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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended JUNE 30, 2019

OR

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

For the transition period from to

Commission File Number 001-37508

Neos Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2834**	**27-0395455**
State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2940 N. Hwy 360
Grand Prairie, TX 75050
(972) 408-1300

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	NEOS	The NASDAQ Global Market

The number of shares outstanding of the registrant's common stock as of August 2, 2019: 49,730,275 shares.

NEOS THERAPEUTICS, INC.

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Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our anticipated cash needs and our estimates regarding our anticipated expenses, capital requirements and our needs for additional financings;
- our ability to successfully commercialize Adzenys XR-ODT®, Cotempla XR-ODT® and Adzenys ER® or develop and commercialize any other future product or product candidate;
- our ability to maintain our license for NT0502, to successfully complete clinical development of this molecule, to file for and obtain regulatory approval of NT0502 and to otherwise realize the intended benefits of this license;
- our debt facility agreement, as amended, with Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. and our ability to satisfy the repayment obligations thereunder;
- the cost or other aspects of the future sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or the timing, cost or other aspects of the commercial launch and future sales of any other future product or product candidate;
- our ability to increase our manufacturing and distribution capabilities for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or any other future product or product candidate;
- the attention deficit hyperactivity disorder patient market size and market adoption of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER by physicians and patients;
- the therapeutic benefits, effectiveness and safety of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or any other future product or product candidate;
- our expectations regarding the commercial supply of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, or any other future products, or our generic Tussionex;
- our ability to receive, and the timing of any receipt of the U.S. Food and Drug Administration, ("FDA"), approvals, or other regulatory action in the United States and elsewhere, for any future product candidate;
- our expectations regarding federal, state and foreign regulatory requirements;
- our entry into the settlement and licensing agreement with Actavis Laboratories FL, Inc. ("Actavis"), the effect of our agreement with Actavis on its Abbreviated New Drug Application ("ANDA") and with the FDA for a generic version of Adzenys XR-ODT, and the expected timing of the marketing of Actavis's generic version of Adzenys XR-ODT under the ANDA;

- our entry into the settlement and licensing agreement with Teva Pharmaceuticals USA, Inc. ("Teva"), the effect of our agreement with Teva on its ANDA and with the FDA for a generic version of Cotempla XR-ODT, and the expected timing of the marketing of Teva's generic version of Cotempla XR-ODT under the ANDA;
- our product research and development activities, including the timing and progress of our ongoing and planned clinical trials, and projected expenditures;
- issuance of patents to us by the U.S. Patent and Trademark Office and other governmental patent agencies;
- our ability to achieve profitability;
- our staffing needs; and
- the additional risks, uncertainties and other factors described under the caption "Risk Factors" in this Quarterly Report on Form 10-Q.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

Furthermore, this Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS.

Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	June 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 25,757	$ 46,478
Short-term investments	4,494	—
Accounts receivable, net of allowances for chargebacks and cash discounts of $2,509 and $1,865, respectively	20,144	27,801
Inventories	12,374	10,367
Other current assets	1,811	4,032
Total current assets	64,580	88,678
Property and equipment, net	7,636	7,914
Operating lease right-of-use assets	3,274	—
Intangible assets, net	13,619	14,616
Other assets	149	149
Total assets	$ 89,258	$ 111,357
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 6,556	$ 12,730
Accrued expenses	33,684	35,818
Current portion of operating lease liabilities	606	—
Current portion of long-term debt	16,372	8,557
Total current liabilities	57,218	57,105
Long-Term Liabilities:		
Long-term debt, net of current portion	28,489	43,217
Operating lease liabilities	3,608	—
Derivative liability	1,373	2,017
Deferred rent	—	989
Other long-term liabilities	182	184
Total long-term liabilities	33,652	46,407
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized at June 30, 2019 and December 31, 2018 ; 49,764,076 and 49,730,275 shares issued and outstanding, respectively, at June 30, 2019; 49,710,104 and 49,676,303 shares issued and outstanding, respectively, at December 31, 2018	50	50
Treasury stock, at cost, 33,801 shares at June 30, 2019 and December 31, 2018	(352)	(352)
Additional paid-in capital	327,035	325,130
Accumulated deficit	(328,346)	(316,983)
Accumulated other comprehensive income	1	—
Total stockholders' equity (deficit)	(1,612)	7,845
Total liabilities and stockholders' equity	$ 89,258	$ 111,357

See notes to condensed consolidated financial statements.

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net product sales	$ 15,643	$ 11,363	$ 30,277	$ 22,092
Cost of goods sold	5,099	6,987	11,495	12,208
Gross profit	10,544	4,376	18,782	9,884
Research and development expenses	2,009	2,381	5,206	4,072
Selling and marketing expenses	7,269	11,557	14,338	24,547
General and administrative expenses	3,712	3,705	7,505	7,051
Loss from operations	(2,446)	(13,267)	(8,267)	(25,786)
Interest expense	(1,987)	(2,232)	(4,102)	(4,452)
Other income, net	670	292	1,006	595
Net loss	$ (3,763)	$ (15,207)	$ (11,363)	$ (29,643)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	49,727,718	29,008,909	49,715,707	29,002,966
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.52)	$ (0.23)	$ (1.02)

See notes to condensed consolidated financial statements.

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (3,763)	$ (15,207)	$ (11,363)	$ (29,643)
Other comprehensive income:				
Net unrealized gain on short-term investments	2	4	1	7
Total other comprehensive income	$ 2	$ 4	$ 1	$ 7
Comprehensive loss	$ (3,761)	$ (15,203)	$ (11,362)	$ (29,636)

See notes to condensed consolidated financial statements.

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except shares)
(unaudited)

	Three Months Ended June 30,			
	2019		2018	
	Shares	Amount	Shares	Amount
	(In $ thousands, except share data)			
Preferred Stock				
Balance as of the beginning of the period	—	$ —	—	$ —
Balance as of the end of the period	—	—	—	—
Common Stock				
Balance as of the beginning of the period	49,756,317	50	29,030,757	29
Issuance of common stock upon RSU conversion	7,759	—	17,832	—
Balance as of the end of the period	49,764,076	50	29,048,589	29
Treasury Stock				
Balance as of the beginning of the period	(33,801)	(352)	(33,801)	(352)
Balance as of the end of the period	(33,801)	(352)	(33,801)	(352)
Additional Paid-In Capital				
Balance as of the beginning of the period		326,014		275,551
Payroll tax withheld for RSU releases		(1)		—
Share-based compensation expense		1,022		1,086
Balance as of the end of the period		327,035		276,637
Retained Earnings				
Balance as of the beginning of the period		(324,583)		(279,744)
Net loss		(3,763)		(15,207)
Balance as of the end of the period		(328,346)		(294,951)
Accumulated Other Comprehensive Income (Loss), Net				
Balance as of the beginning of the period		(1)		(3)
Net unrealized gain on investments		2		4
Balance as of the end of the period		1		1
Total stockholders' deficit		$ (1,612)		$ (18,636)

	Six Months Ended June 30,			
	2019		2018	
	Shares	Amount	Shares	Amount
	(In $ thousands, except share data)			
Preferred Stock				
Balance as of the beginning of the period	—	$ —	—	$ —
Balance as of the end of the period	—	—	—	—
Common Stock				
Balance as of the beginning of the period	49,710,104	50	29,030,757	29
Issuance of common stock upon RSU conversion	18,765	—	17,832	—
Shares issued for exercise of stock options	35,207	—	—	—
Balance as of the end of the period	49,764,076	50	29,048,589	29
Treasury Stock				
Balance as of the beginning of the period	(33,801)	(352)	(33,801)	(352)
Balance as of the end of the period	(33,801)	(352)	(33,801)	(352)
Additional Paid-In Capital				
Balance as of the beginning of the period		325,130		274,584
Shares issued for exercise of stock options		11		—
Payroll tax withheld for RSU releases		(2)		—
Share-based compensation expense		1,896		2,053
Balance as of the end of the period		327,035		276,637
Retained Earnings				
Balance as of the beginning of the period		(316,983)		(265,308)
Net loss		(11,363)		(29,643)
Balance as of the end of the period		(328,346)		(294,951)
Accumulated Other Comprehensive Income (Loss), Net				
Balance as of the beginning of the period		—		(6)
Net unrealized gain on investments		1		7
Balance as of the end of the period		1		1
Total stockholders' deficit		$ (1,612)		$ (18,636)

See notes to condensed consolidated financial statements.

Neos Therapeutics, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Six Months Ended June 30,	
	2019	**2018**
Cash Flows From Operating Activities:		
Net loss	$ (11,363)	$ (29,643)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,896	2,053
Depreciation and amortization of property and equipment	1,049	850
Amortization of patents and other intangible assets	1,052	869
Changes in fair value of earnout, derivative and warrant liabilities	(644)	(349)
Amortization of senior debt discounts	696	427
Amortization of short-term investment purchase discounts	(58)	(106)
(Gain) loss on sale of equipment	(2)	1
Other adjustments	—	(47)
Changes in operating assets and liabilities:		
Accounts receivable	7,657	(4,306)
Inventories	(2,007)	(981)
Other assets	2,221	2,251
Accounts payable	(6,174)	(5,400)
Accrued expenses	(2,134)	13,184
Operating lease liabilities	(49)	—
Net cash used in operating activities	(7,860)	(21,197)
Cash Flows From Investing Activities:		
Purchases of short-term investments	(7,193)	(17,904)
Sales and maturities of short-term investments	2,758	26,743
Capital expenditures	(365)	(814)
Intangible asset expenditures	(55)	(28)
Net cash (used in) provided by investing activities	(4,855)	7,997
Cash Flows From Financing Activities:		
Proceeds from the issuance of common stock, net of issuance costs	11	—
Payments made on borrowings	(8,015)	(451)
Payment of payroll taxes withheld for releases of restricted stock units	(2)	—
Net cash used in financing activities	(8,006)	(451)
Decrease in cash and cash equivalents	(20,721)	(13,651)
Cash and Cash Equivalents:		
Beginning	46,478	31,969
Ending	$ 25,757	$ 18,318
Supplemental Disclosure of Noncash Transactions:		
Acquired equipment under finance lease	406	105
Finance lease liability from purchase of equipment	$ 406	$ 105
Supplemental Cash Flow Information:		
Interest paid	$ 3,510	$ 4,116

See notes to condensed consolidated financial statements.

