is withdrawn under certain circumstances. The Company or Patheon may terminate the agreement for the other s uncured material breach, uncured force majeure or bankruptcy or insolvency-related events.

Other Commitments

As of September 30, 2018, the Company had $4.8 million of noncancelable purchase commitments due within the current fiscal year and $23.3 million due thereafter, primarily related with third party manufacturers.

7. Stockholders Equity

On January 24, 2018, the Company amended its certificate of incorporation to increase the number of shares of common stock authorized for issuance from 100,000,000 to 250,000,000. On January 25, 2018, the Company effected a 1-for-20 reverse stock split of its outstanding common stock.

Equity Line of Credit

On October 20, 2017, the Company entered into a purchase agreement and a registration rights agreement with an accredited investor, Lincoln Park, providing for the purchase of up to $35.0 million worth of the Company s common stock over the term of the purchase agreement (the Equity Line of Credit).

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Under the terms and subject to the conditions of the Equity Line of Credit, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $35.0 million worth of shares of the Company s common stock. The Company s board of directors reserved 392,104 shares for issuance pursuant to the Equity Line of Credit (inclusive of commitment shares). On October 20, 2017, the Company issued 11,375 shares of its common stock, as initial commitment shares, to Lincoln Park with a fair value of $15.30 per share which was recorded as deferred financing costs and is included within other current assets in the accompanying balance sheet as of September 30, 2018. The deferred financing costs are amortized as interest expense using the effective interest rate method over the term of the Equity Line of Credit as there is no guaranty that additional shares will be sold under the Equity Line of Credit. Additionally, the Company will issue, pro rata, up to an additional 11,375 shares of its common stock as additional commitment shares to Lincoln Park in connection with any additional purchases. Such future sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company s option, over the 30-month period that commenced on November 21, 2017, the date that the registration statement was declared effective by the SEC, and the other conditions of the Equity Line of Credit were satisfied. No sales of common stock have been made under the Lincoln Park purchase agreement as of September 30, 2018.

Public Offering March 2017

On March 22, 2017, the Company completed a registered public offering of 977,500 shares of common stock at a price of $30.00 per share, which included the exercise in full by the underwriters of their over-allotment option to purchase up to 127,500 additional shares of common stock. The total proceeds from the offering were $26.6 million, net of underwriters discounts and commissions and offering expenses.

Public Offering April 2018

On April 3, 2018, the Company closed a public offering of 10,000,000 shares of common stock at a public offering price of $5.00 per share. The Company received gross proceeds of $50.0 million and approximately $45.6 million of net proceeds from this offering. The offering was made by the Company pursuant to a registration statement on Form S-1 previously filed with the SEC on December 22, 2017, as amended and declared effective by the SEC on March 28, 2018.

Warrants

Below is a table summarizing the warrants issued and outstanding as of December 31, 2017 and September 30, 2018:

	Warrants Outstanding as of As of December 31, 2017	Warrants Issued	Warrants Exercised	Warrants Expired	Warrants Outstanding As of September 30, 2018	Exercise Price	Expiration Date
PIPE Financing - Series B	195,906				195,906	$ 31.00	8/19/2021
Hercules - June 2014	1,583				1,583	$ 176.80	1/27/2020
Hercules - June 2015	2,035				2,035	$ 147.40	6/23/2020
Trinity - September 2018		75,000			75,000	$ 3.59	9/25/2025
Total	199,524	75,000			274,524		

As of September 30, 2018, the Company had warrants outstanding to purchase 274,524 shares of common stock classified as equity warrants. 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.

8. Stock-Based Compensation

The Amended and Restated 2014 Equity and Incentive Plan

The Amended and Restated 2014 Equity and Incentive Plan (the 2014 Plan) provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company s common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of September 30, 2018, the Company had reserved 1,348,173 shares of its common stock for issuance under its 2014 Plan, subject to automatic annual increases as set forth in the plan. Options and awards under the 2014 Plan may be granted for periods of up to ten years. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions and the right of repurchase by the Company on unvested shares as determined by its board of directors. As of September 30, 2018, the Company had 176,476 shares available for grant under the 2014 Plan. During the nine month period ended September 30, 2018, the Company granted stock options to purchase 131,000 shares of common stock to non-employee directors.

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The following table summarizes option and award activity, excluding inducement grants, for the nine months ended September 30, 2018 (unaudited):

	Shares Available for Grant	Outstanding Number of Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2017	29,571	99,029	$ 25.33		
Additional shares reserved	1,225,223		$		
Options granted	(1,089,450)	1,089,450	$ 4.28		
Options cancelled/forfeited/expired	12,999	(12,999)	$ 13.40		
Shares expired under 2012 Plan	(1,867)		$		
Balance at September 30, 2018	176,476	1,175,480	$ 5.95	9.42	$ 1,170
Exercisable at September 30, 2018		154,081	$ 12.57	8.90	$
Vested or expected to vest at September 30, 2018		1,076,786	$ 6.07	9.41	$ 1,027

The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company s common stock for in-the-money options at September 30, 2018.

