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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 March 31, 2019

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 ☒

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

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Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, 0.0001 par value	ZSAN	The Nasdaq Capital Market

As of May 10, 2019, the registrant had a total of 17,723,039 shares of its common stock, $0.0001 par value per share, outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,142	$ 9,140
Marketable securities at fair value	4,896	13,862
Prepaid expenses and other current assets	921	358
Total current assets	11,959	23,360
Restricted cash	455	455
Property and equipment, net	16,869	11,916
Operating lease right-of-use assets	6,219	—
Other long-term assets	21	49
Total assets	$ 35,523	$ 35,780
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,678	$ 4,450
Accrued compensation	2,742	2,092
Build-to-suit obligation, current portion	2,451	2,326
Operating lease liabilities, current portion	985	—
Other accrued liabilities	5,304	2,419
Total current liabilities	15,160	11,287
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	4,044	4,478
Operating lease liabilities, long-term portion	6,638	—
Other liabilities	30	18
Deferred rent	—	1,287
Total liabilities	25,872	17,070
Commitments and contingencies (note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; none issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, $0.0001 par value; 250,000,000 shares authorized; 11,973,039 shares issued and outstanding as of March 31, 2019 and December 31, 2018	1	1
Additional paid-in capital	280,307	279,946
Accumulated deficit	(270,658)	(261,232)
Accumulated other comprehensive income (loss)	1	(5)
Total stockholders' equity	9,651	18,710
Total liabilities and stockholders' equity	$ 35,523	$ 35,780

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

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

	Three Months Ended March 31,	
	2019	**2018**
Revenue	$ —	$ —
Operating expenses:		
Research and development	6,616	5,806
General and administrative	2,871	2,260
Total operating expenses	9,487	8,066
Loss from operations	(9,487)	(8,066)
Other income (expense):		
Interest income	80	15
Interest expense	(41)	(156)
Other income, net	22	1
Loss before provision for income taxes	(9,426)	(8,206)
Provision for income taxes	—	—
Net loss	$ (9,426)	$ (8,206)
Unrealized gain on marketable securities, net of tax	6	—
Comprehensive loss	$ (9,420)	$ (8,206)
Net loss per common share – basic and diluted	$ (0.79)	$ (4.16)
Weighted-average shares used in computing net loss per common share – basic and diluted	11,973,039	1,973,039

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

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

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
Balance at January 1, 2018	1,973,039	$ —	$ 232,922	$ (225,874)	$ —	$ 7,048
Stock-based compensation	—	—	139	—	—	139
Net loss	—	—	—	(8,206)	—	(8,206)
Balance at March 31, 2018	1,973,039	$ —	$ 233,061	$ (234,080)	$ —	$ (1,019)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at January 1, 2019	11,973,039	$ 1	$ 279,946	$ (261,232)	$ (5)	$ 18,710
Stock-based compensation	—	—	361	—	—	361
Unrealized gain on marketable securities	—	—	—	—	6	6
Net loss	—	—	—	(9,426)	—	(9,426)
Balance at March 31, 2019	11,973,039	$ 1	$ 280,307	$ (270,658)	$ 1	$ 9,651

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

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (9,426)	$ (8,206)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	361	139
Amortization of operating lease right-of-use assets	196	—
Depreciation	164	194
Effective interest on financing obligations	28	41
Accretion of interest on debt securities	(27)	—
Deferred rent	—	314
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(180)	(362)
Accounts payable	654	909
Accrued compensation and other accrued liabilities	983	835
Operating lease liabilities	(222)	—
Net cash used in operating activities	(7,469)	(6,136)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	9,000	—
Purchases of property and equipment	(4,016)	(451)
Net cash provided by (used in) investing activities	4,984	(451)
Cash flows used in financing activities:		
Principal payments made on financing obligations	(513)	(1,527)
Net decrease in cash, cash equivalents and restricted cash	(2,998)	(8,114)
Cash, cash equivalents and restricted cash at beginning of period	9,595	12,106
Cash, cash equivalents and restricted cash at end of period	$ 6,597	$ 3,992
Supplemental cash flow information:		
Cash paid for interest	$ 185	$ 116
Non-cash investing and financing activities:		
Acquisition of property and equipment under accounts payable and other accrued liabilities	$ 4,252	$ 340
Right-of-use assets acquired under finance lease obligations	$ 22	$ —
Accrued offering costs	$ 382	$ 561

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

Zosano Pharma Corporation
Notes to Condensed Financial Statements
(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 its proprietary Adhesive Dermally-Applied Microarray, or ADAM™, technology.

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 three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019, 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, 2018, included in the Company's annual report on Form 10-K and filed with the United States Securities and Exchange Commission ("SEC") on March 25, 2019.

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

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.

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 March 31, 2019, had an accumulated deficit of $270.7 million. As of March 31, 2019, the Company had approximately $11.0 million in cash, cash equivalents and marketable securities. Presently, the Company does not have sufficient cash, cash equivalents and marketable securities 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 for a period of one year from the issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On April 11, 2019, the Company closed a public offering of 5,000,000 shares of common stock at a price to the underwriter of $3.29 per share. On May 8, 2019, the underwriter purchased 750,000 shares at a price to the underwriter of $3.29 per share pursuant to the exercise of the underwriter's option to purchase additional shares. The aggregate net proceeds were approximately $18.4 million, after deducting underwriting costs and estimated offering expenses (See Note 10. *Subsequent Event*).

The Company plans to raise additional funding through financing, a capital offering, a license or collaboration agreement or a combination of such sources of capital. However, 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.

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

The Company's significant accounting policies are included in "Part II - Item 8 - Financial Statements and Supplementary Data - Note 2 - Summary of Significant Accounting Policies" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. As discussed in our Annual Report, the Company adopted the new leases standards in the first quarter of 2019 and otherwise, there have been no other significant changes to these accounting policies during the first three months of 2019.

Leases

ASC Topic 842, *Leases*, requires lessees to recognize right-of-use assets and lease liabilities for most leases on the balance sheet and to provide expanded disclosures about leasing arrangements. The Company adopted Topic 842 effective January 1, 2019 using the optional transition method and did not restate comparative periods. There was no effect on accumulated deficit at adoption.

The Company has elected the package of practical expedients to (i) not reassess whether expired or existing contracts are or contain leases, (ii) not reassess the lease classification for any expired or existing leases and (iii) not reassess the accounting for initial direct costs.

The adoption of the new leases standard resulted in the following adjustments to the consolidated balance sheet as of January 1, 2019:

	December 31, 2018	Adoption Impact	January 1, 2019
	(in thousands)	*(unaudited; in thousands)*	
Operating lease right-of-use assets	$ —	$ 6,415	$ 6,415
Operating leases liabilities, current portion	$ —	$ 945	$ 945
Other accrued liabilities	$ 2,414	$ (143)	$ 2,271
Operating lease liabilities, long-term portion	$ —	$ 6,900	$ 6,900
Deferred rent	$ 1,287	$ (1,287)	$ —

As of December 31, 2018, the short-term portion of deferred rent was recorded in other accrued liabilities. The adoption impact was a non-cash operating activity for the period ended March 31, 2019.