Neos Therapeutics, Inc. and Subsidiaries

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and nature of operations

Neos Therapeutics, Inc., a Delaware corporation, and its subsidiaries (the "Company") is a fully integrated pharmaceutical company. The Company has developed a broad, proprietary modified-release drug delivery technology that enables the manufacture of single and multiple ingredient extended-release ("XR") pharmaceuticals in patient- and caregiver-friendly orally disintegrating tablet ("ODT") and oral suspension dosage forms. The Company has a pipeline of extended-release pharmaceuticals including three products approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of attention deficit hyperactivity disorder ("ADHD"). Adzenys XR-ODT was approved by the FDA in January 2016 and launched commercially in May 2016. The Company received approval from the FDA for Cotempla XR-ODT, its methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, in June 2017, and launched commercially in September 2017. Also, the Company received approval from the FDA for Adzenys ER oral suspension ("Adzenys ER") in September 2017 and launched this product in February 2018. In addition, the Company manufactures and markets a generic Tussionex (hydrocodone and chlorpheniramine) ("generic Tussionex"), extended-release oral suspension for the treatment of cough and upper respiratory symptoms of a cold. In addition to its marketed products, the Company is developing NT0502, its product candidate for the treatment of sialorrhea and NT-0400, its XR-ODT product candidate for nausea and vomiting.

Note 2. Summary of significant accounting policies

Basis of presentation: The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"), for reporting on Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations, and cash flows. In the opinion of management, all adjustments (consisting of normal, recurring adjustments) necessary for a fair presentation of results of operations for and financial condition as of the end of the interim period have been included. Results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results for the year ending December 31, 2019 or any period thereafter. The audited consolidated financial statements as of and for the year ended December 31, 2018 included information and footnotes necessary for such presentation and were included in the Neos Therapeutics, Inc. Annual Report on Form 10-K filed with the SEC on March 18, 2019. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2018.

Principles of consolidation: At June 30, 2019 and December 31, 2018 and for the three and six months ended June 30, 2019 and 2018, the consolidated financial statements include the accounts of the Company and its four wholly-owned subsidiaries. All significant intercompany transactions have been eliminated.

Use of estimates: The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates.

Liquidity: During 2018 and the three and six months ended June 30, 2019, the Company incurred operating losses and used cash to fund operations. Management intends to achieve profitability through revenue growth from its currently marketed pharmaceutical products. The Company does not anticipate it will be profitable until such time as revenues from Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER increase substantially over current levels. In November 2018, the Company completed an offering of its common stock and restructured its outstanding debt, which reduced and possibly could delay the amount of principal payable in cash. Accordingly, management has performed the review required for going concern accounting and believes the Company presently has sufficient liquidity to continue to operate for the next twelve months after the filing of this Report on Form 10-Q.

Cash equivalents: The Company invests its available cash balances in bank deposits and money market funds. The Company considers highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company's primary objectives for investment of available cash are the preservation of capital and the maintenance of liquidity.

Short-term investments: Short-term investments, if any, consist of debt securities that have original maturities greater than three months but less than or equal to one year and are classified as available-for-sale securities. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of material tax effects reported, as accumulated other comprehensive income or loss, which is a separate component of stockholders' equity (deficit). Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in other income in the consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income are recognized in other income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with government agencies, or corporate institutions whose debt is rated as investment grade. The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date, if any, as non-current assets.

Inventories: Inventories are measured at the lower of cost (first in, first out) or net realizable value. Inventories have been reduced by an allowance for excess and obsolete inventories. Cost elements include material, labor and manufacturing overhead. Inventories consist of raw materials, work in process and finished goods.

Until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable, pre-launch inventories are expensed into research and development. Manufacturing costs for the production of Adzenys XR-ODT incurred after the January 27, 2016 FDA approval date, for the production of Cotempla XR-ODT incurred after June 30, 2017, following the FDA approval date of June 19, 2017, and for the production of Adzenys ER incurred after September 30, 2017, following the FDA approval date of September 15, 2017, are being capitalized into inventory.

Derivative liabilities: The Company evaluates its debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in the Company's financial statements. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as a liability and the change in fair value is recorded in other income (expense) in the consolidated results of operations. In circumstances where there are multiple embedded instruments that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

When the Company has determined that the embedded conversion options should not be bifurcated from their host instruments, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption and are classified in interest expense in the consolidated results of operations.

Intangible assets: Intangible assets subject to amortization, which principally include proprietary modified-release drug delivery technology, the costs to acquire the rights to Tussionex Abbreviated New Drug Application and patents, are recorded at cost and amortized over the estimated lives of the assets, which primarily range from 10 to 20

years. The Company estimates that the patents it has filed have a future beneficial value. Therefore, costs associated with filing for its patents are capitalized. Once the patent is approved and commercial revenue realized, the costs associated with the patent are amortized over the useful life of the patent. If the patent is not approved, the costs will be expensed. For new product candidates, patent applications and related expenses are expensed as incurred.

Revenue recognition: Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company makes estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees, wholesaler chargebacks and estimated rebates) to be incurred on the selling price of the respective product sales, and recognizes the estimated amount as revenue when it transfers control of the product to its customers (e.g., upon delivery). Variable consideration is determined using either an expected value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint will require the use of significant management judgment and other market data. The Company provides for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. The Company analyzes recent product return history and other market data obtained from its third party logistics providers ("3PLs") to determine a reliable return rate. Additionally, management analyzes historical savings offers and rebate payments based on patient prescriptions dispensed for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER and information obtained from third party providers to determine these respective variable considerations.

The Company sells its generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to a limited number of pharmaceutical wholesalers, all subject to rights of return. Pharmaceutical wholesalers buy drug products directly from manufacturers. Title to the product passes upon delivery to the wholesalers, when the risks and rewards of ownership are assumed by the wholesaler (freight on board destination). These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

The Company views its operations and manages its business in one operating segment, which is the development, manufacturing and commercialization of pharmaceuticals.

Disaggregation of revenue

The following table disaggregates the Company's net product sales by product:

	Three Months Ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
	(in thousands)			
Adzenys XR-ODT	$ 7,241	$ 6,516	$ 13,898	$ 11,508
Cotempla XR-ODT	6,513	4,342	12,286	7,989
Adzenys ER	146	(28)	331	175
Generic Tussionex	1,743	533	3,762	2,420
	$ 15,643	$ 11,363	$ 30,277	$ 22,092

Net product sales

Net product sales represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER include savings offers, prompt payment discounts, wholesaler fees, estimated rebates to be incurred on the selling price of the respective product sales and estimated allowances for product returns.

Gross to net sales adjustments for generic Tussionex include prompt payment discounts, estimated allowances for product returns, wholesaler fees, estimated government rebates and estimated chargebacks to be incurred on the selling price of generic Tussionex related to the respective product sales.

The Company recognizes total gross product sales less gross to net sales adjustments as revenue based on shipments from 3PLs to the Company's wholesaler customers.

Savings offers for branded products

The Company offers savings programs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. The Company records the amount of redeemed savings offers based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustments at the time revenue is recognized.

Prompt payment discounts

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized.

Wholesale distribution fees

Wholesale distribution fees are based on definitive contractual agreements for the management of the Company's products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

Rebates

The Company's branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER are subject to commercial managed care and government managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating managed care organizations and federal and/or state governments. Calculations related to rebate accruals of branded products are estimated based on information from third-party providers.

The Company's generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Generic Tussionex government rebates are estimated based upon rebate payment data available from sales of the Company's generic Tussionex product over the past three years.

Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized. Historical trends of estimated rebates will be regularly monitored, which may result in adjustments to such estimates in the future.

Product returns

Wholesalers' contractual return rights are limited to defective product, product that was shipped in error, product ordered by customer in error, product returned due to overstock, product returned due to dating or product returned due to recall or other changes in regulatory guidelines. The return policy for expired product allows the wholesaler to return such product starting six months prior to expiry date to twelve months post expiry date. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized.

The Company analyzed recent branded product return history and other market data obtained from the Company's 3PLs, as well as data available from sales of its branded products, to determine a reliable return rate for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Generic Tussionex product returns were estimated based upon return data available from sales of the Company's generic Tussionex product over the past three years.

Wholesaler chargebacks for generic product

The Company's generic Tussionex products are subject to certain programs with wholesalers whereby pricing on products is discounted below wholesaler list price to participating entities. These entities purchase products through wholesalers at the discounted price, and the wholesalers charge the difference between their acquisition cost and the discounted price back to the Company. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized based on information provided by third parties.

Due to estimates and assumptions inherent in determining the amount of returns, rebates and chargebacks, the actual amount of returns, claims for rebates and chargebacks may be different from the estimates, at which time reserves would be adjusted accordingly. Wholesale distribution fees and the allowance for prompt pay discounts are recorded at the time of shipment and such fees and allowances are recorded in the same period that the related revenue is recognized.

Research and development costs: Research and development costs are charged to operations when incurred and include salaries and benefits, facilities costs, overhead costs, raw materials, laboratory and clinical supplies, clinical trial costs, contract services, fees paid to regulatory authorities for review and approval of the Company's product candidates and other related costs.

Advertising costs: Advertising costs are comprised of print and electronic media placements that are expensed as incurred. There were no advertising costs recognized during the three and six months ended June 30, 2019. The Company recognized advertising costs of $0.2 million and $0.4 million during the three and six months ended June 30, 2018, respectively.

Share-based compensation: Share-based compensation awards, including grants of stock options, restricted stock, restricted stock units ("RSUs") and modifications to existing stock options, are recognized in the statement of operations based on their fair values. Compensation expense related to stock-based awards is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

For performance-based stock awards, compensation expense is recognized on a straight-line basis, based on the grant date fair value, over the performance period or through the vesting date, whichever is longer. Management monitors the probability of achievement of the performance conditions and adjusts stock-based compensation expense, if necessary.

After the closing of the Company's IPO, the Company's board of directors has determined the fair value of each share of underlying common stock based on the closing price of the Company's common stock as reported by the NASDAQ Global Market on the date of grant.

Under ASU No. 2017-09 guidance for accounting for share-based payments, the Company has elected to continue estimating forfeitures at the time of grant and, if necessary, revise the estimate in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest.

Paragraph IV litigation costs: Legal costs incurred by the Company in the enforcement of the Company's intellectual property rights, are charged to expense as incurred.

Income taxes: Income taxes are accounted for using the liability method, under which deferred taxes are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax laws that will be in effect when the differences are expected to reverse.