Inducement Grants

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

	Outstanding Number of Shares	Weighted-Average Exercise Price per Share	Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2017	19,350	$ 19.12		
Options granted		$		
Options cancelled/forfeited/expired	(5,513)	$ 15.40		
Balance at September 30, 2018	13,837	$ 20.60	4.77	$
Exercisable at September 30, 2018	9,586	$ 18.14	3.07	$

Vested or expected to vest at September 30, 2018	13,499	$	20.46	4.68	$

The following summarizes the composition of stock options outstanding and exercisable within the approved stock options plans, which excludes inducement grants, as of September 30, 2018:

	Options Outstanding			Options Exercisable	
Exercise Price	**Number of Shares**	**Weighted-Average Remaining Contractual Life (in years)**	**Weighted Average Exercise Price**	**Number of Shares**	**Weighted Average Exercise Price**
$3.97 - $3.97	9,750	9.93	$ 3.97		$
$4.24 - $4.24	939,533	9.53	$ 4.24	98,364	$ 4.24
$4.27 - $181.00	224,647	8.95	$ 11.94	54,423	$ 23.52
$182.60 - $182.60	150	6.57	$ 182.60	128	$ 182.60
$185.80 - $185.80	1,400	6.64	$ 185.80	1,166	$ 185.80

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Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(unaudited; in thousands)		*(unaudited; in thousands)*	
Research and development	$ 160	$ 61	$ 369	$ 198
General and administrative	186	85	446	364
	$ 346	$ 146	$ 815	$ 562

As of September 30, 2018, the Company had $3.5 million of total unrecognized stock-based compensation, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 3.5 years.

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

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2018	2017	2018	2017
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	2.80%	1.94%	2.74% - 3.00%	1.90% - 2.13%
Expected volatility	89%	89%	89%	89%
Expected term (years)	6.08	6.08	6.08	6.08

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our

Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission, or SEC, on March 12, 2018, as amended. This discussion contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such forward looking statements involve risks and uncertainties. We use words such as may, continue, goal, would, could, might, project, anticipate, intend, forecast, designated, approximate, will, expect, anticipate, estimate, intend, plan, predict, potential, believe, should or negatives of these words and similar expressions and references to future periods to identify forward-looking statements. Although we believe the expectations reflected in these forward- looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. These statements appearing throughout this Quarterly Report on Form 10-Q are statements regarding our intent, belief, or current expectations, primarily regarding our operations. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, such as those set forth under Risk Factors under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

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Overview

We are a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM , technology. In February 2017, we announced positive results from our ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, for 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 commercialization.

ADAM is our proprietary, investigational technology platform designed to offer rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. ADAM consists of an array of drug-coated titanium microprojections mounted on an adhesive backing that is pressed on to the skin using a reusable handheld applicator. The microprojections penetrate the stratum corneum, the outermost layer of skin of the epidermis, and allow the drug to be absorbed into very small blood vessels, microcapillaries, that connect to the larger blood vessels that transport the drug to the systemic circulation. We focus on developing products based on our ADAM technology for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, for markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, M207. M207 is our proprietary formulation of zolmitriptan delivered utilizing our ADAM technology. Zolmitriptan is one of a class of serotonin receptor agonists known as triptans and is used as an acute treatment for migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. The objective of M207 is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding the gastrointestinal tract. The United States Food and Drug Administration, or FDA, has indicated that one positive pivotal efficacy study, in addition to the required safety study, would be sufficient for approval of M207 for the treatment of migraine.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the FDA or equivalent foreign regulatory bodies, to market and sell M207, or any other product candidate that we develop. Accordingly, our success depends not only on the development, but also on our ability to finance the development of M207, or any other product candidate that we develop. We will require substantial additional funding to complete development and seek regulatory approval for M207, or any other product candidate that we develop. Additionally, we currently have no sales, marketing or distribution capabilities and thus our ability to market our products in the future will depend in part on our ability to develop such capabilities either alone or with collaboration partners.

M207 Long-Term Safety Study

In November 2017, we announced the initiation of our long-term safety study for M207 as an acute treatment for migraine, with the enrollment of the first subject in the study. M207-ADAM is an open label study evaluating the safety of the 3.8 mg dose of zolmitriptan in migraine subjects who have historically experienced at least two migraines per month. Subjects are expected to treat a minimum of two migraines per month on average, with no maximum treatment limits. The study will evaluate at least 150 subjects for six months, and 50 subjects for a year at 31 sites in the U.S. The study is open-label, with investigator visits at months one, two, three, six, nine and twelve. The primary objective of our long-term safety study is to assess the safety of M207 during repeated use over six and twelve

months. Other endpoints are electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response.

In October 2018, we announced that, of the 344 subjects enrolled, more than 150 evaluable subjects have completed their six month visit in the M207-ADAM study. This marked the completion of the first major goal of this study, a defined data set per the protocol in which 150 subjects must treat on average at least two migraines per month for six months and 50 subjects must treat at least two migraines per month for one year. Study subjects have treated more than 4,000 migraines since study initiation. We expect clinical completion by March 2019, when at least 50 of these subjects will complete one year in the study and have treated at least two migraines per month.

As of the date of this filing, we completed the manufacturing of our registration batches in support of the New Drug Application (NDA) for M207.

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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 condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of our financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. Our management believes judgment is involved in determining revenue recognition, the fair value-based measurement of stock-based compensation, and accruals. Our management evaluates estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the financial statements. If our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our results of operations, liquidity and financial condition.

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

There have been no significant and material changes in our critical accounting policies and use of estimates during the nine months ended September 30, 2018, as compared to those disclosed in Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC.

Financial Operations Overview

As of September 30, 2018, we had an accumulated deficit of $251.1 million. We have incurred significant losses and expect to incur significant losses in the foreseeable future as we advance M207 into later stages of development, and if approved, commercialization. On April 3, 2018, the Company closed a public offering of 10,000,000 shares of common stock at a public offering price of $5.00 per share. The net proceeds of the offering were approximately $45.6 million. We are using the net proceeds from this offering to advance the long-term safety study of M207 and for working capital and general corporate purposes.

We expect our research and development expenses to increase significantly as we continue to advance M207 through clinical development. Because of the numerous risks and uncertainties associated with our technology and drug development, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve commercialization, revenue or profitability.