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

Cash, Cash Equivalents, and Restricted Cash

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

As of March 31, 2019 and December 31, 2018, the Company had restricted cash of approximately $0.5 million consisting of deposits of $0.3 million to secure its building lease until the end of the lease term, a deposit of approximately $0.1 million to a utility provider and $35,000 to secure corporate purchasing cards.

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

	March 31, 2019	March 31, 2018
	(unaudited; in thousands)	
Cash and cash equivalents	$ 6,142	$ 3,537
Restricted cash	455	455
Total	$ 6,597	$ 3,992

Marketable Securities

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

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

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.

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 I: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level II: 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 III: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

Net Loss Per Common Share

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

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

	March 31, 2019	March 31, 2018
	(unaudited)	
Warrants to purchase common stock	274,524	199,524
Options to purchase common stock	1,456,126	124,379
Total	1,730,650	323,903

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU2018-15, *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. ASU2018-15 is effective for the Company in the first quarter of 2020. Early adoption is permitted. ASU2018-15 permits either a prospective or retrospective transition approach. The Company is currently evaluating ASU2018-15 to determine the impact to its financial statements and related disclosures.

In August 2018, the FASB issued ASU2018-13, *Fair Value Measurement (Topic 820)*. The new guidance modifies the disclosure requirements on fair value measurements. ASU2018-13 is effective for the Company beginning in the first quarter of 2020 and must be adopted on a modified retrospective basis, with certain exceptions. Early adoption is permitted. The Company does not expect ASU2018-13 to have a significant impact to its financial statements and disclosures.

In June 2016, the FASB issued ASU2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and in November 2018, issued ASU2018-19, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses*. This new guidance is intended to present credit losses on available for sale debt securities as an allowance rather than as a write-down. Entities are required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. ASU2016-13 and ASU2018-19 are effective for the Company in the first quarter of 2020. The Company is currently evaluating ASU2016-13 and ASU2018-19 to determine the impact to its financial statements and disclosures.

3. Cash Equivalents and Investments in Marketable Securities

The following tables present summaries of the Company's cash equivalents and marketable securities measured at fair value on a recurring basis:

		Fair Value Measurements		
	Total	Quoted prices in active market Level I	Significant other observable inputs Level II	Significant unobservable inputs Level III
		(unaudited; in thousands)		
As of March 31, 2019:				
Money market funds	$ 4,905	$ 4,905	$ —	$ —
Corporate notes and bonds	1,500	—	1,500	—
U.S. treasuries	3,396	3,396	—	—
Total	$ 9,801	$ 8,301	$ 1,500	$ —
Classified as:				
Cash equivalents	$ 4,905			
Marketable securities at fair value	4,896			
Total	$ 9,801			

	Total	Fair Value Measurements: Quoted prices in active market Level I	Significant other observable inputs Level II	Significant unobservable inputs Level III
		(in thousands)		
As of December 31, 2018:				
Money market funds	$ 4,830	$ 4,830	$ —	$ —
Commercial paper	1,497	—	1,497	—
Corporate notes and bonds	6,989	—	6,989	—
U.S. treasuries	8,375	8,375	—	—
Total	$ 21,691	$ 13,205	$ 8,486	$ —
Classified as:				
Cash equivalents	$ 7,829			
Marketable securities at fair value	13,862			
Total	$ 21,691			

The Company did not transfer any marketable securities measured at fair value on a recurring basis to or from Level I and Level II during the three month period ended March 31, 2019.

The following tables summarize the unrealized positions for available-for-sale fixed maturity debt securities disaggregated by class of instrument:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(unaudited; in thousands)		
As of March 31, 2019:				
Money market funds	$ 4,905	$ —	$ —	$ 4,905
Corporate notes and bonds	1,500	—	—	1,500
U.S. treasuries	3,395	1	—	3,396
Total	$ 9,800	$ 1	$ —	$ 9,801

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
As of December 31, 2018:				
Money market funds	$ 4,830	$ —	$ —	$ 4,830
Commercial paper	1,497	—	—	1,497
Corporate notes and bonds	6,994	—	(5)	6,989
U.S. treasuries	8,375	—	—	8,375
Total	$ 21,696	$ —	$ (5)	$ 21,691

4. Balance Sheet Components

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

	March 31, 2019	December 31, 2018
	(unaudited; in thousands)	*(in thousands)*
Offering costs	$ 517	$ 114
Prepaid insurance	241	45
Other	163	199
Total	$ 921	$ 358

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

	March 31, 2019	December 31, 2018
	(unaudited; in thousands)	*(in thousands)*
Construction-in-progress obligations	$ 2,969	$ 395
Pre-clinical and clinical study	971	483
Professional service fees	301	112
Contract manufacturing	407	834
Accrued taxes	50	187
Other	606	408
Total	$ 5,304	$ 2,419

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

	March 31, 2019	December 31, 2018
	(unaudited; in thousands)	*(in thousands)*
Leasehold improvements	$ 16,951	$ 16,690
Manufacturing equipment	11,833	10,387
Laboratory and office equipment	1,479	1,434
Computer equipment and software	235	206
Construction-in-progress	12,895	9,558
	43,393	38,275
Less: accumulated depreciation	(26,524)	(26,359)
Total	$ 16,869	$ 11,916

Depreciation expense was approximately $0.2 million and $0.2 million for the three months ended March 31, 2019 and 2018, respectively.

The gross property and equipment and accumulated depreciation presented in the above table includes right-of-use assets acquired under finance leases and the related accumulated amortization, respectively. Right-of-use assets under finance leases were comprised of office and computer equipment of approximately $43,000 and $24,000 at March 31, 2019 and December 31, 2018, respectively. Accumulated amortization related to right-of-use assets under finance leases was approximately $15,000 at March 31, 2019.

As of March 31, 2019, construction-in-progress included $9.7 million of an asset relating to the build-to-suit arrangement for construction of the Company's commercial coating and primary packaging system, of which capitalized construction period interest was $0.7 million (See Note 6. *Debt Financing*).

5. Leases

Operating Leases

The Company has a non-cancelable operating lease with BMR-34790 Ardentech Court LP for office, research and development, and manufacturing facilities in Fremont, California through August 31, 2024, with an option to further extend the lease for an additional 60 months subject to certain terms and conditions.

The lease agreement calls for monthly base rent of approximately $136,000 for the period commencing September 1, 2017, with annual increases on September 1 of each subsequent year until the lease year beginning September 1, 2023. The agreement also provided for rent abatements, subject to certain conditions, totaling $0.3 million and certain tenant improvements to be completed at the landlord's expense of approximately $1.0 million.

The Company entered into a three year, noncancelable lease for telephone equipment in January 2018.

Per the terms of the agreements, the Company does not have any residual value guarantees. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate. The Company has elected to account for each lease component and its associated non-lease components as separate lease components. The building lease includes non-lease components (i.e. common area maintenance) which are charged and paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability but reflected in operating expense in the period incurred.

Finance Leases

The Company leases certain equipment under non-cancelable agreements which expire between 2021 and 2022 that were accounted for as capital leases under ASC840. The leases were not reassessed at adoption of ASC842 as the Company elected the practical expedient to not reassess existing leases.