Management evaluates the Company's tax positions in accordance with guidance on accounting for uncertainty in income taxes. Using that guidance, tax positions initially need to be recognized in the financial statements when it is more likely than not that the position will be sustained upon examination. As of June 30, 2019 and December 31, 2018, the Company has unrecognized tax benefits associated with uncertain tax positions in the consolidated financial statements. These uncertain tax positions were netted against net operating losses (NOLs) with no separate reserve for uncertain tax positions required.

Deferred tax assets should be reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized. In evaluating the objective evidence that historical results provide, the Company considered that three years of cumulative operating losses was significant negative evidence outweighing projections for future taxable income. Therefore, at June 30, 2019 and December 31, 2018, the Company determined that it is more likely than not that the deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance to reduce deferred tax assets to zero. The Company may not ever be able to realize the benefit of some or all of the federal and state loss carryforwards, either due to ongoing operating losses or due to ownership changes, which limit the usefulness of the loss carryforwards.

Recent accounting pronouncements: In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The standard is effective for public entities for the fiscal years ending after December 15, 2020, with early adoption permitted for the removed disclosures and delayed adoption permitted for the new disclosures. The removed and modified disclosures will be adopted on a retrospective basis and the new disclosures will be adopted on a prospective basis. The Company is currently evaluating the impact of adopting ASU 2018-13 on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a write-down. The standard is effective for public entities for the fiscal years ending after December 15, 2020, with early adoption permitted through a modified retrospective approach. The Company is currently evaluating the impact of adopting ASU 2016-13 on its consolidated financial statements.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement -Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the TCJA, and requires certain disclosures about stranded tax effects. ASU 2018-02 is effective for entities for fiscal years beginning after December 15, 2018 with early adoption permitted, and shall be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the corporate income tax rate in the TCJA is recognized. This standard became effective for the Company on January 1, 2019. The adoption of this standard did not have a material impact on the Company's consolidated results of operations or financial position.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (the "New Lease Standard"). The New Lease Standard supersedes the lease guidance under FASB Accounting Standards Codification ("ASC") *Topic 840, Leases* ("Prior GAAP"), resulting in the creation of FASB ASC Topic 842, Leases. Under the new guidance, lessees are required to recognize in the statement of financial position the following for all finance and operating leases (with the exception of short-term leases) at the commencement date: 1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and 2) a right-of-use ("ROU") asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term.

In January, July and December 2018, the FASB issued additional amendments to the new lease guidance relating to, transition, and clarification. The July 2018 amendment, ASU No. 2018-11, Leases (Topic 842): Targeted

Improvements, provides an optional transition method that allows entities to elect to apply the standard using the modified retrospective transition method, which did not require the Company to adjust comparative periods.

The Company adopted this standard on the effective date of January 1, 2019 and elected to use the modified retrospective transition method approach at transition. Therefore, no adjustments are made to amounts in prior period financial statements.

In addition, the Company elected the following practical expedients:

1) the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allows the Company to carry forward the historical lease classification;

2) the land easements practical expedient, which allows the Company to carry forward the accounting treatment for land easements on existing agreements;

3) the short-term lease practical expedient, which allows the Company to exclude short-term leases from recognition in the unaudited consolidated balance sheets; and

4) the bifurcation of lease and non-lease components practical expedient, which does not require the Company to bifurcate lease and non-lease components for all classes of assets.

The adoption of this accounting standard resulted in the recording of Operating lease ROU assets and Operating lease liabilities of $3.4 million and $4.3 million, respectively, as of January 1, 2019. The difference between the operating lease assets and liabilities was recorded as an adjustment to deferred rent for $0.9 million relating to real estate leases. The adoption of ASU 2016-02 had no impact on Accumulated Deficit.

The Company implemented additional internal controls to identify lease contracts and enable the preparation of financial information related to the New Lease Standard. See Note 9 for additional information.

From time to time, additional new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Note 3. Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. Potentially dilutive securities, which include warrants, outstanding stock options under the stock option plans and shares issuable in future periods, such as RSU awards, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position. Restricted stock is considered legally issued and outstanding on the grant date, while RSUs are not considered legally issued and outstanding until the RSUs vest. Once the RSUs vest, equivalent common shares will be issued or issuable to the grantee and therefore the RSUs are not considered for inclusion in total common shares issued and outstanding until vested.

The following potentially dilutive securities outstanding as of June 30, 2019 and 2018 were excluded from consideration in the computation of diluted net loss per share of common stock for the three and six months ended June 30, 2019 and 2018, respectively, because including them would have been anti-dilutive:

	June 30,	
	2019	2018
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	70,833	70,833
Stock options outstanding	4,528,342	3,576,062
RSUs outstanding	55,626	159,064

Note 4. Fair value of financial instruments

The Company records financial assets and liabilities at fair value. The carrying amounts of certain financial assets and liabilities including cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued liabilities, approximated their fair value due to their short-term maturities. The remaining financial instruments were reported on the Company's condensed consolidated balance sheets at amounts that approximate current fair values based on market based assumptions and inputs.

As a basis for categorizing inputs, the Company uses a three tier fair value hierarchy, which prioritizes the inputs used to measure fair value from market based assumptions to entity specific assumptions as follows:

Level 1: Unadjusted quoted prices for identical assets in an active market.

Level 2: Quoted prices in markets that are not active or inputs that are observable either directly or indirectly for substantially the full-term of the asset.

Level 3: Prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. They reflect management's own assumptions about the assumptions a market participant would use in pricing the asset.

The following table presents the hierarchy for the Company's financial instruments measured at fair value on a recurring basis for the indicated dates:

	Fair Value as of June 30, 2019			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash and cash equivalents	$ 25,007	$ 750	$ —	$ 25,757
Short-term investments	—	4,494	—	4,494
Total financial assets	$ 25,007	$ 5,244	$ —	$ 30,251
Earnout liability	$ —	$ —	$ 37	$ 37
Derivative liability (see Note 8)	—	—	1,373	1,373
Total financial liabilities	$ —	$ —	$ 1,410	$ 1,410

	Fair Value as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash and cash equivalents	$ 27,419	$ 19,059	$ —	$ 46,478
Total financial assets	$ 27,419	$ 19,059	$ —	$ 46,478
Earnout liability	$ —	$ —	$ 37	$ 37
Derivative liability (see Note 8)	—	—	2,017	2,017
Total financial liabilities	$ —	$ —	$ 2,054	$ 2,054

The Company's Level 1 assets included bank deposits, certificates of deposit and actively traded money market funds with an original maturity of 90 days or less at June 30, 2019 and December 31, 2018. Asset values were considered to approximate fair value due to their short-term nature.

The Company's Level 2 assets included commercial paper and corporate bonds with maturities of less than one year that are not actively traded which were classified as available-for-sale securities. The level 2 cash equivalents consist of U.S. agency bonds and corporate commercial paper that mature in less than 90 days which are valued using quoted prices and other data values. The estimated fair values of these securities were determined by third parties using valuation techniques that incorporate standard observable inputs and assumptions such as quoted prices for similar assets, benchmark yields, reported trades, broker/dealer quotes, issuer spreads, benchmark securities, bids/offers and other pertinent reference data.

The Company's cash and cash equivalents and short-term investments had quoted prices at June 30, 2019 and December 31, 2018 as shown below:

	June 30, 2019		
	Amortized Cost	Unrealized Gain / (Loss)	Market Value
	(in thousands)		
Bank deposits and money market funds	$ 25,007	$ —	$ 25,007
Financial and corporate debt securities	5,243	1	5,244
	$ 30,250	$ 1	$ 30,251

	December 31, 2018		
	Amortized Cost	Unrealized Gain / (Loss)	Market Value
	(in thousands)		
Bank deposits and money market funds	$ 27,419	$ —	$ 27,419
Financial and corporate debt securities	19,059	—	19,059
	$ 46,478	$ —	$ 46,478

The Company's Level 3 liability included the fair value of the earnout liability and the fair value of the Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. derivative liability at June 30, 2019 and December 31, 2018.

The fair value of the derivative liability was determined after taking into consideration valuations using the Monte Carlo method based on assumptions at June 30, 2019 and December 31, 2018. There were no significant changes

in the pricing assumptions during the three and six months ended June 30, 2019. The methodologies and significant inputs used in the determination of the fair value of the debt derivative liability were as follows:

	Derivative Liability	
Date of Valuation	6/30/2019	12/31/2018
Valuation Method	Monte Carlo	Monte Carlo
Volatility (annual)	N/A	N/A
Time period from valuation until maturity of debt (yrs.)	2.9	3.4
Cumulative probability of a change in control prepayment implied by model	24 %	25 %
Cumulative probability of other accelerated prepayments implied by model	11 %	14 %
Discount rate	24.80 %	23.12 %
Fair value of liability at valuation date (thousands)	$ 1,373	$ 2,017

Significant changes to these assumptions would result in increases/decreases to the fair value of the debt derivative liabilities.

Changes in Level 3 liabilities measured at fair value for the periods indicated were as follows:

	Level 3 Liabilities (in thousands)
Balance at December 31, 2018	$ 2,054
Change in fair value	(644)
Balance at June 30, 2019	$ 1,410

Note 5. Inventories

Inventories at the indicated dates consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Raw materials	$ 4,007	$ 3,845
Work in progress	3,806	2,704
Finished goods	4,833	4,259
Inventory at cost	12,646	10,808
Inventory reserve	(272)	(441)
	$ 12,374	$ 10,367

Note 6. Sale-leaseback transaction

The Company accounts for the sale and leaseback transactions discussed below as capital leases. Accordingly, the leased assets are recorded in property and equipment and the capitalized lease obligations are included in long-term liabilities at the present value of the future lease payments in accordance with the terms of the lease (see Note 8). Lease payments are applied using the effective interest rate inherent in the leases. Depreciation of the property and equipment is included within cost of goods sold and operating expenses in the consolidated statements of operations and within depreciation and amortization of property and equipment in the consolidated statements of cash flows.

In February 2017, the Company entered into an agreement with Essex Capital Corporation (“Essex”) for the sale-leaseback of newly acquired assets of up to $5.0 million to finance its capital expenditures. Each lease under this

master agreement is for an initial term of 36 months and has an option to purchase the equipment at the end of the respective lease that management considers to be a bargain purchase option. Under this agreement, the Company entered into leases and sold assets with a total capitalized cost of $481,000 and $2,742,000 at effective interest rates of 14.3% and 14.9% on February 13, 2017 and June 30, 2017, respectively. The February sale resulted in net gains of $14,000 which has been deferred and is being amortized over the 36-month term of the lease. There was no gain or loss on the June 2017 sale.