Research and development expenses

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

Research and development expenses consist of:

production costs which include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation expense, and fees paid to conduct nonclinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;

expenses related to the purchase of active pharmaceutical ingredients and raw materials for the production of product candidates based on our ADAM technology, including fees paid to contract manufacturing organizations (CMOs);

fees paid to contract research organizations (CROs), clinical consultants, clinical trial sites and vendors, including institutional review boards (IRBs), in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, subject screening fees, laboratory work and statistical compilation and analysis;

fees paid to conduct clinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;

other consulting fees paid to third parties; and

allocation of certain shared costs, such as facilities-related costs and information technology (IT) support services.

For the immediate future, our research and development efforts and resources will be focused primarily on advancing our product candidate M207 through clinical development.

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We cannot forecast with any degree of certainty if any of our product candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development.

Other income and expenses

Interest expense, net. Interest expense, net of interest income, consists primarily of interest costs related to our debt and the amortization of debt discount and issuance costs. Interest expense for the nine months ended September 30, 2018 reflects accrued and paid interest related to our secured term loan facility (Hercules Term Loan) with Hercules Capital, Inc. (Hercules), and the related amortization of debt discount and issuance costs.

Other income, net. Other income, net of other expense, consists of certain miscellaneous income or expenses that are not included in other categories of the condensed statements of operations. (See explanations under the subheading, Results of Operations).

Results of Operations

Comparison of the three months ended September 30, 2018 and 2017

Research and development expenses

	Three months ended September 30,		Change	
	2018	2017	Amount	%
	(In thousands)			
Research and development	$ 5,899	$ 5,683	$ 216	4%

Research and development expenses increased approximately $0.2 million, or 4%, for the three months ended September 30, 2018, as compared to the same period in 2017. The increase in research and development expense was primarily attributable to an increase in clinical trial costs of $0.7 million related to the M207 long-term safety study, offset by a decrease of $0.4 million in clinical supply costs due to completion of the registration batches.

General and administrative expenses

	Three months ended September 30,		Change	
	2018	2017	Amount	%
	(In thousands)			
General and administrative	$ 2,353	$ 2,036	$ 317	16%

General and administrative expenses increased approximately $0.3 million, or 16%, for the three months ended September 30, 2018 as compared to the same period in 2017. Increases in expenses were primarily due to increase Enterprise Resource Planning (ERP) implementation costs as well as increases in payroll and stock compensation costs.

Other income (expenses)

	Three months ended September 30,		Change	
	2018	2017	Amount	%
	(In thousands)			
Interest income (expense), net	$ 74	$ (154)	$ 228	148%
Other income (expense), net	9		9	100%

Interest expense, net increase approximately $0.2 million, or 148%, for the three months ended September 30, 2018, as compared to the same period in 2017. Interest expense is primarily attributable to the Hercules Term Loan, for which the outstanding obligation was paid in full in September 2018. The decrease in interest expense is attributable to the lower interest costs resulting from the lower loan principal balance during the three months ended September 30, 2018 as compared to the same period in 2017, offset by interest income from marketable securities.

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Comparison of the nine months ended September 30, 2018 and 2017

Research and development expenses

	Nine months ended September 30,		Change	
	2018	2017	Amount	%
	(In thousands)			
Research and development	$ 18,238	$ 14,672	$ 3,566	24%

Research and development expenses increased approximately $3.6 million, or 24%, for the nine months ended September 30, 2018, as compared to the same period in 2017. The increase in research and development expense was primarily attributable to an increase in clinical trial costs of $3.2 million related to the long-term safety study and to an additional increase $0.4 million attributed to an increase in costs related to the production of our registration batches.

General and administrative expenses

	Nine months ended September 30,		Change	
	2018	2017	Amount	%
	(In thousands)			
General and administrative	$ 6,887	$ 6,346	$ 541	9%

General and administrative expenses increased approximately $0.5 million or 9% for the nine months ended September 30, 2018 as compared to the same period in 2017. Increases in expenses were primarily due to increase in building rent and franchise taxes.

Other income (expenses)

	Nine months ended September 30,		Change	
	2018	2017	Amount	%
	(In thousands)			
Interest expense, net	$ (99)	$ (608)	$ (509)	(84%)
Other income (expense), net	13	10	3	(30%)

Interest expense, net decreased approximately $0.5 million, or 84%, for the nine months ended September 30, 2018, as compared to the same period in 2017. Interest expense is primarily attributable to the Hercules Term Loan. The decrease in interest expense is attributable to the lower interest costs resulting from the lower loan principal balance during the nine months ended September 30, 2018 as compared to the same period in 2017. The outstanding obligation under the Hercules Term Loan was paid in full in September 2018.

Other income was primarily comprised of gains from the sale of equipment during both periods presented.

Liquidity and Capital Resources

Since inception, we have incurred recurring operating losses and negative cash flows from operating activities, and as of September 30, 2018, had an accumulated deficit of $251.1 million. We expect to incur additional losses in the

future to conduct research and development of our M207 product candidate and to conduct pre-commercialization manufacturing activities. As of September 30, 2018, we had approximately $29.5 million in cash, cash equivalents, and investments. Presently, we do not believe we have sufficient cash, cash equivalents, and investments to fund our anticipated level of operations based on our current operating plans for at least the next twelve months following the date of issuance of this Quarterly Report on From 10-Q. The aforementioned factors raise substantial doubt about the Company s ability to continue as a going concern.

Our accumulated deficit, negative cash flows and insufficient cash resources raise substantial doubt regarding the Company s ability to continue as a going concern. There are no assurances that additional funding will be achieved and that we will succeed in our future operations. 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.