The finance lease obligations were as follows:

	March 31, 2019	December 31, 2018
	(unaudited; in thousands)	*(in thousands)*
Finance lease obligations, current portion	$ 13	$ 5
Finance lease obligations, long-term portion	$ 30	$ 18

The components of lease cost were as follows:

Description of lease costs	Three months ended March 31, 2019
	(unaudited; in thousands)
Finance Lease Cost	
Amortization of finance lease right-of-use assets	$ 15
Interest on finance lease obligations	9
Operating lease costs	410
Total	$ 434

Cash payments for leases were as follows:

Description of cash payment	Three months ended March 31, 2019
	(unaudited; in thousands)
Operating cash flows from operating leases	$ 436
Operating cash flows from finance leases	$ 3
Financing cash flows from finance leases	$ 3

Lease term and discount rate were as follows:

	March 31, 2019	
Description of other lease information	Operating leases	Finance leases
	(unaudited)	
Weighted-average remaining lease term	5.49	2.51
Weighted average discount rate	11%	27%

As of March 31, 2019, annual scheduled lease payments were as follows:

Year	Operating leases	Finance leases
	(unaudited; in thousands)	
Remainder of 2019	$ 1,326	$ 18
2020	1,815	24
2021	1,863	14
2022	1,914	3
2023	1,970	—
2024	1,340	—
Total undiscounted cash flows	10,228	59
Less: amount representing interest	(2,605)	(16)
Present value of leased liabilities	$ 7,623	$ 43

6. 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") in order to obtain financing for the third party construction of the Company's commercial coating and primary packaging system (the "Equipment"), expected to be completed in the second quarter of 2020. Under the agreement, Trinity will make available to the Company $14.0 million for equipment costs and associated soft costs ("Total Cost"), with an initial drawdown of $5.0 million and additional drawdowns in increments of not less than $0.5 million, until March 30, 2020. At March 30, 2020, any unused portion of the $14.0 million will be subject to a non-utilization fee equal to 3% of the unused amount. In consideration of the financing arrangement, as collateral, the Company granted Trinity a first-priority lien and security interest in substantially all the Company's assets.

The Company determined that it is the deemed owner, for financial reporting purposes, of the Equipment during the construction period due to its involvement in and its obligations related to the construction of the Equipment. Accordingly, construction costs incurred were recorded as construction-in-progress, a component of property and equipment on the balance sheet and the Trinity financing obligation was recorded as a build-to-suit obligation on the balance sheet.

Under the financing arrangement, each individual drawdown represents a separate financing arrangement with its own 36-month-term and stated interest rate. Each drawdown is non-cancelable, with no prepayment options. Each drawdown has embedded optional purchase options to (i) extend the term for an additional three months, with the option to purchase the equipment at 4% of the Total Cost, which is equal to the drawdown amount, following the end of such extended term, or (ii) purchase the equipment at 12% of the Total Cost, which is equal to the drawdown amount, at the end of the 36-month-term. The Company intends to exercise

the optional purchase option of 12% at the end of each 36-month-term ("Purchase Option Fee"). The transfer of title from Trinity to the Company will occur at the end of the final 36-month-term, provided that the purchase option was executed, and the Purchase Option Fee was paid in full at the end of each 36-month-term. Failure to pay any of the Purchase Option Fees will result in Trinity retaining title to the Equipment and the Company paying a 6% restocking fee.

In September 2018, upon commencement of this arrangement, the Company drew its first drawdown of $5.0 million, of which $2.7 million was for the Company's commercial coating and primary packaging system, $2.0 million was used to extinguish an existing loan (see below), and the remaining $0.3 million was withheld by Trinity for interim interest and a security deposit that will be applied to the final monthly payment. The monthly loan payment is $160,000, with a stated and effective interest rate of 9.43% and 26.28%, respectively. The Purchase Option Fee was recorded as a discount to the principal balance. The first drawdown of $5.0 million matures on October 1, 2021.

In connection with the build-to-suit arrangement, the Company issued common stock warrants ("Trinity Warrants") for a total of 75,000 shares of common stock at an exercise price of $3.59 per share. The Trinity Warrants will expire on September 25, 2025. Proceeds allocated to the Trinity Warrants based on their relative fair value approximated $243,000 and were recorded as a discount to the initial $5.0 million drawdown under the Trinity financing arrangement and are being amortized as interest over the term of the September 2018 drawdown.

In December 2018, the Company drew a second drawdown of $2.8 million, of which $2.6 million was for the Company's commercial coating and primary packaging system, and the remaining $0.2 million was withheld by Trinity for interim interest, the first monthly payment and a security deposit that will be applied to the final monthly payment. The monthly loan payment is approximately $90,000 with a stated and effective interest rate of 9.68% and 19.58%, respectively. The Purchase Option Fee was recorded as a discount to the principal balance. The second drawdown of $2.8 million matures on January 1, 2022.

As of March 31, 2019, the Company had an aggregate commercial coating and primary packaging system construction-in-progress ("CIP") balance of $9.7 million that included $0.7 million of interest related to its build-to-suit obligation, of which $71,000 was attributable to the Trinity Warrants; and a net build-to-suit obligation of $6.5 million. As of March 31, 2019, $6.2 million remains available to the Company under the Trinity build-to-suit arrangement.

The following table is a summary of the Company's build-to-suit obligation as of March 31, 2019 *(unaudited; in thousands)*:

Build-to-suit obligation principal amount	$	6,609
Build-to-suit obligation Purchase Option Fees		760
Less: unamortized Purchase Option Fees		(534)
unamortized fair value of free-standing warrants		(173)
unamortized debt discount		(149)
unamortized debt issuance costs		(18)
Build-to-suit obligation, net of debt issuance costs and discount	$	6,495

Build-to-suit obligation, current portion	$	2,451
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount		4,044
Build-to-suit obligation, net of debt issuance costs and discount	$	6,495

For the three months ended March 31, 2019, the Company capitalized $0.4 million of interest as CIP, a component of property and equipment on the Company's balance sheet.

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

Year	Principal	Interest	Purchase Option Fees
		(unaudited; in thousands)	
Remainder of 2019	$ 1,815	$ 433	$ —
2020	2,632	367	—
2021	2,162	107	936
Total	$ 6,609	$ 907	$ 936

Senior Secured Term Loan with Hercules

In June 2014 and June 2015, the Company entered into a loan and security agreement and the first amendment to the loan and security agreement, respectively, with Hercules Capital Inc. ("Hercules"). Hercules provided the Company a $15.0 million loan ("Hercules Term Loan") of which equal installment payments of principal and interest were due monthly, with a scheduled 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%. On September 25, 2018, the Company paid all its outstanding obligations under the Hercules Term Loan, including an end of term charge of $0.4 million.

For the three months ended March 31, 2018, the Company recorded total interest expense of $0.2 million related to the Hercules Term Loan.