For each of the three months ended June 30, 2019 and 2018, approximately $1,000, and for each of the six months ended June 30, 2019 and 2018, approximately $2,000, of the net gain on sale-leasebacks was recognized in other income on the condensed consolidated statements of operations.

Note 7. Accrued expenses

Accrued expenses as of June 30, 2019 and December 31, 2018 consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Accrued savings offers	$ 13,142	$ 11,289
Accrued rebates	5,036	7,762
Accrued customer returns	5,356	5,157
Accrued wholesaler fees	3,455	4,249
Accrued payroll and benefits	4,088	4,555
Other accrued expenses	2,607	2,806
Total accrued expenses	$ 33,684	$ 35,818

Note 8. Long-term debt

Long-term debt at the indicated dates consists of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Deerfield senior secured credit facility, net of discount of $2,639 and $3,334, respectively	$ 43,111	$ 49,916
Financing and capital leases, maturing through May 2024	1,750	1,858
	44,861	51,774
Less current portion	(16,372)	(8,557)
Long-term debt	$ 28,489	$ 43,217

Senior secured credit facility: On May 11, 2016, the Company entered into a $60.0 million senior secured credit facility (the "Facility") with Deerfield Private Design Fund III, L.P. (66 2/3% of Facility) and Deerfield Special Situations Fund, L.P. (33 1/3% of Facility) (collectively, "Deerfield"), as lenders. In February 2017, the Company closed an underwritten public offering of 5,750,000 shares of its common stock at a public offering price of $5.00 per share (see Note 10). Deerfield, the Company's senior lender, participated in the purchase of the Company's common shares as part of this public offering, and as a result, was classified as a related party at the time of the corresponding transactions.

Principal on the Facility was due in three equal annual installments beginning in May 2019 and continuing through May 2021, with a final payment of principal, interest and all other obligations under the Facility due May 11, 2022. Interest is due quarterly beginning in June 2016, at a rate of 12.95% per year. The Company had an option, which it exercised, to defer payment of each of the first four interest payments, adding such amounts to the outstanding loan principal. The aggregate $6.6 million in deferred interest payments (the "Accrued Interest") was due and payable on June

1, 2017. Borrowings under the Facility are collateralized by substantially all of the Company's assets, except the assets under capital lease. The terms of the Facility require the Company to maintain cash on deposit of not less than $5.0 million.

On June 1, 2017 (the "Amendment Date"), the Company and Deerfield entered into a First Amendment (the "Amendment") to the Facility which extended the date to repay the Accrued Interest under the Facility to June 1, 2018 (the "PIK Maturity Date"), which could have been extended to June 1, 2019 at the election of the Company if certain conditions had been met as specified in the Amendment. However, as described below, the accrued interest amount was converted into shares of common stock.

The right to payment of the Accrued Interest was memorialized in the form of senior secured convertible notes (the "Convertible Notes") issued to Deerfield on the Amendment Date. Interest was due quarterly at a rate of 12.95% per year. The principal amount of the Convertible Notes issued under the Amendment and all accrued and unpaid interest thereon was to become due and payable upon written notice from Deerfield, and if either (a) the Company did not meet certain quarterly sales milestones specified in the Amendment or (b) the Company had not received and publicly announced FDA approval of the new drug applications on or before the applicable Prescription Drug User Fee Act goal date as set forth on the schedules to the Amendment. Per the Amendment, the Company will prepay all of the outstanding obligations under the Facility and the Convertible Notes upon the occurrence of a change in control or a sale of substantially all of the Company's assets and liabilities. The Amendment increased the staggered prepayment fees for prepayments due upon a change of control or any other prepayment made or required to be made by the Company by 300 basis points from June 1, 2017 through the period ending prior to May 11, 2020 for the change in control prepayment fees and through the period ending prior to May 11, 2022 for any other prepayments, respectively (the "Prepayment Premiums"). Such Prepayment Premiums, as amended, ranged from 12.75% to 2%.

The $6.6 million of Convertible Notes was convertible into shares of the Company's common stock at the noteholder's option at any time up to the close of business on the date that was five days prior to the PIK Maturity Date. The per share conversion price was the greater of (a) 95% of the average of the volume weighted average prices per share of the Company's common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion, and (b) $7.00. Deerfield cannot own more than 9.985% of the Company's outstanding shares at any one time, and the aggregate conversion cannot exceed 19.9% of the Company's outstanding common stock as of June 1, 2017.

On October 26, 2017, Deerfield provided a conversion notice electing to convert the entire $6.6 million of Convertible Notes into shares of the Company's common stock at a conversion price of $7.08 per share. The conversion price was based on 95% of the average of the volume weighted average prices per share of the Company's common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion. This resulted in issuing 929,967 shares of the Company's common stock to Deerfield on this date and the Convertible Notes were cancelled. The Company has filed a registration statement with the SEC covering the registration of these shares, as noted below.

In conjunction with the Amendment to the Facility and the related issuance of the Convertible Notes, the Company entered into a Registration Rights Agreement (the "Registration Agreement") which required the Company to file a registration statement with the SEC to register the shares of common stock issued or issuable upon conversion of the Convertible Notes (the "Conversion Shares") (subject to certain adjustment for stock split, dividend or other distribution, recapitalization or similar events, the "Registrable Securities") within 30 days from June 1, 2017, which was to become effective per the SEC no later than 75 days thereafter. The Company filed a registration statement on Form S-3 to comply with the Registration Agreement on June 30, 2017, which became effective on July 11, 2017. This filing covered 940,924 shares, which is the number of shares that would be issued at the floor conversion rate of $7.00 per share. The Company was also required to, among other things, maintain the effectiveness of such registration statement, continue to file the required SEC filings on a timely basis, use its best efforts to ensure that the registered securities are listed on each securities exchange on which securities of the same class or series as issued by the Company are then listed and comply with any Financial Industry Regulatory Authority ("FINRA") requests. The Company's obligations with respect to each registration end at the date which was the earlier of (a) when all of the Registrable Securities covered by such registration have been sold or (b) when Deerfield or any of its transferees or assignees under the

Registration Agreement cease to hold any Registrable Securities. For each registration, the Company bore all reasonable expenses, other than underwriting discounts and commissions, and was to reimburse Deerfield or any assignee or transferee for up to $25,000 in legal fees. The Company had satisfied all of its obligations under this Registration Agreement and did not pay any damages pursuant to this agreement; therefore, no liability had been recorded (see Note 13), and as of September 30, 2018, Deerfield or any of its transferees or assignees under the Registration Agreement reported that it had ceased to hold any Registrable Securities.

The Company has accounted for the Amendment as a debt modification as the instruments were not substantially different; therefore, the remaining debt discount on the original Facility is being amortized using the effective interest method over the remaining term of the modified debt. The Company evaluated the Amendment together with the Convertible Notes to determine if those contracts or embedded components of those contracts qualified as derivatives requiring separate recognition. This evaluation identified a derivative liability of $2.1 million for the fair value of the change in control and other accelerated payment features as the prepayment fees resulted in premiums that were greater than 10%. As of June 30, 2019, the fair value of the derivative was $1.4 million (see Note 4). As the change in control and other accelerated payments terms, including the prepayment fees, were applied to the entire debt per the terms of the amended Facility, the corresponding debt discount will be amortized using the effective interest method over the remaining term of the Facility. The fees paid to or on behalf of the creditor for the debt modification totaled $40,000 and were recorded as additional debt discount on the amended Facility to be amortized to interest expense using the effective interest method over the term of the Facility. The Company's evaluation also determined that the embedded conversion options should not be bifurcated as derivatives from the Convertible Notes host instruments. Therefore, the Company recorded a $0.6 million discount to the convertible notes for the intrinsic value of the embedded conversion option based upon the difference between the fair value of the underlying common stock on June 1, 2017 and the effective conversion price embedded in the Convertible Notes, which was amortized using the effective interest method to interest expense over the one-year term of the Convertible Notes. The Company recorded a $0.6 million corresponding credit to a beneficial conversion feature classified as additional paid in capital on June 1, 2017 in stockholders' equity (deficit) in the Company's financial statements.

In connection with the Facility, the Company paid a $1,350,000 yield enhancement fee to Deerfield, approximately $173,000 of legal costs to the Company's attorneys and $58,000 of legal costs on behalf of Deerfield's attorneys, all of which were recorded as debt discount and amortized over the six-year term of the Facility, using the effective interest method.

On November 5, 2018, the Company and Deerfield entered into an amendment (the "Second Amendment") to the Facility pursuant to which the Company agreed to pay $7.5 million of principal under the Facility otherwise due in May 2019 upon completion of an underwritten public offering of the Company's shares of its common stock for gross proceeds of at least $30.0 million, plus additional shares of the Company's shares of its common stock for additional gross proceeds of at least $4.5 million (the "November Offering"). The remaining $52.5 million of principal under the Facility is due as follows: $7.5 million on May 11, 2019, $15.0 million on May 11, 2020 (the "2020 Principal Payment"), $15.0 million on May 11, 2021 and $15.0 million on May 11, 2022; provided, that the 2020 Principal Payment due date shall be extended to May 11, 2021 or May 11, 2022 subject to certain achievement of net sales during periods ending 2019 and 2020, respectively. If all or any of the principal are prepaid or required to be prepaid under the Second Agreement prior to December 31, 2021, then the Company shall pay, in addition to such prepayment and accrued interest thereon, a prepayment premium equal to 6.25% of the amount of principal prepaid. Additionally, the Company shall pay all interest which, absent such prepayment, would have accrued on the principal prepaid through May 11, 2020 in connection with a prepayment due to a Change of Control of the Company or through December 31, 2020 in connection with any other prepayment, whether voluntary or in an Event of Default. If such prepayment occurs after December 31, 2021 then no prepayment premium is due. In addition, upon the payment in full of the Obligations (whether voluntarily, in the connection with a Change of Control or an Event of Default and whether before, at the time of or after the Maturity Date,) the Company shall pay to Deerfield a non-refundable exit fee in the amount of $750,239, which shall be due and payable in cash.

Pursuant to the terms of the Facility, as amended, a $7.5 million principal payment was paid in cash in May 2019 and, the remaining principal outstanding as of June 30, 2019 is $45.0 million.