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In October 2017, we entered into the Lincoln Park Purchase Agreement with Lincoln Park. Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park up to $35.0 million worth of shares of our common stock. Such future sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our option, over a 30 month period that commenced on November 21, 2017. No sales of common stock have been made under the Lincoln Park Purchase Agreement as of September 30, 2018. See Note 7 to the accompanying condensed financial statements for additional information on the Lincoln Park Purchase Agreement. On April 2018, we closed a public offering of 10,000,000 shares of common stock at a public offering price of $5.00 per share. We received gross proceeds of $50.0 million and approximately $45.6 million of net proceeds from the offering and are using the net proceeds from the offering to fund the long-term safety study of M207, and for working capital and general corporate purposes. On September 2017, we entered into a build-to-suit obligation with Trinity Capital Fund III, L.P. (Trinity) that provides us access to funds in the aggregate principal amount of up to $14 million. We drew the first advance of $5 million and may draw up to an additional $9 million, at any time prior to March 30, 2020.

Historically, our major sources of cash have comprised proceeds from various public and private offerings of our common stock, warrant exercises, and debt financings. To date, we have no product candidates approved by the FDA for sale. We will continue to require additional financing to develop M207, develop additional product candidates and fund operating losses. Management intends to seek capital to support the Company s initiatives through equity or debt financing, collaboration or other arrangements with corporate partners, and/or other sources of financing. Management plans to meet its operating cash flow requirements include financing activities such as public or private offerings of its common stock, and/or preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate resources. However, if such financing is not available at adequate levels or on acceptable terms, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of or eliminate some of its development programs, out-license intellectual property rights, or a combination of the above, which may have a material adverse effect on the Company s business, results of operations, financial condition and/or its ability to meet its scheduled obligations on a timely basis, if at all.

We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including, but not limited to:

- the scope, progress, expansion, costs, and results of our clinical trials;
- the scope, progress, expansion, and costs of manufacturing our product candidates;
- the timing of and costs involved in obtaining regulatory approvals;
- the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;
- our ability to establish and maintain development partnering arrangements;

the timing, receipt and amount of contingent, royalty, and other payments from any of our future development partners;

the emergence of competing technologies and other adverse market developments;

the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

the resources we devote to marketing, and if approved, commercializing our product candidates;

our ability to draw funds from our equipment lease line of credit; and

the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

There are no assurances that such additional funding will be achieved and that we will succeed in our future operations. Adequate additional funding may not be available to us on acceptable terms or 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.

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Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (22,370)	$ (20,955)
Investing activities	(21,527)	(7,247)
Financing activities	44,208	26,491
Net increase (decrease) in cash and cash equivalents	$ 311	$ (1,711)

Operating Cash Flow: Net cash used in operating activities was approximately $22.4 million and $21.0 million for the nine months ended September 30, 2018 and 2017, respectively. Net cash used during the first nine months of 2018 was primarily due to tenant improvements for our operating lease for the Company headquarters, in addition to other research and development and administrative expenses incurred in the course of our continuing operations. Net cash used during the first nine months of 2017 was primarily due to the closing costs of the ZOTRIP trial and start-up costs for our upcoming long-term safety study, in addition to other research and development and administrative expenses incurred in the course of our continuing operations.

Investing Cash Flow: Net cash used in investing activities was approximately $21.5 million and $7.2 million for the nine months ended September 30, 2018 and 2017, respectively. Net cash used in investing activities during the first nine months of 2018 was primarily the result of the purchase of certain marketable securities. Net cash used in investing activities during the first nine months of 2017 was primarily due to the purchase of investments in marketable securities.

Financing Cash Flow: Net cash provided by financing activities was approximately $44.2 million and $26.5 million for the nine months ended September 30, 2018 and 2017, respectively. Net cash provided by financing activities for the first nine months of 2018 was primarily from $45.6 million in net proceeds from a registered public offering of common stock. Net cash generated by financing activities for the first nine months of 2017 was primarily due to proceeds from a registered public offering of $26.6 million, net of underwriter s discounts, commissions, and offering expenses and to warrant exercises to purchase 136,301 shares common stock for proceeds of $4.0 million. The increase was partially offset by payments on the Hercules Term Loan of approximately $4.3 million.

Contractual Obligations and Commitments

Operating Lease. We have an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings and related party, for its office, research and development, and manufacturing facilities in Fremont, California. The lease for our headquarters extends through August 2024. See Note 6 to the accompanying condensed financial statements for a discussion of the related party operating lease for our headquarters. As of September 30, 2018, the total noncancelable obligation was $11.1 million, which is classified within current liabilities and non-current liabilities on our condensed balance sheets.

Equipment Purchase Commitment. In May 2018, we entered into a Purchase Order with Harro Hofliger Packaging Systems to purchase a commercial coating and primary packaging machine for the production of our product candidate, M207, for an aggregate purchase price of $12.2 million. The terms of the purchase commitment are contingent upon performance of certain milestones. We anticipate that the obligation will be paid over an eighteen-month period. As of September 30, 2018, we had made payments totaling $3.0 million which were recorded in construction-in-progress and the total remaining obligation on the equipment purchase commitment was $9.2 million.

Build-to-Suit Obligation. In September 2018, we entered into a build-to-suit Obligation with Trinity. Under the Lease Agreement, Trinity agreed to provide us with access to an equipment lease in an aggregate principal amount of up to $14.0 million. We are obligated to make monthly rent payments based on a monthly rate factor of 0.0320 for a term of thirty-six months on the principal amount drawn. As of September 30, 2018, we had an outstanding obligation of $5.0 million on the equipment.