7. Warrants

The following table summarizes the warrants issued and outstanding as of March 31, 2019:

	Warrants Outstanding as of As of December 31, 2018	Warrants Issued	Warrants Exercised	Warrants Expired	Warrants Outstanding As of March 31, 2019	Exercise Price	Expiration Date
			(unaudited)				
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	274,524	—	—	—	274,524		

8. Commitments and Contingencies

Employment Arrangements

The Company has entered into employment agreements with its executive officers. Generally, the terms of these agreements provide for base salary, health care coverage, annual bonus and stock options. In addition, 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 as well as automatic acceleration of vesting, at a certain percentage (25% or 100%), of their unvested stock options and other equity awards on the date of such termination.

Equipment Purchase Commitments

In May 2018 and February 2019, the Company entered into a $12.2 million purchase order and a $1.3 million revision to the purchase order with an equipment manufacturer to purchase a commercial coating and primary packaging system for the production of its product candidate, Qtrypta™ (M207), for an aggregate purchase price of $13.5 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 18-month period. As of March 31, 2019, the Company had made payments totaling $5.9 million.

The Company also entered into agreements with equipment manufacturers to produce its patch assembly machine and its applicator and retainer machinery. The aggregate purchase price of this equipment is $3.6 million of which $1.6 million was paid as of March 31, 2019.

Contract Manufacturing Organizations

In September 2018, the Company entered into a manufacturing and supply agreement with a contract manufacturing organization ("CMO") to provide services related to the manufacture and commercialization of Qtrypta™ (M207). During the term of the agreement, the CMO will provide services related to processing, packaging, labeling and storing Qtrypta™ (M207), in addition to other services such as stability testing, quality control and assurance, and waste disposal.

The agreement calls for annual fees of $1.0 million in 2019 escalating to $14.0 million in 2024, to be paid in equal monthly installments. Beginning in 2020, the annual fee includes the production of a defined number of units with an option to purchase

additional units at a defined price. The agreement contains negotiated representations and warranties, indemnification, limitations of liability, and other provisions. The initial term of the agreement continues until the seventh anniversary of the date on which the Company receives New Drug Application approval of Qtrypta™ (M207) in the United States.

The Company may elect to terminate the agreement at any time prior to certain regulatory approvals or if such regulatory approval is withdrawn under certain circumstances. Upon termination of the contract, the Company would incur cancellation fees of 50% of the annual fee due in the year that the contract is terminated, estimated to be between $1.0 million and $1.4 million, and costs to remove the Company's equipment and restore the CMO's facility to its original condition. The Company or the CMO may terminate the agreement for the other's uncured material breach, uncured force majeure or bankruptcy or insolvency-related events.

As of March 31, 2019, the Company had entered into agreements with CMOs for the construction of manufacturing space and technology transfer fees of $4.1 million of which $0.6 million had been paid.

Indemnification and Guarantees

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its officers and directors for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company has director and officer insurance that may enable the Company to recover a portion of any amounts paid for future potential claims. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of March 31, 2019.

Legal Proceedings

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

9. Stock-Based Compensation

The Amended and Restated 2014 Equity and Incentive Plan

The Amended and Restated 2014 Equity and Incentive Plan ("2014 Plan") provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company's common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of March 31, 2019, the Company had reserved 1,767,229 shares of its common stock for issuance under its 2014 Plan, subject to automatic annual increases as set forth in the 2014 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 of unvested shares as determined by its board of directors. As of March 31, 2019, the Company had 327,848 shares available for grant under the 2014 Plan. During the three month period ended March 31, 2019, the Company granted stock options to purchase 32,500 shares of common stock to non-employee directors.

The following table summarizes option and award activity, excluding inducement grants, for the three months ended March 31, 2019 *(unaudited)*:

	Shares Available for Grant	Number of Shares Subject to Outstanding Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at January 1, 2019	55,799	1,296,157	$ 5.75	9.23	$ —
Additional shares reserved	419,056	—	$ —		
Options granted	(179,250)	179,250	$ 4.13		
Options canceled/forfeited/expired	32,243	(32,243)	$ 5.28		
Balance at March 31, 2019	327,848	1,443,164	$ 5.56	9.05	$ 775,606
Exercisable at March 31, 2019		298,777	$ 9.26	8.47	$ 123,891
Vested or expected to vest at March 31, 2019		1,340,746	$ 5.64	9.04	$ 722,306

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 March 31, 2019.

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 activity *(unaudited)*:

	Number of Shares Subject to Outstanding Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at January 1, 2019	13,837	$ 20.60	4.52	$ —
Options granted	—	$ —		
Options canceled/forfeited/expired	(875)	$ 22.80		
Balance at March 31, 2019	12,962	$ 20.45	3.51	$ —
Exercisable at March 31, 2019	10,357	$ 18.75	2.33	$ —
Vested or expected to vest at March 31, 2019	12,788	$ 20.36	3.45	$ —

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows:

	Three months ended March 31,	
	2019	2018
	(unaudited; in thousands)	
Research and development	$ 165	$ 67
General and administrative	196	72
Total	$ 361	$ 139

As of March 31, 2019, the Company had $3.7 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 3.14 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. As the Company does not have sufficient historical stock price information to meet the expected life of the stock-based awards, the Company uses a blended volatility that includes the Company's common stock trading history and supplements the remaining historical information with the trading history from the common stock of a set of comparable publicly traded biopharmaceutical companies. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of the Company's stock price becomes available. 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 *(unaudited)*:

	For the three months ended March 31,	
	2019	**2018**
Dividend yield	—%	—%
Risk-free interest rate	2.50% - 2.66%	2.46%
Expected volatility	106%	89%
Expected term (years)	6.08	10

10. Subsequent Event

On April 11, 2019, the Company closed a public offering of 5,000,000 shares of common stock at an assumed public offering price of $3.50 per share. The Company received approximately $16.0 million of net proceeds from this offering, after deducting estimated offering expenses payable by the Company. The offering was made pursuant to a registration statement on Form S-3 filed with the Securities Exchange Commission on February 14, 2019.

In addition, under the terms of an underwriting agreement entered into with the underwriter of the April 2019 offering, the Company granted the underwriter a 30-day option to purchase up to 750,000 additional shares of common stock. On May 8, 2019, the underwriter purchased 750,000 shares at a price to the underwriter of $3.29 per share pursuant to the exercise of the underwriter's option to purchase additional shares. The aggregate net proceeds were approximately $2.4 million, after deducting underwriting costs and estimated offering expenses.

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, 2018, filed with the Securities and Exchange Commission, or SEC, on March 25, 2019. 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.

Overview

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM, technology. In February 2017, we announced positive results from our ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated Qtrypta™ (M207), which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. In February 2019, we announced the completion of the final milestone in our long-term safety study for Qtrypta™ (M207). We are focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, in markets where patients remain underserved by existing therapies. 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 and allow the drug to be absorbed into the microcapillary system of the skin. We focus on developing products based on our ADAM technology for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, in markets where there is a need for more effective therapies.