Pursuant to the Second Amendment, upon the effectiveness thereof, the Company amended and restated its outstanding notes under the Second Agreement in the form of senior secured convertible notes (the "A&R Notes"). Under the terms of the Second Amendment and the A&R Notes, beginning on or about May 11, 2019, the Company has the right to pay principal and future interest in shares of Common Stock not to exceed 2,135,625 shares in the aggregate. The payment share price will be 93% of the lesser of (A) the Last Bid Price prior to the payment date and (B) the arithmetic average of the volume weighted average price on each of the ten consecutive trading days immediately preceding the payment date. Principal may not be satisfied at a price less than $3.00 per share, and the Company may not issue to Deerfield a number of shares upon any such payment to the extent that, upon such issuance, the number of shares beneficially owned by Deerfield and its affiliates would exceed 4.985% of the total number of shares of the Company's common stock then issued and outstanding (the "4.985% Cap"). Additionally, Deerfield has the right to convert the remaining principal into shares of Common Stock not to exceed 3,796,668 shares in the aggregate (collectively, the "Conversion Shares"); provided, that the Lenders may only convert up to 50% of the remaining principal on or before November 5, 2019. Deerfield's per share conversion price will be 95% reducing to a maximum 83% by one full percentage point for each full or partial calendar month between the date of the applicable conversion and the date on which such principal payment would otherwise be due, of the greater of (A) the average of the volume weighted average prices per share of the Common Stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion, and (B) $10.00 (subject to adjustment for Stock Events e.g. stock dividend, stock split etc.). Deerfield may not acquire a number of shares upon any such conversion to the extent that, upon such conversion, the number of shares beneficially owned by Deerfield and its affiliates would exceed the 4.985% Cap.

In conjunction with the Second Amendment to the Facility and the related issuance of the A&R Notes, the Company entered into a Registration Rights Agreement (the "Second Registration Agreement") pursuant to which the Company was required to file a registration statement with the SEC to register the Conversion Shares within 30 days from November 5, 2018, which was to become effective per the SEC no later than 75 days thereafter. The filing deadline was subsequently extended to December 21, 2018. The Company filed a registration statement on Form S-3 to comply with the Second Registration Agreement on December 11, 2018, which became effective on December 20, 2018. This filing covered 3,796,668 shares, which is the maximum number of shares that may be converted. The Company is also required to, among other things, maintain the effectiveness of such registration statement, continue to file the required SEC filings on a timely basis, use its best efforts to ensure that the registered securities are listed on each securities exchange on which securities of the same class or series as issued by the Company are then listed and comply with any FINRA requests. The Company's obligations with respect to each registration end at the date which is the earlier of (a) when all of the Registrable Securities covered by such registration have been sold or (b) when Deerfield or any of its transferees or assignees under the Second Registration Agreement cease to hold any Registrable Securities. For each registration, the Company shall bear all reasonable expenses, other than underwriting discounts and commissions, and shall reimburse Deerfield or any assignee or transferee for up to $25,000 in legal fees. The Company expects to satisfy all of its obligations under the Second Registration Agreement and did not expect to pay any damages pursuant to this agreement; therefore, no liability had been recorded (see Note 13).

Pursuant to the A&R Notes, if the Company fails to provide the number of Conversion Shares, then the Company would have to pay damages to Deerfield or subsequent holder or any designee for each day after the third business day after receipt of notice of conversion that such conversion is not timely effected. The Facility also contains certain customary nonfinancial covenants, including limitations on the Company's ability to transfer assets, engage in a change of control, merge or acquire with or into another entity, incur additional indebtedness and distribute assets to shareholders. Upon an event of default, the lenders may declare all outstanding obligations accrued under the Facility to be immediately due and payable, and exercise its security interests and other rights. As of June 30, 2019, the Company was in compliance with the covenants under the Facility.

Debt discount amortization for the Facility, including the Amendment after June 1, 2017, was calculated using the effective interest rates of 15.03% on the original facility debt, 25.35% on the Convertible Notes and after the Second Amendment on November 5, 2018, using the effective interest rate of 16.69%, charged to interest expense and totaled $339,000 and $696,000 for the three and six months ended June 30, 2019, respectively, and $218,000 and $427,000 for the three and six months ended June 30, 2018, respectively.

Financing and capital lease obligations: Financing and capital lease obligations consist of sale-leaseback and equipment leases, both of which include options to purchase and was classified as finance lease as of June 30, 2019 and capital lease as of December 31, 2018. As described in Note 6, during the year ended December 31, 2017, the Company entered into an agreement with Essex for the sale-leaseback of newly acquired assets with a total capitalized cost of $3.2 million. The approximate imputed interest rate on these leases is 14.9%. In addition, during the year ended December 31, 2018 and the quarter ended June 30, 2019, the Company entered into equipment leases with a total capitalized cost of $0.1 million and $0.4 million, respectively. The approximate interest rate on these leases is 5.3% and 6.5%, respectively. Interest expense on these leases was $58,000 and $122,000 for the three and six months ended June 30, 2019, respectively, and $91,000 and $189,000 for the three and six months ended June 30, 2018, respectively.

Future principal payments of long-term debt including financing leases are as follows:

Period ending:	June 30, (in thousands)
2020	$ 16,372
2021	15,096
2022	15,852
2023	96
Thereafter	84
Future principal payments	$ 47,500
Less unamortized debt discount related to long-term debt	(2,639)
Less current portion of long-term debt	(16,372)
Total long-term debt, net of current portion	$ 28,489

Note 9. Leases

The Company leases real estate, warehouses and certain equipment. The Company determines if an arrangement is a lease at inception. Leases with an initial term of 12 months or less ("short-term leases") are not recorded on the unaudited condensed consolidated balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term at commencement date. Because most of the Company's operating leases do not provide an implicit rate of return, the Company considered its other similar term collateralized financing arrangements, including the Essex sale-leaseback and equipment leases, certain vendor-direct equipment financing and the Deerfield debt facility, as amended, to determine its incremental borrowing rate. Operating lease ROU assets are comprised of the lease liability plus prepaid rents and are reduced by lease incentives and deferred rents. The Company has lease agreements with non-lease components which are not bifurcated.

Most leases include one or more options to renew, with renewal terms that can extend the lease term from one to 10 years. The exercise of a lease renewal option typically occurs at the discretion of both parties. Certain leases also include options to purchase the leased property. For purposes of calculating operating lease liabilities, lease terms are deemed not to include options to extend the lease termination until it is reasonably certain that the Company will exercise that option. Certain of the Company's lease agreements include payments adjusted periodically for fair market value and certain other percentage increases. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The components of lease expense are as follows:

	Three Months Ended June 30, 2019 (in thousands)	Six Months Ended June 30, 2019 (in thousands)	Statement of Operations Classification
Lease cost:			
Operating lease cost	$ 269	$ 533	Cost of goods sold and operating expenses
Short-term lease cost	12	24	Cost of goods sold and operating expenses
Variable lease cost	59	112	Cost of goods sold and operating expenses
Finance lease cost:			
Amortization of leased assets	133	252	Cost of goods sold
Interest on lease liabilities	58	122	Interest expense
Total net lease cost	$ 531	$ 1,043	

Supplemental unaudited consolidated balance sheet information related to leases is as follows:

	June 30, 2019 (in thousands)	Balance Sheet Classification
Leases:		
Assets:		
Operating lease assets	$ 3,274	Operating lease right-of-use assets
Finance lease assets	2,848	Property, plant and equipment, net
Total leased assets	$ 6,122	
Liabilities:		
Current:		
Operating leases	$ 606	Current portion of operating lease liabilities
Finance leases	1,372	Current portion of long-term debt
Noncurrent:		
Operating leases	3,608	Operating lease liabilities
Finance leases	378	Long-term debt, net of current portion
Total lease liabilities	$ 5,964	

	June 30, 2019
Weighted-Average Remaining Lease Term (years)	
Operating lease assets	5.2
Finance lease assets	1.9
Weighted-Average Discount Rate	
Operating lease assets	15.0 %
Finance lease assets	12.6 %

Supplemental unaudited interim consolidated cash flow information related to leases is as follows:

	Six Months Ended June 30, 2019
	(in thousands)
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	$ 581
Operating cash flows from finance leases	121
Financing cash flows from finance leases	515
ROU assets obtained in exchange for new finance lease liabilities	406
ROU assets obtained in exchange for new operating lease liabilities	$ 135

Maturities of lease liabilities are as follows:

	June 30, 2019	
	Operating Leases	Finance Leases
	(in thousands)	
2019	$ 587	$ 677
2020	1,225	893
2021	1,118	117
2022	1,060	115
2023	1,055	95
Later years	1,106	40
Total lease payments	$ 6,151	$ 1,937
Less amount representing interest	(1,937)	(187)
Total lease obligations	$ 4,214	$ 1,750

Disclosures related to periods prior to adoption of ASU 2016-02

Future minimum lease payments under non-cancelable rental and lease agreements which had initial or remaining term in excess of one year are as follows:

	December 31, 2018	
	Operating Leases	Capital Leases
	(in thousands)	
2019	$ 1,180	$ 1,257
2020	1,195	798
2021	1,062	21
2022	1,055	20
2023	1,055	—
Later years	1,106	—
Minimum lease commitment	$ 6,653	$ 2,096
Less amount representing interest		(238)
Present value of net minimum lease obligations		$ 1,858

Note 10. Common stock

On August 1, 2016, the Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on August 12, 2016. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $125.0 million of its common stock, preferred stock, debt securities, warrants and/or units (the "2016 Shelf"). The Company simultaneously entered into a sales agreement with Cowen and Company, LLC, as sales agent, to provide for the offering, issuance and sale by the Company of up to $40.0 million of its common stock from time to time in "at-the-market" offerings under the 2016 Shelf (the "Cowen Sales Agreement").

In February 2017, the Company closed an underwritten public offering of 5,750,000 shares of its common stock under the 2016 Shelf at a public offering price of $5.00 per share, which included 750,000 shares of its common stock resulting from the underwriters' exercise of their over-allotment option. Deerfield participated in the purchase of the Company's common shares as part of this public offering, and as a result, was classified as a related party at the time of the corresponding transactions. The net proceeds to the Company from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were approximately $26.7 million.