Manufacturing and Supply Agreement with Patheon. In September 2018, we entered into a manufacturing and supply agreement with Patheon Manufacturing Services LLC (Patheon), for Patheon to provide services related to the manufacture and commercialization of M207. During the term of the agreement, Patheon will provide manufacturing services to us for the manufacturing of M207, including, services related to processing, packaging, labelling and storing of M207, in addition to other services such as stability testing, quality control and assurance and waste disposal.

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We are required to pay for commercial supply by Patheon in annual base fees in equal monthly installments in the amounts specified in the agreement. In addition, we are required to pay an additional product fee for units in excess of the number of units covered by the base fee at the price per unit provided for in the agreement. The agreement contains negotiated representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the agreement continues until the seventh anniversary of the date on which we receive NDA approval of M207 in the United States.

We may terminate the agreement if M207 is not granted certain regulatory approvals or if such regulatory approval is withdrawn under certain circumstances. We or Patheon may terminate the agreement for the other s uncured material breach, uncured force majeure or bankruptcy or insolvency-related events.

Other Commitments. As of September 30, 2018, we had $4.8 million of noncancelable purchase commitments due in 2018 and $23.3 million due thereafter, primarily related with third party manufacturers.

Recent Accounting Pronouncements

See Note 2 to the accompanying condensed financial statements for the Recent Accounting Pronouncements.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities or 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 short-term marketable securities. We had cash and cash equivalents of $12.0 million as of September 30, 2018, which consisted of bank deposits and money market funds. We had short-term investment in marketable securities of $17.5 million as of September 30, 2018, which consisted primarily of commercial paper, corporate notes and bonds, and U.S. treasuries. 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. In addition, the monthly rent factor on the equipment lease is determined and indexed to the Prime Lending Rate as reported in the Wall Street Journal. 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, 2018. The term disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, 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.

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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

During the quarter ended September 30, 2018, we completed the implementation of several significant Enterprise Resource Planning System (ERP), modules including core financial and purchasing modules. In connection with the implementation of the ERP system, we updated the processes that constitute our internal control over financial reporting to accommodate changes to our business processes and accounting procedures.

Except as otherwise described above, there have been no other 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, 2018, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 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 for the year ended December 31, 2017 and other documents that we file with the U.S. Securities and Exchange Commission, or the SEC. Any of the following risks could have a material adverse effect on our business, operating results, financial condition and prospects and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. You should also refer to the other information contained in this Annual Report on Form 10-K, including our audited financial statements and the related notes thereto.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

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

Developing and commercializing biopharmaceutical products, including launching new products into the marketplace and conducting preclinical studies and clinical trials, is an expensive and highly uncertain process that takes years to complete. As of September 30, 2018, we had an accumulated deficit of $251.1 million as well as negative cash flows from operating activities. We will continue to require substantial funds to continue research and development, including clinical trials of our lead product candidate, M207. Presently, we do not believe we have sufficient cash, cash equivalents and investments to fund our anticipated level of operations based on our current operating plans for

at least the next twelve months following the date of issuance of this Quarterly Report on Form 10-Q. The aforementioned factors raised substantial doubt about the Company s ability to continue as a going concern. We expect to finance our cash needs through a combination of equity offerings, debt financing and license and collaboration agreements. There is no assurance that such additional funds will be obtained for our ongoing operations or that we will succeed in it future operations. Our audited financial statements included in our Annual Report for the year ended December 31, 2017 include a going concern disclosure that may discourage some third parties from contracting with us and some investors from purchasing our stock or providing alternative capital financing, which could adversely affect our business, financial condition, results of operations and prospects.

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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 period ended September 30, 2018 we incurred a net loss of $25.2 million. As of September 30, 2018, we had an accumulated deficit of $251.1 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 we develop. These expenditures will be incurred for development, clinical trials, regulatory compliance, infrastructure, and manufacturing. Even if we succeed in developing, obtaining regulatory approval for and commercializing M207 or any other product 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, costs, and results of our clinical trials;

the scope, progress, expansion, and costs of manufacturing our product candidates;

the timing of and costs involved in obtaining regulatory approvals;

the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;

our ability to establish and maintain development partnering arrangements;

the timing, receipt and amount of contingent, royalty, and other payments from any of our future development partners;

the emergence of competing technologies and other adverse market developments;

the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

the resources we devote to marketing, and if approved, commercializing our product candidates;

our ability to draw funds from our equipment lease line of credit; and

the costs associated with being a public company.

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Our equipment lease with 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 equipment lease.

We also agreed to covenants in connection with the Trinity equipment lease 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 loan facility or the secured note, as applicable, 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 equipment lease, as applicable, and possibly foreclose on the collateral, which would potentially include our intellectual property. Any such action on the part of Trinity would significantly harm our business and our ability to operate.

We have limited operating history and capabilities.

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

continuing to conduct clinical development of our product candidates;

obtaining required regulatory approvals;

formulating and manufacturing products; and

conducting sales and marketing activities.

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

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

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

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

We have focused our clinical development efforts on our product candidate, M207. The development and commercialization of 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 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;

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the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies or trials;

the FDA may not accept data generated at our clinical trial sites;

we may be unable to obtain and maintain regulatory approval of our product candidates in the United States and foreign jurisdictions;

potential side effects of our product candidates could delay or prevent commercialization, limit the indications for any approved product candidates, require the establishment of a risk evaluation and mitigation strategy, or REMS, or cause an approved product candidate to be taken off the market;

the FDA may identify deficiencies in our manufacturing processes or facilities or those of our CMOs;

the FDA may change its approval policies or adopt new regulations;

we may need to depend on third-party manufacturers to supply or manufacture our products;

we depend on contract research organizations to conduct our clinical trials;

we may experience delays in the commencement of, enrollment of patients in and timing of our clinical trials;

we may not be able to demonstrate that any of our product candidates are safe and effective as a treatment for their respective indications to the satisfaction of the United States Food and Drug Administration (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;

we may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;

we may experience competition from existing products or new products that may emerge; and

we and our licensors may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our products.