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

We will use contract manufacturers for the production of Qtrypta™ (M207). These contract manufacturers include companies that will produce our applicator, the various components that comprise our patch, as well as the final packaging of the finished product. Where required, these contract manufacturers will operate within the specifications and in accordance with good manufacturing practices as defined by the FDA. These companies are located in the United States and have expertise and experience in contract manufacturing.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the FDA, or equivalent foreign regulatory bodies, to market and sell our product candidate. Accordingly, our success depends not only on the development, but also on our ability to finance the development of the product. We will require substantial additional funding to complete development and seek regulatory approval for these products. 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 enrollment in our long-term safety study for Qtrypta™ (M207) as an acute treatment of migraine ("M207-ADAM"). M207-ADAM was an open label study evaluating the safety of the 3.8mg dose of Qtrypta™ (M207) in migraine patients who had historically experienced at least two migraines per month. Patients were expected to treat a minimum of two migraines per month on average, with no maximum treatment limits. The study was conducted at 31 sites in the United States with a defined data set per protocol in which 150 subjects received repeated doses for six months and 50 subjects received repeated doses for one year. The study was open-label, with investigator visits at months one, two, three, six, nine and twelve to record adverse events, if any. The primary objective of M207-ADAM was to assess safety of Qtrypta™ (M207) during repeated use over six and twelve months. Other endpoints were electrocardiography and laboratory parameters, as well as percentage of headaches with pain-free response.

In October 2018, we announced the completion of the first phase of our long-term safety study with more than 150 evaluable subjects completing six months of treatment with Qtrypta™ (M207). In February 2019, we announced the completion of the second phase of our long-term safety study with more than 50 evaluable subjects completing one year of treatment with Qtrypta™ (M207). As of February 2019, more than 5,800 migraines had been treated with Qtrypta™ (M207). Investigators reported 831 adverse events, of which 297 were reported as application site reactions and 161 were reported as treatment related adverse events. As of February 2019, following treatment with Qtrypta™ (M207), 44% of patients reported pain freedom at two hours, 68% of patients reported relief from most bothersome symptom, while pain relief at two hours was reported for 81% of migraine attacks treated.

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 United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported results of operations during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from these estimates under different assumptions or conditions.

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 material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, other than changes to our critical accounting policies resulting from the Company's adoption of the new leases standard, ASC842 in the first quarter of 2019.

Leases

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

Financial Operations Overview

General

As of March 31, 2019, we had an accumulated deficit of $270.7 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our Qtrypta™ (M207) product candidate into later stages of development and, if approved, commercialization. We cannot assure you that we will receive additional capital or collaboration revenue in the future, as a result of any partnership that we might pursue.

We expect our research and development expenses and manufacturing expenses related to the development of our Qtrypta™ (M207) product candidate to increase as we continue to advance this program towards regulatory filing and approval. Because of the numerous risks and uncertainties associated with our technology and drug development, we cannot forecast with any degree of certainty the timing or amount of expenses incurred or when, or if, we will be able to achieve profitability.

We will require additional capital to undertake our planned research and development activities and to meet our operating requirements beyond the fourth quarter of 2019. We intend to raise such capital through the issuance of additional equity through public or private offerings, debt financing, strategic alliances with pharmaceutical partners, or any combination of the above. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to further reduce our operating expenses and suspend, delay or reduce the scope of our Qtrypta™ (M207) development program, out-license intellectual property rights to our intracutaneous delivery technology, or a combination of the above, which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all.

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, drug formulation, and clinical trials;

- expenses related to the purchase of active pharmaceutical ingredients and raw materials for the production of our intracutaneous delivery system, including fees paid to contract manufacturing organizations;
- fees paid to contract research organizations ("CRO"), clinical consultants, clinical trial sites and vendors, including institutional review boards ("IRB"), in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- 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.

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

Our research and development efforts and resources have focused primarily on advancing the development of Qtrypta™ (M207). While we currently intend to continue clinical development of Qtrypta™ (M207) through commercialization in the United States ourselves, we remain open to opportunities with potential strategic partners to ensure Qtrypta™ (M207) will receive the best chance of commercial success. We are actively seeking opportunities to evaluate collaborations with strategic partners to further the clinical and commercial development of our other product candidates. We cannot forecast with any degree of certainty if Qtrypta™ (M207) or our future product candidates, if any, will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements. As a result of these uncertainties, we are unable to determine the duration and completion 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. As a public company, we expect to invest significant resources to comply with evolving laws, regulations and standards, including the implementation of effective internal controls over financial reporting and compliance with the Sarbanes-Oxley Act.

Other Income and Expenses

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

Interest expense. Interest expense consists of interest costs and associated amortization of debt discount and issuance costs, if any, related to debt financing and an Equity Line of Credit.

Other income, net. Other income, net consists of miscellaneous income or expenses that are not included in other categories of the statement of operations and comprehensive loss.

Results of Operations

Comparison of the three months ended March 31, 2019 and 2018

Research and development expenses

	Three months ended March 31,		Change	
	2019	2018	Amount	%
	(unaudited; in thousands)			
Research and development	$ 6,616	$ 5,806	$ 810	14%

Research and development expenses increased approximately $0.8 million, or 14%, for the three months ended March 31, 2019, as compared to the same period in 2018. The increase was primarily attributable to $1.1 million in technology transfers costs incurred in conjunction with services performed by our contract manufacturer to install and qualify pilot coater equipment. An additional increase of $0.5 million in research and development was due to an increase in compensation costs as a result of an increase of employees during the period ended March 31, 2019 and to an increase in stock compensation expense. These increases were offset by a decrease of $0.8 million in Qtrypta™ (M207) long-term safety study costs as compared to the same period in 2018.

General and administrative expenses

	Three months ended March 31,		Change	
	2019	2018	Amount	%
	(unaudited; in thousands)			
General and administrative	$ 2,871	$ 2,260	$ 611	27%

General and administrative expenses increased approximately $0.6 million, or 27.0%, for the three months ended March 31, 2019 as compared to the same period in 2018. The increase was primarily attributable to $0.4 million in professional fees and to an increase of $0.3 million in additional compensation expense. These increases were partially offset by a decrease of $0.1 million in corporate tax.

Other income and expense

	Three months ended March 31,		Change	
	2019	2018	Amount	%
	(unaudited; in thousands)			
Interest income	$ 80	$ 15	$ 65	433%
Interest expense	$ (41)	$ (156)	$ (115)	74%
Other income, net	$ 22	$ 1	$ 21	*

* Not meaningful

Interest income resulted primarily from interest recognized related to our marketable securities. The increase for the three months ended March 31, 2019 as compared to the same period in 2018 resulted from higher balances in investment holdings.

Interest expense decreased approximately $0.1 million, or 74%, for the three months ended March 31, 2019, as compared to the same period in 2018. For the period ended March 31, 2018, interest expense was primarily attributable to the Hercules Term Loan, for which the outstanding obligation was paid in full in September 2018. For the period ended March 31, 2019, interest expense was primarily attributed to amortization of deferred offering costs for our Equity Line of Credit.

The increase in other income, net is primarily attributed to an insurance reimbursement.

Liquidity and Capital Resources

As of March 31, 2019, we had an accumulated deficit of $270.7 million and $7.5 million of negative cash flows from operating activities for the three months ended March 31, 2019. As of March 31, 2019, we had approximately $11.0 million in cash, cash equivalents, and marketable securities. Presently, we do not have sufficient cash, cash equivalents and marketable securities to enable us to fund our anticipated level of operations and meet our obligations as they become due during the twelve months following the date of issuance of this Quarterly Report on Form 10-Q. Further, to continue operations for the remainder of 2019, we will need to obtain additional capital resources by the end of the fourth quarter of 2019 through an equity offering, a debt financing, a license or collaboration agreement, or through a combination of such sources of capital. The aforementioned factors raise substantial doubt about our ability to continue as a going concern.