On June 30, 2017, the Company closed an underwritten public offering of 4,800,000 shares of its common stock under the 2016 Shelf at a public offering price of $6.25 per share for total proceeds of $30.0 million before estimated offering costs of $0.2 million. The Company also granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of its common stock which was exercised in full on July 26, 2017. The net proceeds to the Company through July 26, 2017 from this offering, after deducting offering expenses payable by the Company, were approximately $34.3 million.

During the year ended December 31, 2017, the Company sold an aggregate 749,639 shares of common stock under the Cowen Sales Agreement, at an average sale price of approximately $5.01 per share for gross proceeds of $3.7 million and net proceeds of $3.6 million and paying total compensation to the sales agent of approximately $0.1 million.

On October 26, 2017, Deerfield provided a conversion notice electing to convert the entire $6.6 million of Convertible Notes into shares of the Company's common stock at a conversion price of $7.08 per share. The conversion price was based on 95% of the average of the volume weighted average prices per share of the Company's common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion. This resulted in issuing 929,967 shares of the Company's common stock to Deerfield on this date and the Convertible Notes were cancelled.

During the year ended December 31, 2018, the Company sold an aggregate 651,525 shares of common stock under the Cowen Sales Agreement, at an average sale price of approximately $6.25 per share for gross proceeds of $4.1 million and net proceeds of $3.9 million and paying total compensation to the sales agent and other costs of approximately $0.2 million.

On November 5, 2018, the Company filed Supplement No. 1 to the prospectus dated August 12, 2016, which reduced the size of the continuous offering by the Company under such prospectus relating to the offering of Common Stock pursuant to the Sales Agreement. Following the reduction, the Company was authorized to issue up to $7,825,113 of its common stock pursuant to the Sales Agreement (inclusive of amounts previously sold thereunder prior to the date hereof). Aggregate gross proceeds of sales of the Company's common stock under the Sales Agreement total $7,825,113, and sales of common stock under the Sales Agreement have been suspended.

On November 8, 2018, the Company closed an underwritten public offering of 19,999,999 shares of its common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of its common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. The net proceeds to the Company from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company were approximately $43.4 million. This offering met the criteria for the November Offering.

During the six months ended June 30, 2019, the Company issued 18,765 shares of common stock pursuant to the conversion of vested RSUs and 35,207 shares of common stock pursuant to the exercise of vested stock options. During the year ended December 31, 2018, the Company issued 26,991 shares of common stock pursuant to the conversion of vested RSUs and 832 shares of common stock pursuant to the exercise of vested stock options.

On March 18, 2019, the Company filed a shelf registration statement covering the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants and/or units (the "2019 Shelf"), which was declared effective by the SEC on May 1, 2019. Effective as of August 12, 2019, the 2016 Shelf is no longer available for further primary offerings or sales of our securities. The Company simultaneously entered into a sales agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the offering,

issuance and sale by the Company of up to $30.0 million of its common stock from time to time in "at-the-market" offerings under the 2019 Shelf (the "Cantor Sales Agreement").

Note 11. Share-based Compensation

Share-based Compensation Plans

In July 2015, the Company adopted the Neos Therapeutics, Inc. 2015 Stock Option and Incentive Plan ("2015 Plan") which became effective immediately prior to the closing of the IPO and initially had 767,330 shares of common stock reserved for issuance. On January 1, 2016 and each January 1 thereafter, the number of shares of common stock reserved and available for issuance under the 2015 Plan shall be cumulatively increased by five percent of the number of shares of stock issued and outstanding on the immediately preceding December 31 or such lesser number of shares determined by the administrator of the 2015 Plan. Accordingly, on January 1, 2019 and 2018, the Company added 2,483,815 shares and 1,449,847 shares, respectively, to the option pool. The 2015 Plan superseded the Neos Therapeutics, Inc. 2009 Equity Plan ("2009 Plan"), originally adopted in November 2009 and which had 1,375,037 shares reserved and available for issuance. Effective upon closing of the IPO, the Company's Board of Directors determined not to grant any further awards under the 2009 Plan.

The shares of common stock underlying any awards that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) under the 2009 Plan will be added to the shares of common stock available under the 2015 Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. The 2015 Plan is administered by the Company's Compensation Committee, which has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants and to determine the specific terms and conditions of each award, subject to the provisions of the 2015 Plan. The Company's Compensation Committee may delegate authority to grant certain awards to the Company's chief executive officer. Through June 30, 2019, the Company has granted options, restricted stock and RSUs under the 2015 Plan. The exercise price per share for the stock covered by a stock award granted shall be determined by the administrator at the time of grant but shall not be less than 100 percent of the fair market value on the date of grant. Unexercised stock awards under the 2015 Plan expire after the earlier of 10 years or termination of employment, except in the case of any unexercised vested options, which generally expire 90 days after termination of employment.

The 2009 Plan allowed the Company to grant options to purchase shares of the Company's common stock and to grant restricted stock awards to members of its management and selected members of the Company's board of directors. Restricted stock awards are recorded as deferred compensation and amortized into compensation expense, on a straight-line basis over a defined vesting period ranging from 1 to 48 months. Options were granted to officers, employees, nonemployee directors and consultants, and independent contractors of the Company. The Company also granted performance-based awards to selected management. The performance options vested over a three-year period based on achieving certain operational milestones and the remaining options vest in equal increments over periods ranging from two to four years. Unexercised options under the 2009 Plan expire after the earlier of 10 years or termination of employment, except in the case of any unexercised vested options, which generally expire 90 days after termination of employment. All terminated options are available for reissuance under the 2015 Plan. Since the inception of the 2015 Plan through December 31, 2018, 82,635 shares related to forfeited 2009 Plan options were added to the shares available under the 2015 Plan. During the six months ended June 30, 2019, 350,396 shares related to forfeited 2009 Plan options were added to the shares available under the 2015 Plan. As of June 30, 2019, 3,161,056 shares of common stock remain available for grant under the 2015 Plan.

In June 2018, the Company adopted the Neos Therapeutics, Inc. 2018 Inducement Plan (the "Inducement Plan") which had 800,000 shares of common stock reserved and available for issuance. The Inducement Plan allows the Company to grant equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Company to accept employment and provide them with a proprietary interest in the Company. The Inducement Plan is administered by the Company's compensation committee. The exercise price per share for the stock covered by a stock award granted pursuant to the Inducement Plan shall be determined by the administrator at the time of grant but shall not be less than 100 percent of the fair market value on the date of grant. Unexercised stock awards under

the Inducement Plan expire after 10 years following the grant date. Under the Company's employment agreement dated June 27, 2018 with Gerald McLaughlin, the Company's Chief Executive Officer, the Company granted Mr. McLaughlin, under the Inducement Plan, an option to purchase 600,000 shares of the Company's common stock, which vests in equal annual installments over four years from Mr. McLaughlin's start date. In addition, on July 30, 2018, the Company granted Mr. McLaughlin, under the Inducement Plan, an option to purchase 200,000 shares of the Company's common stock. The shares underlying this option shall vest subject to certain performance metrics to be evaluated for the fiscal year ending December 31, 2019. As of June 30, 2019, no shares of common stock remain available for grant under the Inducement Plan.

Share-based Compensation Expense

The Company has reported share-based compensation expense for the three and six months ended June 30, 2019 and 2018, respectively, in its condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)			
Cost of goods sold	$ 143	$ 123	$ 287	$ 242
Research and development	115	121	205	199
Selling and marketing	91	306	211	563
General and administrative	673	536	1,193	1,049
	$ 1,022	$ 1,086	$ 1,896	$ 2,053

The total share-based compensation expense included in the table above is attributable to stock options and RSUs of $978,000 and $44,000 for the three months ended June 30, 2019, respectively, and $1.8 million and $95,000 for the six months ended June 30, 2019, respectively. The total share based compensation expense included in the table above is attributable to stock options and RSUs of $986,000 and $101,000 for the three months ended June 30, 2018, respectively, and $1.9 million and $137,000 for the six months ended June 30, 2018, respectively.

As of June 30, 2019, there was $5.4 million of compensation costs, adjusted for any estimated forfeitures, related to non-vested stock options and RSUs granted under the Company's equity incentive plans not yet recognized in the Company's financial statements. The unrecognized compensation cost is expected to be recognized over a weighted average period of 2.6 years for stock options and 2.4 years for RSUs. There is no unrecognized compensation cost associated with grants of restricted stock.

Stock Options

During the six months ended June 30, 2019, the Company granted 1,951,208 options under the 2015 Plan. During the year ended December 31, 2018, the Company granted 953,539 options under the 2015 Plan. In June and July 2018, the Company granted 600,000 and 200,000 options, respectively, under the Inducement Plan to Gerald McLaughlin, the Company's Chief Executive Officer, at an exercise price of $6.20 and $5.55 per share, respectively.

The Company estimates the fair value of all stock options on the grant date by applying the Black-Scholes option pricing valuation model. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. Prior to the IPO, given the absence of an active market for the Company's common stock prior to its IPO, the Company's board of directors was required to estimate the fair value of its common stock at the time of each option grant primarily based upon valuations performed by a third-party valuation firm.

The weighted-average key assumptions used in determining the fair value of options granted during the period indicated are as follows:

	Six Months Ended June 30, 2019
Estimated dividend yield	0.00 %
Expected stock price volatility	60.00 %
Weighted-average risk-free interest rate	2.50 %
Expected life of option in years	6.07
Weighted-average option fair value at grant	$ 1.27

A summary of outstanding and exercisable options as of June 30, 2019 and December 31, 2018 and the activity from December 31, 2018 through June 30, 2019, is presented below:

	Number of Options	Weighted-Average Exercise Price	Intrinsic Value (in thousands)
Outstanding at December 31, 2018	3,446,885	$ 8.935	$ 70
Exercisable at December 31, 2018	1,643,011	$ 10.627	$ 70
Granted	1,951,208	2.21	
Exercised	(35,207)	0.32	
Expired, forfeited or cancelled	(834,544)	10.92	
Outstanding at June 30, 2019	4,528,342	$ 5.74	$ 17
Exercisable at June 30, 2019	1,277,610	$ 9.42	$ 17

The weighted-average remaining contractual life of options outstanding and exercisable on June 30, 2019 was 8.7 and 7.1 years, respectively. The option exercise prices for all options granted January 1, 2019 through June 30, 2019 ranged from $1.44 per share to $3.14 per share. The weighted-average remaining contractual life of options outstanding and exercisable on December 31, 2018 was 7.9 and 6.6 years, respectively. The option exercise price for all options granted in the year ended December 31, 2018 ranged from $4.76 to $10.40 per share.