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

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

After receiving positive results from our ZOTRIP Phase 2/3 efficacy trial of M207, the next step in the regulatory approval process is to complete a long-term safety study. We initiated this study in the second half of 2017. To complete the safety study, we will need to raise additional capital to fund the manufacture of sufficient supply of M207 and to continue to enroll subjects in the study. There are no assurances that such additional capital will be available to us on terms that are favorable to us or our existing stockholders or at all. The study will also need to produce results that satisfy FDA requirements. Any failure or setback in completing any of these required steps could require us to delay, limit, reduce or terminate our development of M207. Also, even though we have discussed our development strategy with the FDA on our M207 program and received feedback from the FDA about the size and the length of the safety study, the FDA may decide to expand on the requirements that have already been provided to us, which would further delay the regulatory approval process and require additional clinical work.

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

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

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

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

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

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

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

inability or unwillingness of medical investigators to follow our clinical protocols.

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

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

be delayed in obtaining marketing approval for our product candidates;

not obtain marketing approval at all;

obtain approval for indications or patient populations that are not as broad as intended or desired;

obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

be subject to additional post-marketing testing requirements; or

have our product candidate(s) removed from the market after obtaining marketing approval.

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

The results of our clinical trials may not support the intended use of M207 or any other product candidates we may develop.

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

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

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

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

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

There is no guarantee that data from these clinical trials will be accepted by regulators approving our product candidates for commercial sale. In the case of the United States, although the FDA may accept data from clinical trials

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

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

foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;

administrative burdens of conducting clinical trials under multiple foreign regulatory schema;

foreign exchange fluctuations; and

diminished protection of intellectual property in some countries.

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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, we may still face future development and regulatory difficulties.

The manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for our product candidates will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices, or cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. The regulatory approvals for our product candidates may be subject to limitations on the indicated uses for which the products may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product candidates. The FDA closely regulates the post-approval marketing and promotion of drugs and drug delivery devices to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers communications regarding off-label use and, if we do not market our product candidates for their approved indications, we may be subject to enforcement action for off-label marketing.

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

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

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

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

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

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

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

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

We currently do not have any products approved for sale and currently are focusing our clinical development efforts solely on M207. Currently, we do not have any collaborations with any partners for any of our products.

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

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

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

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

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

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

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

M207 and any other product candidates we develop in the future may have undesirable side effects, or have characteristics that are unexpected.

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

- regulatory authorities may impose a clinical hold which could result in substantial delays and adversely impact our ability to continue development of the product candidate;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product candidate is administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product candidate;
- we may be required to limit the patients who can receive the product candidate;
- we may be subject to limitations on how we promote the product candidate;

sales of the product candidate may decrease significantly;

regulatory authorities may require us to take our approved product candidate off the market;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

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

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

While we currently manufacture M207 internally, we have entered into agreements with third party CMOs, including Patheon related to the development, manufacture, and supply of M207 as we transition to rely on such CMOs to manufacture and supply M207 on our behalf. Any failure or delay in our internal manufacturing operations or those of our CMOs, or the technology transfer process in connection with our plan to transition to rely on such CMOs for manufacture and supply, could cause us to be unable to meet the demand for product candidates for our clinical trials and delay the development or regulatory approval 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 future product candidates, are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Regulatory approval of M207 or our future product candidates could be impeded, delayed, limited or denied if the FDA does not maintain the approval of the manufacturing processes and facilities in which such product candidates are made.

Difficulties in relevant manufacturing processes and facilities implicated could result in supply shortfalls of M207 or our future product candidates, and could delay our preclinical studies, clinical trials and regulatory submissions with respect thereto. In addition, M207 (or our future product candidates) that has been produced and is 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 product candidate to no longer be suitable for its intended use in clinical trials or other development activities. If the defective product candidate 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 candidates, including M207, and to date have only manufactured our product candidates for our clinical trials. If any of our product candidates are approved, we will need to scale up our own capabilities or those of our CMOs to support the production of commercial level quantities of our product candidates, which may require expensive process improvements.

While we intend to rely on CMOs, including Patheon, to support commercial scale manufacture of M207 and have entered into agreements, including with Patheon, regarding the same, we may nevertheless not be able to successfully produce, develop and market one or more of M207 or our future product candidates, or we may be delayed in doing so. For example, we may be required to devote substantial resources to the construction or purchase of a commercial scale manufacturing facility, the purchase of manufacturing equipment and hiring additional personnel, including as currently contemplated under our agreement with Patheon with respect to M207. Significant scale up of manufacturing may also require process improvements as well as additional technologies and validation studies, which are costly, may not be successful and which the FDA must review and approve. If we 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 implement necessary process improvements, we may be unable to produce commercial materials or meet demand, if any should develop, for M207 or our future 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 product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our CMOs to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. CMOs may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If our CMOs are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects. Our reliance on 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.

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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 reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payers.

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

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

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

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

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

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

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

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

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

There can be no assurance that our supply of these various components will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers and cannot ensure that they will deliver to us the components we order on time, or at all. Any failure or refusal to supply the components for M207 or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our CMOs were to fail to fill our purchase orders, the development or commercialization of the affected product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable, the lead time needed to establish a new relationship can be lengthy, and because the expenses relating to the transfer

of necessary technology and processes could be significant. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA, the European Medicines Agency, or EMA, or any other relevant regulatory authorities.