On April 11, 2019, we closed a public offering of 5,000,000 shares of common stock at a price to the underwriter of $3.29 per share. On May 8, 2019, the underwriter purchased 750,000 shares at a price to the underwriter of $3.29 per share pursuant to the exercise of the underwriter's option to purchase additional shares. The aggregate net proceeds were approximately $18.4 million, after deducting underwriting costs and estimated offering expenses.

Our ability to complete the sale and access the market as a source of liquidity is dependent on investor demand, market conditions and other factors. Therefore, we can provide no assurance that any such offering will be on terms favorable to us or our stockholders,

or that such offering will be successful at all. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

Since our inception in October 2006, we have funded our operations primarily through a combination of equity offerings, secured and unsecured borrowings from private investors, bank credit facilities, and licensing and service revenue from license and collaboration agreements. We also have an equity line of credit pursuant to a purchase agreement with Lincoln Park Capital, LLC, which provides for the purchase of up to $35.0 million worth of our common stock over the term of the purchase agreement, subject to certain conditions and limitations. Additionally, we have access to $6.2 million from our Trinity arrangement to fund the manufacture of our commercial coating and primary packaging system.

We expect to incur additional losses in the future and will require additional financing to develop our Qtrypta™ (M207) product candidate, conduct pre-commercialization manufacturing activities and fund our operations. Failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

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

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

Cash Flows

The following table shows a summary of our cash flows:

	Three Months Ended March 31,	
	2019	2018
	(unaudited; in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (7,469)	$ (6,136)
Investing activities	4,984	(451)
Financing activities	(513)	(1,527)
Net decrease in cash and cash equivalents	$ (2,998)	$ (8,114)

Operating Cash Flow: Net cash used in operating activities was approximately $7.5 million and $6.1 million for the three months ended March 31, 2019 and 2018, respectively. Net cash used during the first three months of 2019 was primarily due to clinical trial costs for the long-term safety study and technology transfer costs incurred in conjunction with services performed by our contract manufacturer. Net cash used during the first three months of 2018 was primarily due to clinical trial costs for the 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 provided by investing activities was approximately $5.0 million for the three months ended March 31, 2019 and net cash used in investing activities was $0.5 million for the three months ended March 31, 2018. Net cash provided by investing activities during the first three months of 2019 was primarily the result of $9.0 million of proceeds from maturities of marketable securities, offset by $4.0 million of property and equipment purchases for our pre-commercialization activities. Net cash used in investing activities during the first three months of 2018 was primarily due to the purchase of property and equipment.

Financing Cash Flow: Net cash used in financing activities was approximately $0.5 million and $1.5 million for the three months ended March 31, 2019 and 2018, respectively. Net cash used in financing activities for the first three months of 2019 was primarily due to principal payments on the build-to-suit obligation with Trinity. Net cash used in financing activities for the first three months of 2018 was primarily due to principal payments on the Hercules Term Loan of approximately $1.5 million.

Contractual Obligations and Commitments

Our contractual obligations primarily consist of our obligations under non-cancelable operating and finance leases, our build-to-suit obligation with Trinity, and other purchase obligations, such as those for equipment purchases and for contract manufacturing.

There were no material changes in our commitments under contractual obligations, as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 25, 2019.

Recent Accounting Pronouncements

See Note 2. *Summary of Significant Accounting Policies*, to the accompanying condensed financial statements for 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 marketable securities. We had cash and cash equivalents of $6.1 million as of March 31, 2019, which consisted of bank deposits and money market funds. We had investments in marketable securities at fair value of $4.9 million as of March 31, 2019, which consisted primarily of U.S. treasuries and corporate notes and bonds. 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 future drawdowns from our build-to-suit arrangement 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 March 31, 2019. 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Act of 1933, as amended, is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934, as amended) during the quarter ended March 31, 2019, 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, 2018 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 Quarterly Report on Form 10-Q, including our condensed financial statements and the related notes thereto.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

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

Developing and commercializing biopharmaceutical products, including launching new products into the marketplace and conducting preclinical studies and clinical trials, is an expensive and highly uncertain process that takes years to complete. As of March 31, 2019, we had an accumulated deficit of $270.7 million as well as negative cash flows from operating activities. As of March 31, 2019, we had approximately $11.0 million in cash, cash equivalents and marketable securities, and we do not have sufficient cash, cash equivalents and marketable securities to fund our anticipated level of operations and meet our obligations as they become due during the twelve months following the date of issuance of this Quarterly Report on Form 10-Q. The aforementioned factors raise substantial doubt about our ability to continue as a going concern.

There is no assurance that such additional funds will be obtained for our ongoing operations or that we will succeed in our future operations. Our audited financial statements included in our Annual Report for the year ended December 31, 2018 include an explanatory paragraph regarding our ability to continue as a going concern which may discourage some third parties from contracting with us and some investors from purchasing our stock or providing alternative capital financing, which could adversely affect our business, financial condition, results of operations and prospects.

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

Since inception, we have incurred significant operating losses. For the quarter ended March 31, 2019 we incurred a net loss of $9.4 million. As of March 31, 2019, we had an accumulated deficit of $270.7 million. We expect to continue to incur additional significant operating losses and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we continue the development of our product candidate, Qtrypta™ (M207), or any other products 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 Qtrypta™ (M207) or any other products 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 candidate, which may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or lead product candidate.

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 candidate 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 candidate that we would otherwise prefer to develop and market ourselves. The amount and timing of our future financing requirements will depend on many factors, including:

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

Our build-to-suit arrangement 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 build-to-suit obligation.

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

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

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

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

which would potentially include our intellectual property. Any such action on the part of Trinity would significantly harm our business and our ability to operate.

We have limited operating history and capabilities.

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

- continuing to conduct clinical development of our product candidate;
- obtaining required regulatory approvals;
- formulating and manufacturing product; 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 product candidate.

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 CANDIDATE

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

We have focused our clinical development efforts on our product candidate, Qtrypta™ (M207). The development and commercialization of Qtrypta™ (M207) and any product candidate 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 candidate;
- we may experience delays in regulatory review and approval of our product candidate in clinical development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies or trials;
- 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 candidate in the United States and foreign jurisdictions;
- potential side effects of our product candidate could delay or prevent commercialization, limit the indications for any approved product candidate, require the establishment of a risk evaluation and mitigation strategy ("REMS"), or cause an approved product candidate to be taken off the market;
- the FDA may identify deficiencies in our manufacturing processes or facilities or those of our contract manufacturing organizations, or 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 our product candidate is safe and effective as a treatment for its intended indications to the satisfaction of the FDA or other similar regulatory bodies;
- we may be unable to establish or maintain collaborations, licensing or other arrangements;
- the market may not accept our product candidate;
- 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 product candidate.