Restricted Stock Units

On May 1, 2017, the Company granted 78,750 RSUs to members of its management which vest in four equal annual installments, beginning May 1, 2018. On October 2, 2017, the Company granted 6,250 RSUs to a member of its management which vest in four equal annual installments, beginning October 2, 2018. On March 1, 2018, the Company granted 93,750 RSUs to members of its management which vest in four equal annual installments, beginning March 1, 2019.

The Company satisfies its RSUs by issuing shares of the Company's common stock when RSUs vest and are issued. In addition, when RSUs vest and are issued, RSU recipients may elect to have the Company withhold units as consideration for the tax withholding obligation for their vested RSUs. During the six months ended June 30, 2019, 19,688 vested RSUs were converted into an equivalent 18,765 shares of common stock. The Company withheld 923 shares of its common stock to partially satisfy tax withholding obligations upon vesting of the RSUs for the six months ended June 30, 2019. During the year ended December 31, 2018, 33,748 vested RSUs were converted into an equivalent 26,991 shares of common stock. The Company withheld 6,757 shares of its common stock to partially satisfy tax withholding obligations upon vesting of the RSUs for the year ended December 31, 2018.

A summary of outstanding RSUs as of June 30, 2019 and December 31, 2018 and the activity from December 31, 2018 through June 30, 2019, is presented below:

	Number of RSUs	Weighted-Average Fair Value
Outstanding at December 31, 2018	75,314	$ 7.93
Granted	—	—
Vested	(19,688)	7.76
Expired, forfeited or cancelled	—	—
Outstanding at June 30, 2019	55,626	$ 7.99

Restricted stock

The Company did not issue any shares of restricted stock for the six months ended June 30, 2019, or for the year ended December 31, 2018. No vested restricted stock awards were settled during the six months ended June 30, 2019.

The Company had no unvested restricted stock as of June 30, 2019 and December 31, 2018. For the six months ended June 30, 2019, there were no shares of restricted stock granted or forfeited.

Note 12. Treasury stock

The Company has the authority to repurchase common stock from former employees, officers, directors or other persons who performed services for the Company at the lower of the original purchase price or the then-current fair market value. On October 16, 2017, October 17, 2016 and October 16, 2015, 14,895 shares, 9,709 shares and 9,197 shares, respectively, of restricted stock were surrendered by the holder to the Company to cover taxes associated with vesting of restricted stock and such shares were added back into the treasury stock of the Company, increasing total treasury stock to 33,801 shares as of June 30, 2019 and December 31, 2018.

Note 13. Commitments and contingencies

Registration Payment Arrangement: On November 5, 2018, in conjunction with the Second Amendment to the Facility and the related issuance of the Convertible Notes, the Company entered into the Second Registration Agreement which required the Company to file a registration statement with the SEC to register the Registrable Securities (see Note 8) within 30 days from November 5, 2018, which was to become effective per the SEC no later than 75 days thereafter. The filing deadline was subsequently extended to December 21, 2018. The Company filed a registration statement on Form S-3 to comply with the Registration Agreement on December 11, 2018, which became effective on December 20, 2018. This filing covered 3,796,668 shares, which is the number of shares that would be issued up to the Exchange Cap as (defined in the agreement). The Company is also required to, among other things, maintain the effectiveness of such registration statement, continue to file the required SEC filings on a timely basis, use its best efforts to ensure that the registered securities are listed on each securities exchange on which securities of the same class or series as issued by the Company are then listed and comply with any FINRA requests. Upon any Registration Failure, the Company shall pay additional damages to the Holder for each 30-day period (prorated for any partial period) after the date of such Registration Failure in an amount in cash equal to two percent of the original principal amount of the Convertible Notes. The Company's obligations with respect to each registration end at the date which is the earlier of (a) when all of the Registrable Securities covered by such registration have been sold or (b) when Deerfield or any of its transferees or assignees under the Registration Agreement cease to hold any of the Registrable Securities. For each registration filing, the Company shall bear all reasonable expenses, other than underwriting discounts and commissions, and shall reimburse Deerfield or any assignee or transferee for up to $25,000 in legal fees. The Company currently expects to satisfy all of its obligations under the Registration Agreement and does not expect to pay any damages pursuant to this agreement; therefore, no liability has been recorded.

Patent Infringement Litigation: On October 31, 2017, the Company received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising the Company that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Cotempla XR-ODT. On December 13, 2017, the Company filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva alleging that Teva infringed the Company's Cotempla XR-ODT patents. On December 21, 2018, the Company entered into a Settlement Agreement (the "Teva Settlement Agreement") and a Licensing Agreement (the "Teva Licensing Agreement" and collectively with the Teva Settlement Agreement, the "Teva Agreement") with Teva that resolved all ongoing litigation involving the Company's Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, the Company granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

On July 25, 2016, the Company received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising the Company that Actavis had filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Adzenys XR-ODT. On September 1, 2016, the Company filed a patent infringement lawsuit in federal district court against Actavis alleging that Actavis infringed the Company's Adzenys XR-ODT patents. On October 17, 2017, the Company entered into a Settlement Agreement (the "Actavis Settlement Agreement") and a Licensing Agreement (the "Actavis Licensing Agreement" and collectively with the Actavis Settlement Agreement, the "Actavis Agreement") with Actavis that resolved all ongoing litigation involving the Company's Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, the Company granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

Other Litigation: On March 7, 2018 and April 18, 2019, the Company received citations advising the Company that the County of Harris Texas ("Harris County") and the County of Walker Texas ("Walker County") filed lawsuits on December 13, 2017 and January 11, 2019, respectively, against the Company and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through these lawsuits, each of Harris County and Walker County seek to recoup as damages some of the expenses they allegedly have incurred to combat opioid use and addiction. Each of Harris County and Walker County also seeks punitive damages, disgorgement of profits and attorneys' fees.

While the Company believes that these lawsuits are without merit and intends to vigorously defend against them, the Company is not able to predict at this time whether these proceedings will have a material impact on its results of operations.

Operating lease: The Company leases its Grand Prairie, Texas office space and manufacturing facility under an operating lease which expires in 2024. In addition, in December 2015, the Company executed a 60- month lease for additional office space in Blue Bell, Pennsylvania, which commenced on May 1, 2016. Prior to the adoption of the New Lease Standard on January 1, 2019, the Company accounted for rent expense on long-term operating leases on a straight-line basis over the life of the lease resulting in a deferred rent balance of $989,000 at December 31, 2018. The Company adopted ASU No. 2016-02 at January 1, 2019 and recognized an operating lease liability of $4.3 million under the New Lease Standard (See Note 2 and 9). The Company is also liable for a share of operating expenses for both premises as defined in the lease agreements. The Company's share of these operating expenses was $60,000 and $112,000 for the three and six months ended June 30, 2019, respectively, and $52,000 and $106,000 for the three and six months ended June 30, 2018, respectively. Rent expense for these leases, excluding the share of operating expenses, was $252,000 for each of the three months ended June 30, 2019 and 2018, and $505,000 for each of the six months ended June 30, 2019 and 2018.

Cash incentive bonus plan: In July 2015, the Company adopted the Senior Executive Cash Incentive Bonus Plan ("Bonus Plan"). The Bonus Plan provides for cash payments based upon the attainment of performance targets established by the Company's compensation committee. The payment targets will be related to financial and operational

measures or objectives with respect to the Company, or corporate performance goals, as well as individual targets. The Company has recorded $528,000 and $995,000 of compensation expense for the three and six months ended June 30, 2019, respectively, and $467,000 and $811,000 for the three and six months ended June 30, 2018, respectively, under the Bonus Plan.

Note 14. License agreements

On October 23, 2018, the Company entered into an Exclusive License Agreement ("NeuRx License") with NeuRx Pharmaceuticals LLC ("NeuRx"), pursuant to which NeuRx granted the Company an exclusive, worldwide, royalty-bearing license to research, develop, manufacture, and commercialize certain pharmaceutical products containing NeuRx's proprietary compound designated as NRX-101, referred to by the Company as NT0502. NT0502 is a new chemical entity that is being developed by the Company for the treatment of sialorrhea, which is excessive salivation or drooling. Under the NeuRx License, the Company made an upfront payment of $175,000 to NeuRx upon the execution of the agreement and may in the future be required to make certain development and milestone payments and royalties based on annual net sales, as defined in the NeuRx License. Royalties are to be paid on a country-by-country and licensed product-by-licensed product basis, during the period of time beginning on the first commercial sale of such licensed product in such country and continuing until the later of: (i) the expiration of the last-to-expire valid claim in any licensed patent in such country that covers such licensed product in such country; and/or (ii) expiration of regulatory exclusivity of such licensed product in such country.

Under the Teva Licensing Agreement, the Company granted Teva a non-exclusive license to certain patents owned by the Company by which Teva has the right to manufacture and market its generic version of Cotempla XR-ODT under its ANDA beginning on July 1, 2026, or earlier under certain circumstances. The Teva Licensing Agreement has been submitted to the applicable governmental agencies (see Note 13).

Under the Actavis Licensing Agreement, the Company granted Actavis a non-exclusive license to certain patents owned by the Company by which Actavis has the right to manufacture and market its generic version of Adzenys XR-ODT under its ANDA beginning on September 1, 2025, or earlier under certain circumstances. The Licensing Agreement has been submitted to the applicable governmental agencies (see Note 13).

On July 23, 2014, the Company entered into a Settlement Agreement and an associated License Agreement (the "2014 License Agreement") with Shire LLC ("Shire") for a non-exclusive license to certain patents for certain activities with respect to the Company's New Drug Application (the "NDA") No. 204326 for an extended-release orally disintegrating amphetamine polistirex tablet. In accordance with the terms of the 2014 License Agreement, following the receipt of the approval from the FDA for Adzenys XR-ODT, the Company paid a lump sum, non-refundable license fee of an amount less than $1.0 million in February 2016. The Company is paying a single digit royalty on net sales of Adzenys XR-ODT during the life of the patents.

On March 6, 2017, the Company entered into a License Agreement (the "2017 License Agreement") with Shire, pursuant to which Shire granted the Company a non-exclusive license to certain patents owned by Shire for certain activities with respect to the Company's NDA No. 204325 for an extended-release amphetamine oral suspension. In accordance with the terms of the 2017 License Agreement, following the receipt of the approval from the FDA for Adzenys ER, the Company paid a lump sum, non-refundable license fee of an amount less than $1.0 million in October 2017. The Company is paying a single digit royalty on net sales of Adzenys ER during the life of the patents.