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

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

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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 as a result of 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 good clinical practices (GCPs) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CRO fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed, or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

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

We currently depend on a single source supplier for manufacture of our product. If this manufacturer fails 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 other product candidates.

We have contracted with CMOs (including Patheon) to produce, in collaboration with us, M207, for commercial use in the United States. We have not entered into any agreements with any alternate suppliers for M207 product or API. Even if we were able to enter into other long-term agreements for manufacture of commercial supply on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of M207. Additionally, if M207 or any other future product candidates is approved by the FDA or other regulatory agencies for commercial sale or if M207 is approved for commercial sale in jurisdictions outside the United States, we will need to contract with a third party to manufacture such products for commercial sale in the United States and/or in such other jurisdictions.

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 regulatory or quality compliance issues, or other legal or reputational issues.

Even though we have an agreement with a CMO, Patheon, to supply 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 future 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.

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The manufacturer(s) of M207 are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs, and we have limited control over the ability of CMOs to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance to cGMPs. In addition, the facilities used by our CMOs to manufacture M207 must be approved by the FDA pursuant 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 the FDA s strict regulatory requirements pass regulatory inspections, they will not be able to secure or maintain approval for the manufacturing facilities. Additionally, a failure by any of our CMOs to establish and follow cGMPs or to document their adherence to such practices may negatively impact our commercialization or lead to significant delays in the launch and commercialization of any other products that we may have in the future. Failure by our CMOs or us to comply with application regulations could result sections 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, 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 commercialize of M207 and could have a material adverse effect on our business, results of operations, financial conditions and prospects.

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

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

We face significant competition in seeking appropriate collaborators. 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.

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

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In addition, any 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 candidates due to a change in business strategy, or a merger, acquisition, sale or downsizing;

- a collaboration partner may not devote sufficient resources towards, or cease development in, therapeutic areas which are the subject of our strategic collaboration;

- a collaboration partner may change the success criteria for a product candidate thereby delaying or ceasing development of such candidate;

- a collaboration partner could develop a product candidate that competes, either directly or indirectly, with our product candidate;

- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;

a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;

a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;

a dispute may arise between us and a collaboration partner concerning the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources;

a collaboration partner may use our products or technology in such a way as to invite litigation from a third party; and

a collaboration partner may exercise a contractual right to terminate a strategic alliance, making us ineligible to receive milestone or royalty payments under such agreement.

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RISKS RELATED TO MARKETING AND SALE OF OUR PRODUCTS

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

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate developing adequate sales and marketing support for any of our product candidates, if approved by the FDA. Although we may develop a targeted commercial infrastructure to market and distribute our proprietary product candidates, our future success may depend, in part, on our ability to enter into and maintain collaborative relationships to provide such capabilities, on the collaborators strategic interest in the product candidates under development and on such collaborators ability to successfully market and sell any such product candidates. There can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our product candidates, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with the needed technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our products in the United States or overseas.

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

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

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

developing drugs;

undertaking preclinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

The development and commercialization of new products to treat migraine is highly competitive. We expect to have considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies. Companies marketing products that treat migraine that may compete with our M207 product candidate include Alder Biopharmaceuticals, Allergan, Inc., AstraZeneca plc, Biohaven Pharmaceuticals, Eli Lilly & Company, GlaxoSmithKline plc, Promius Pharma, LLC, Teva Pharmaceutical Industries, Inc., and Zogenix, Inc.

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

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

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

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

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. 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. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on any product that we may commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, several states have not implemented certain sections of the ACA, including 19 that have rejected the expansion of Medicaid eligibility for low income citizens, and some members of the U.S. Congress are still working to repeal the ACA. More recently, President Trump and the Republican majorities in both houses of the U.S. Congress have been seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the individual mandate . Congress may consider other legislation to repeal or replace elements of the ACA in the future. We cannot predict what legislation, if any, to repeal or replace the ACA will become law, or what impact any such legislation may have on our product candidates. 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 one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover the product candidate. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our product candidates, once approved, market acceptance of the product could be reduced.

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

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our

product candidate. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

costs of related litigation;

substantial monetary awards to patients or other claimants;

decreased demand for an approved product and loss of revenue;

impairment of our business reputation;

diversion of management and scientific resources from our business operations; and

the inability to commercialize an approved product candidate.

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

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

The patent 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, or 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 candidates without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may have patents that could prevent us from marketing our own patented product candidates. Third parties may also seek to market generic versions of any of our approved products. 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 new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

whether we will require licenses from such third parties. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications.

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;

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

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

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved product or the FDA s prior findings of safety and effectiveness for a previously approved product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant s application relies and that are listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed by the original

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

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

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

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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. If we initiate legal proceedings against a third party to enforce a patent covering any of our product candidates, the defendant could counterclaim that the patent covering our product candidate is 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 one or more of 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.

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

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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 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 products 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.

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If we do not obtain patent term extensions and data exclusivity for our 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.

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RISKS RELATED TO LEGISLATION AND ADMINISTRATIVE ACTIONS

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

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

the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals;

the federal transparency requirements under the ACA require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

analogous state laws and regulations, such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

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

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

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

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

The final rule implementing the Physician Payments Sunshine Act is complex, ambiguous, and broad in scope. When and if M207 and any other product candidates we develop in the future are approved, we will within a defined time period become subject to the reporting and disclosure provisions of the Physician Payments Sunshine Act. Accordingly, we will be required to collect, and report detailed information regarding certain financial relationships we have with physicians, dentists and teaching hospitals. It is difficult to predict how the new requirements may impact existing relationships among manufacturers, distributors, physicians, dentists and teaching hospitals. The Physician Payments Sunshine Act preempts similar state reporting laws, although we may also be required to continue to report under certain provisions of such state laws. While we expect to have substantially compliant programs and controls in place to comply with the Physician Payments Sunshine Act requirements, our compliance with the new final rule will impose additional costs on us. Additionally, failure to comply with the Physician Payment Sunshine Act may subject us to civil monetary penalties.