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

The long-term safety study for Qtrypta™ (M207) is an important step in the development of Qtrypta™ (M207). If we cannot produce results that satisfy FDA requirements, the regulatory approval process could be delayed, and our business could be adversely affected.

In February 2019, we announced the completion of the final phase of our long-term safety study where more than 50 evaluable subjects were treated for a year. This long-term safety study will need to produce results that satisfy FDA requirements. If the results do not satisfy the FDA's requirements it could require us to delay, limit, reduce or terminate our development of Qtrypta™ (M207). Also, even though we have discussed our development strategy with the FDA on our Qtrypta™ (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 candidate satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of our product candidate under Section 505(b)(2) are not as we expect, the approval pathway for our product candidate will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our product 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 Cosmetics Act ("FDCA"). Section 505(b)(2) permits the filing of a New Drug Application ("NDA") where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us or any partner with which we collaborate to pursue the 505(b)(2) regulatory pathway for our product candidate, we or they may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, we or they will need to successfully complete additional Phase 2 and/or Phase 3 clinical trials and submit to the FDA for approval one or more NDAs in order to obtain FDA approval to market our product candidate. The time and financial resources required to obtain FDA approval for our product candidate 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 Qtrypta™ (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 Qtrypta™ (M207) or for any other product candidate we may develop in the future.

Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidate, 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 candidate, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

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

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

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

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

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

If we are required to conduct additional clinical trials or other testing of our product candidate beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidate 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 candidate;
- 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.

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 candidate or allow our competitors to bring a product candidate to market before we do, and thereby impair our ability to successfully commercialize our product candidate.

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

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

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

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

We cannot assure you that we will receive the approvals necessary to commercialize Qtrypta™ (M207) or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidate 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 candidate will ultimately be considered safe for humans and effective for indicated uses by the FDA. The FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review. Delays in obtaining regulatory approvals may:

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

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

Even if Qtrypta™ (M207) or any other product candidates we develop in the future receive regulatory approval, our business is subject to extensive regulatory requirements which include ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize our products.

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

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing authorization to certain physicians or medical centers that have undergone specialized training, limiting treatment to 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.

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 candidate, 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

We may not be able to complete the clinical trials required for our product candidate 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 candidate, 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 candidate on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would harm our long-term business, results of operations, financial condition and prospects.

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

Qtrypta™ (M207) and any other product candidates we develop in the future may have undesirable side effects or have characteristics that are unexpected. These could be attributed to the active ingredient or class of drug or to our unique formulation of our product candidate, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials, including the imposition of clinical holds, and could result in a more restrictive label or delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

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

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

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

While we currently manufacture Qtrypta™ (M207) internally, we have entered into agreements with third party CMOs related to the development, manufacture, and supply of Qtrypta™ (M207). 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 hinder our ability to meet Qtrypta™ (M207) production demand for our clinical trials and delay the development or regulatory approval of Qtrypta™ (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 Qtrypta™ (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 incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Regulatory approval of Qtrypta™ (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 Qtrypta™ (M207) or our future product candidates, and could delay our preclinical studies, clinical trials and regulatory submissions with respect thereto. In addition, Qtrypta™ (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 candidate for our clinical trials and we have no experience manufacturing on a commercial scale.

We have limited experience manufacturing our product candidate, Qtrypta™ (M207), and to date have only manufactured our product candidate for our clinical trials. If our product candidate is approved, we will need to scale up our own capabilities or those of our CMOs to support the production of commercial level quantities of our product candidate, which may require expensive process improvements.

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

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

If approved for marketing, the commercial success of Qtrypta™ (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 our product candidate is approved but does 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 candidate 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 candidate 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 candidate not commercially viable. For example, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our product candidate 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 candidate. Moreover, approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of product candidate. Any of the foregoing scenarios could materially harm the commercial success of our product candidate.

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

Because we have limited financial and managerial resources, we have decided to focus on developing our product candidate Qtrypta™ (M207) for treatment of migraine. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current

and future research and development programs and product candidate for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We use customized equipment to coat and package our microneedle patch system; any production or equipment performance failures could negatively impact our clinical trials of Qtrypta™ (M207) or any other product candidates we may develop or sales of our product candidate(s), 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 of any future product candidates and if approved, our customers' demands for Qtrypta™ (M207) or our future approved product candidate(s), if any each of which could adversely affect our business, financial condition and results of operations.

We 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 or fail to maintain or achieve satisfactory regulatory compliance.

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

There can be no assurance that our supply of these various components will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers and cannot ensure that they will deliver to us the components we order on time, or at all. Any failure or refusal to supply the components for Qtrypta™ (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 candidate could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable, the lead time needed to establish a new relationship can be lengthy, and because the expenses relating to the transfer of necessary technology and processes could be significant. It may take several years to establish an alternative source of supply for our product candidate and to have any such new source approved by the FDA, the European Medicines Agency, 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 comply with applicable regulatory requirements or 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.

There are limited number of third party service providers that specialize or have the expertise required to achieve our business objectives. In particular, there would be a significant increase in clinical trial expenses, including adopting a new electronic data capture platform or other technology platforms, the need to enter into new contracts and costs associated with the transfer of data,

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

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

We currently depend primarily on one 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 fails to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize Qtrypta™ (M207) or any other product candidates we may develop.

We have contracted with CMOs (including Patheon) to produce, in collaboration with us, Qtrypta™ (M207), for commercial use in the United States. We have not entered into any agreements with any alternate suppliers for Qtrypta™ (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 Qtrypta™ (M207). Additionally, if Qtrypta™ (M207) or any other future product candidates is approved by the FDA or other regulatory agencies for commercial sale or if Qtrypta™ (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 Qtrypta™ (M207) exposes us to certain risks, including the following:

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

Even though we have an agreement with a CMO, Patheon, to supply Qtrypta™ (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 Qtrypta™ (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.

The manufacturer(s) of Qtrypta™ (M207) are obliged to operate in accordance with FDA-mandated 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 Qtrypta™ (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 and the FDA's strict regulatory requirements, and 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 in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspensions or withdrawal of approvals, seizures or recalls of product, operating restrictions, and criminal prosecutions.

The manufacturer of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly-enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of Qtrypta™ (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 Qtrypta™ (M207) in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand for Qtrypta™ (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 Qtrypta™ (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, Qtrypta™ (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 candidate to market and generate revenue.

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

RISKS RELATED TO MARKETING AND SALE OF OUR PRODUCTS

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

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to 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 Qtrypta™ (M207) does not obtain sufficient market share against competitive products, we may not achieve substantial product revenues and our business will suffer.

The market for our product candidate is characterized by intense competition and rapid technological advances. Our product candidates will, if approved, compete with a number of existing and future drug delivery systems and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our product candidate or may offer comparable performance at a lower cost. If our product candidate fails 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 Qtrypta™ (M207) 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 candidate or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our product candidate 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.

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 candidate in clinical trials and the sale of any product candidate for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product 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 candidate, but we may be unable to obtain commercially reasonable product liability insurance for any product candidate approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or a series of claims brought against us, particularly if judgments exceed our insurance coverage, could cause our stock price to decline and could adversely affect our results of operations and business.