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

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

As noted above, the ACA is significantly changing the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on any product that we may commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, several states have not implemented certain sections of the ACA, including 19 that have rejected the expansion of Medicaid eligibility for low income citizens, and some members of the U.S. Congress are still working to repeal the ACA. More recently, President Trump and the Republican majorities in both houses of the U.S. Congress have been seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the individual mandate . Congress may consider other legislation to repeal or replace elements of the ACA in the

future. We cannot predict what legislation, if any, to repeal or replace the ACA will become law, or what impact any such legislation may have on our product candidates.

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

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

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

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

RISKS RELATED TO EMPLOYEE MATTERS, OUR OPERATIONS AND MANAGING GROWTH

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

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

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

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

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

We are highly dependent on our chief executive officer and our chief financial officer. We do not have key person life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise

of any of our key personnel could result in delays in product development and diversion of management resources, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

We may not successfully manage our growth.

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

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

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

Risks 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 began implementing a company-wide ERP system in the third fiscal quarter of 2018 to handle the business and financial processes within our operations and corporate functions. To reap the benefits of our ERP system, we were required 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 during 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 implement,

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.

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Failure in our information technology systems, including by cybersecurity attacks or other data security incidents, could significantly disrupt our operations.

Our operations depend, in part, on the continued performance of our information technology systems. 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. 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.

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 September 30, 2018, for example, our stock has traded in a range with a low of $3.66 and a high of $18.49. 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 explanation for the volatility in our stock price or the heavy volume of trading (on some days exceeding six times the number of shares currently outstanding) that has occurred in our common stock in February and March of 2018. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;
- results of clinical trials of our product candidates or those of our competitors;
- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;

conditions or trends in our industry;

changes in laws or other regulatory actions affecting us or our industry;

stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;

announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

capital commitments;

investors general perception of our company and our business;

disputes concerning our intellectual property or other proprietary rights;

recruitment or departure of key personnel; and

sales of our common stock, including sales by our directors and officers or specific stockholders.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources from our business.

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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. On November 28, 2017, we received a letter from the Nasdaq Stock Market, LLC (the Letter) stating that we had failed to maintain at least a $1.00 minimum bid price for its common stock (the Minimum Bid Requirement) as required for continued listing of our common stock on the Nasdaq Capital Market. We subsequently effected a 1-for-20 reverse stock split of our outstanding common stock and, on February 9, 2018, we received a letter from the Director of Nasdaq Listing Qualifications indicating that we had regained compliance with the Minimum Bid Requirement under Nasdaq Rule 5550(a)(2).

If, for any reason, Nasdaq should delist our securities from trading on its exchange (including if we fail to comply with the Minimum Bid Requirement in the future) 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.

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, or are perceived by the public market as intending to sell substantial amounts of our common stock, the trading price of our common stock could decline significantly. As of March 1, 2018, we had 1,973,039 shares of common stock outstanding. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur may reduce the prevailing market price of our common stock and make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, certain holders of our common stock and a warrant 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.

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

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

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

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

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

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

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

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

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

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

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

As a public reporting company, we are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in

reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

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

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

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

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

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

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

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

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

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

not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements;

reduced disclosure obligations regarding executive compensation; and

not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

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We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenue of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement filed under the Securities Act.

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

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.

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Item 6. Exhibits

Exhibit number	Description
4.1	Warrant to Purchase Stock, dated as of September 25, 2018 *(Incorporated by reference to the registrant s current report on Form 8-K filed with the SEC on September 26, 2018).*
10.1	Amended and Restated Employment Agreement dated September 18, 2018 with Donald Kellerman, Pharm.D. (Incorporated by reference to the registrant s current report on Form 8-K filed with the SEC on September 24, 2018).
10.2	Amended and Restated Employment Agreement dated September 18, 2018 with Hayley Lewis *(Incorporated by reference to the registrant s current report on Form 8-K filed with the SEC on September 24, 2018).*
10.3	Amendment Agreement dated October 15, 2018 with Donald Kellerman, Pharm.D. *(Incorporated by reference to the registrant s current report on Form 8-K filed with the SEC on October 16, 2018).*
10.4	Amendment Agreement dated October 15, 2018 with Hayley Lewis *(Incorporated by reference to the registrant s current report on Form 8-K filed with the SEC on October 16, 2018).*
10.5	Employment Agreement dated September 25, 2018 with Greg Kitchener *(Incorporated by reference to the registrant s current report on Form 8-K filed with the SEC on October 16, 2018).*
10.6	Master Lease Agreement, dated September 25, 2018, with Trinity Capital Fund III, L.P.
10.7 *	Manufacturing and Supply Agreement, dated September 25, 2018 with Patheon Manufacturing Services LLC
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 **	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document XBRL
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* *Filed herewith*

Confidential treatment has been requested for certain information contained in this Exhibit (indicated by asterisk). Such information has been omitted and filed separately with the SEC.

** *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.*

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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 15, 2018

Zosano Pharma Corporation

(Registrant)

/s/ John Walker
John Walker
Chief Executive Officer

(Principal Executive Officer)

/s/ Gregory Kitchener
Gregory Kitchener
Chief Financial Officer

(Principal Financial and Accounting Officer)