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

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

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

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

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

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

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

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

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 candidate. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or product that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

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

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

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or

products in a non-infringing manner. Third parties may have patents that could prevent us from marketing our own patented product candidate. Third parties may also seek to market generic versions of any of our approved product. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidate. 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.

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 candidate, and our patent protection could be reduced or eliminated for non-compliance for these requirements.

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

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

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

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

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

We conduct freedom-to-operate studies to guide our early-stage research and development away from areas where we are likely to encounter obstacles in the form of third party intellectual property conflicts, and to assess the advisability of licensing third party intellectual property or taking other appropriate steps to address any freedom-to-operate or development issues. However, with respect to third party intellectual property, it is impossible to establish with certainty that our product candidate will be free of claims by third party intellectual property holders or whether we will require licenses from such third parties. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications.

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

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

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

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

We intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for Qtrypta™ (M207) and potentially for our future product candidates where applicable. Such filings involve significant costs, and we may also encounter difficulties or delays in obtaining regulatory approval for Qtrypta™ (M207) or any future product candidates under Section 505(b)(2).

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

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved product or the FDA's prior findings of safety and effectiveness for a previously approved product, the Section 505(b)(2) applicant must submit patent certifications in its Section 505(b)(2) application with respect to any patents for the previously approved product on which the applicant's application relies and that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (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 candidate 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 candidate only to be subject to significant delay and patent litigation before our product candidate may be commercialized, if at all.

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

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

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. If we initiate legal proceedings against a third party to enforce a patent covering our product candidate, 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 our product candidate, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

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

On September 16, 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position.

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

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain

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

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

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

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

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

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

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

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

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

If we do not obtain patent term extensions and data exclusivity for Qtrypta™ (M207) or any of our future product candidates, our business may be materially harmed.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidate, 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 candidate, which are aimed initially at the generic market and are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

RISKS RELATED TO LEGISLATION AND ADMINISTRATIVE ACTIONS

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including 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. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties and exclude the entity from participation in Medicare, Medicaid and other government healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); 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.

- 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.

Our ability to generate revenue from the sale of our product candidate 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.

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

Additionally, healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidate 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 our product candidate, once approved, market acceptance of the product could be reduced.

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

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 ("ACA") is significantly changing the way healthcare is financed by both governmental and private insurers. From time to time, legislation is implemented to rein in rising healthcare expenditures. The ACA included a number of provisions affecting the pharmaceutical 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. The ACA included new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, entities that manufacture, produce or import medical devices were required to pay an excise tax in an amount

equal to 2.3% of the price for which such devices are sold in the United States. Through a series of legislative amendments, the tax was suspended for 2016 through 2019, but is scheduled to return beginning in 2020, absent further Congressional action. In addition, among other things, the ACA also established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. The increased funding and focus on comparative clinical effectiveness research, which compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products, may result in lower reimbursements by payers for our product and decreased profits to us. Other federal legislative changes have been proposed and adopted since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2027 unless additional Congressional action is taken. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our out-licensed products and product candidates (if and when approved) and accordingly, our financial results.

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 is 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”. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business. 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 candidate.

If our product candidate becomes 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 product 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 candidate in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those actions as recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement for our product candidate 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.

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 candidate 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 completed the implementation of a company-wide ERP system in the first fiscal quarter of 2019 to handle the business and financial processes within our operations and corporate functions. 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 following the implementation process, or if the systems and the associated process changes do not give rise to the benefits that we expect. If we do not effectively maintain or integrate the ERP system as planned or if the systems do not operate as intended, it may adversely affect our ability to manage and run our business operations, file reports with the SEC in a timely manner, and/or otherwise affect our internal control environment. Any of these consequences could have an adverse effect on our results of operations and financial condition.

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 December 31, 2018, for example, our stock has traded in a range with a low of $1.85 and a high of $25.70. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. We do not, for example, have any 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.

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

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

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

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

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

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

The trading market for our common stock depends in part on the research and reports that securities and industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes unfavorable

research about our business, or if our clinical trials or operating results fail to meet the analysts' expectations, our stock price would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

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.

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.

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 ("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.

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, 2020, 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.

Item 6. Exhibits

Exhibit number	Description
10.1	Purchase Order #9186, dated as of February 14, 2019 between Zosano Pharma Corporation and Harro Hofliger Packaging Systems.
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*

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: May 14, 2019

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)

ZOSANO PHARMA

Zosano Pharma Corporation
34790 Ardentech Court
Fremont, CA 94555
United States
Phone: 510-745-1200

Purchase Order	Revision	Order Date
P09186	1	5/23/2018
Supplier		Print Date
10230		2/14/2019

Purchase Order

Supplier
Harro Hofliger Packaging Systems
350 S. Main St.
Suite 315
Doylestown, PA 18901
United States

Ship To
Zosano Pharma Corporation
34790 Ardentech Court
Fremont, CA 94555
United States
510-745-1200

Contact	Ship Via
	Best Way
Payment Terms	**FOB**
Net 30 days	Destination

Line	Item Number	Rev	Due Date	Qty Ord	Qty Open	UM	T	Unit Cost	Extended Cost
1	ZCAP		12/31/2019	8,545,711.0	5,659,283.	DL	Y	1.00	5,659,283.30
	Primary Packaging Machin								
	Supplier Item: M207								
	Payment terms: 30% down with order 20% after finalizing/approval of design 20% after completion of manufacturing of parts/at assembly start 20% after approval at manufacturer's plant & before shipment 10% within 30 days at the latest after date of invoice, net								
	Costs based on total of €9,800,000.00 with exchange rate of €1 to $1.178 as quote on yahoo.com on 5/22/18								
2	Change Order #1		12/31/2019	1,320,538.0	1,320,538.	DL	Y	1.00	1,320,538.00
	Design changes								
	Per quote 5035-6661/18 PR108313 Payment schedule: 1/1/19 13% $171,669.94 with order 1/1/19 13% $171,669.94 60 days after PO acceptance 1/1/19 25% $330,134.50 after design approval 5/31/19 20% $264,107.60 at assembly start 2/28/20 20% $264,107.60 after approval at plant/before shipment 3/27/20 9% $118,848.42 30 days after final invoice								
	Approved by Univeral Written Consent of Board of Directors. See contract # 2019-016 Harro Hofliger.								

		Tax Rate	Taxable	Non Taxable Amount	Tax Date
		9.25%	6,979,821.3	0.00	

USD	Line Total	6,979,821.30
	Total Tax	645,633.48
	Total Amount	7,625,454.78

Exhibit 31.1

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

I, John Walker, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 14, 2019

By: /s/ John Walker
John Walker
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Gregory Kitchener, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 14, 2019

By: /s/ Gregory Kitchener
Gregory Kitchener
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

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

1. The Quarterly Report on Form 10-Q for the period ended March 31, 2019 of the Company (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

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

Date: May 14, 2019

By: /s/ John Walker
John Walker
Chief Executive Officer
(Principal Executive Officer)

Date: May 14, 2019

By: /s/ Gregory Kitchener
Gregory Kitchener
Chief Financial Officer
(Principal Financial and Accounting Officer)