Such license fees are capitalized as an intangible asset and are amortized into cost of goods sold over the life of the longest associated patent. The royalties are recorded as cost of goods sold in the same period as the net sales upon which they are calculated.

Additionally, each of the 2014 and 2017 License Agreements contains a covenant from Shire not to file a patent infringement suit against the Company alleging that Adzenys XR-ODT or Adzenys ER, respectively, infringes the Shire patents.

Note 15. Related party transactions

In February 2017, the Company closed an underwritten public offering of 5,750,000 shares of its common stock at a public offering price of $5.00 per share, which includes 750,000 shares of the Company's common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price on February 17, 2017. On June 30, 2017, the Company closed an underwritten public offering of 4,800,000 shares of its common stock at a public offering price of $6.25 per share for total proceeds of $30.0 million before estimated offering costs of $0.2 million. The Company also granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of its common stock. Deerfield, the Company's senior lender, participated in the purchase of the Company's common shares as part of both public offerings, and as a result, is classified as a related party. The Company is obligated under a $60.0 million senior secured credit Facility that was issued by the Company to Deerfield. On June 1, 2017, the Company and Deerfield entered into an Amendment to the Company's existing Facility with Deerfield which extended the date to repay the Accrued Interest under the Facility to June 1, 2018, which may have been extended to June 1, 2019 at the election of the Company if certain conditions have been met as specified in the Amendment. The right to payment of the Accrued Interest was memorialized in the form of Convertible Notes issued to Deerfield on the Amendment Date. On October 26, 2017, Deerfield provided a conversion notice electing to convert the entire $6.6 million of Convertible Notes into shares of the Company's common stock at a conversion price of $7.08 per share. The conversion price was based on 95% of the average of the volume weighted average prices per share of the Company's common stock on the NASDAQ Global Market for the three trading day period immediately preceding such conversion. This resulted in issuing 929,967 shares of the Company's common stock to Deerfield on this date and the Convertible Notes were cancelled (see Note 8).

On November 5, 2018, the Company and Deerfield entered into the Second Amendment to the Facility pursuant to which the Company agreed to pay $7.5 million of principal under the Facility otherwise due in May 2019 upon completion of the November Offering. The Second Amendment provides an option for the $15.0 million principal on the Facility due in May 2020 to be paid in either May 2021 or May 2022 upon the achievement of certain revenue milestones as described in the Second Amendment. Also, pursuant to the Second Amendment, the Company amended and restated its outstanding notes under the Facility in the form of senior secured convertible notes. The Company has the right to pay principal and future interest in shares of Common Stock not to exceed 2,135,625 shares in the aggregate. Additionally, subject to the terms of the amended and restated convertible notes, Deerfield has the right to convert the remaining principal under the Facility into shares of Common Stock not to exceed 3,796,668 shares in the aggregate at a conversion price ranging from 95% to 83% of the greater of the average of the volume weighted average price per share of the Common Stock for the three trading day period immediately preceding such conversion and $10.00. On November 8, 2018, the Company closed an underwritten public offering of 19,999,999 shares of its common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of its common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. The net proceeds to the Company from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company were approximately $43.4 million. Deerfield also participated in the purchase of the Company's common shares as part of this offering (see Note 8).

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements for the years ended December 31, 2018 and 2017 and notes thereto included in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" in Part II, Item 1A. of this Quarterly Report on Form 10-Q.

OVERVIEW

We are a pharmaceutical company focused on developing, manufacturing and commercializing products utilizing our proprietary microparticle modified-release drug delivery technology platform, which we have already used to develop Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER oral suspension ("Adzenys ER"), for the treatment of attention deficit hyperactivity disorder ("ADHD"). Our products and product candidates are extended-release ("XR"), medications in patient-friendly, orally disintegrating tablets ("ODT") or liquid suspension dosage forms. Our microparticle technology platform has enabled us to create novel, extended-release ODT and liquid suspension dosage forms. We received approval from the U.S. Food and Drug Administration ("FDA") for Adzenys XR-ODT, our amphetamine XR-ODT, on January 27, 2016 and commercially launched this product in May 2016. We received approval from the FDA for Cotempla XR-ODT, our methylphenidate XR-ODT for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017 and commercially launched this product in September 2017. Also, we received approval from the FDA for Adzenys ER, our amphetamine extended-release oral suspension, on September 15, 2017, and commercially launched this product in February 2018. We believe Adzenys XR-ODT and Cotempla XR-ODT are the first amphetamine XR-ODT and the first methylphenidate XR-ODT, respectively, for the treatment of ADHD on the market. In addition to our marketed products, we are developing NT0502, our preclinical product candidate for the treatment of sialorrhea and NT-0400, our preclinical XR-ODT product candidate, for nausea and vomiting.

We are commercializing Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in the United States using our own commercial infrastructure. We manufacture Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in our current Good Manufacturing Practice ("cGMP") and U.S. Drug Enforcement Administration ("DEA")-registered manufacturing facilities, which help control supply quality and timing. We also currently use these facilities to manufacture our generic equivalent to the branded product, Tussionex, an XR oral suspension of hydrocodone and chlorpheniramine indicated for the relief of cough and upper respiratory symptoms of a cold ("generic Tussionex").

On October 23, 2018, we entered into an Exclusive License Agreement (the "License Agreement") with NeuRx Pharmaceuticals LLC ("NeuRx"), pursuant to which NeuRx granted us an exclusive, world-wide, royalty-bearing license to research, develop, manufacture, and commercialize certain pharmaceutical products containing NeuRx's proprietary compound designated as NRX 101, referred to by us as NT0502. NT0502 is a new chemical entity that is being developed by us for the treatment of sialorrhea, which is excessive salivation or drooling. We are utilizing our microparticle technology platform to develop NT0502 to address the significant unmet medical needs for the treatment of chronic sialorrhea in adult and pediatric patients with neurological conditions including cerebral palsy, Parkinson's disease, mental retardation, and amyotrophic lateral sclerosis or ALS. Investigational New Drug ("IND")-enabling studies are ongoing and we anticipate initiating a Phase 1 clinical trial in the first half of 2020

On August 28, 2014, we completed an acquisition of all of the rights to the Tussionex Abbreviated New Drug Application ("Tussionex ANDA"), which include the rights to produce, develop, market and sell, as well as all the profits from such selling activities, our generic Tussionex, which we previously owned the rights to manufacture, but which was marketed and sold by the generic drug division of Cornerstone Biopharma, Inc. ("Cornerstone"). These rights were acquired from the collaboration of the Company, Cornerstone and Coating Place, Inc. Prior to the acquisition, we shared profits generated by the sale and manufacture of the product under a development and manufacturing agreement with those companies.

On July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis has filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Adzenys XR-ODT. On October 17, 2017, we entered into a Licensing Agreement with Actavis under which we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances.

On October 31, 2017, we received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. On December 21, 2018, we entered into a Licensing Agreement with Teva under which we granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances.

Our predecessor company was incorporated in Texas on November 30, 1994 as PharmaFab, Inc. and subsequently changed its name to Neostx, Inc. On June 15, 2009, we completed a reorganization pursuant to which substantially all of the capital stock of Neostx, Inc. was acquired by a newly formed Delaware corporation, named Neos Therapeutics, Inc. The remaining capital stock of Neostx, Inc. was acquired by us on June 29, 2015, and Neostx, Inc. was merged with and into Neos Therapeutics, Inc. Historically, we were primarily engaged in the development and contract manufacturing of unapproved, or Drug Efficacy Study Implementation ("DESI"), pharmaceuticals and, to a lesser extent, nutraceuticals for third parties. The unapproved or DESI pharmaceuticals contract business was discontinued in 2007, and the manufacture of nutraceuticals for third parties was discontinued in March 2013.

Since our reorganization in 2009, we have devoted substantially all of our resources to funding our manufacturing operations, the development of our product candidates, and the commercialization of our approved products; these activities include the implementation of our commercialization strategies, conducting research and development activities and clinical trials for our product candidates, providing general and administrative support of these operations, and seeking and maintaining intellectual property protection. Prior to our initial public offering of our common stock in July 2015, we funded our operations principally through private placements of our common stock, redeemable convertible preferred stock, bank and other lender financings and through payments received under collaborative arrangements.

We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $11.4 million and $51.8 million for the six months ended June 30, 2019 and the year ended December 31, 2018, respectively. As of June 30, 2019 and December 31, 2018, we had accumulated deficits of approximately $328.4 million and $317.0 million, respectively. We expect to continue to incur significant expenses in connection with our ongoing activities, including, among other things:

- sales and marketing efforts for Adzenys XR-ODT, Cotempla XR-ODT, and Adzenys ER;
- research and development activities for new product candidates;
- post-marketing approval research activities for our approved products;
- manufacture of supplies for our preclinical studies and ongoing and planned clinical trials;
- protection and enforcement of our intellectual property rights; and
- general operations as a public company.

FINANCIAL OPERATIONS OVERVIEW

Revenue

Prior to 2017, our revenue was generated primarily from product sales of our generic Tussionex recorded on a net sales basis. Sales of our generic Tussionex are seasonal and correlate with the cough and cold season. We launched commercialization of Adzenys XR-ODT on May 16, 2016, initiated an early experience program with Cotempla XR-ODT with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017 and launched commercialization of Adzenys ER on February 26, 2018. We sell our products to drug wholesalers in the United States. We have also established indirect contracts with drug, food and mass retailers that order and receive our generic Tussionex product through wholesalers. As a result of the continuing commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, we expect our future revenue to increase from historical levels.

Beginning in January 2019, we have restructured our commercialization efforts for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to focus on more profitable business channels and market segments. As a result, although product mix has changed, average net price per pack has increased. Unit shipments of Adzenys XR-ODT for the three and six months ended June 30, 2019 were 61,987 and 122,800, respectively, as compared to 68,467 and 126,606, respectively, for the three and six months ended June 30, 2018. Unit shipments of Cotempla XR-ODT for the three and six months ended June 30, 2019 were 51,410 and 107,852, respectively, as compared to 49,008 and 101,229, respectively, for the three and six months ended June 30, 2018. Unit shipments of Adzenys ER, which launched commercially on February 26, 2018, for the three and six months ended June 30, 2019 were 504 and 1,118, respectively, as compared to negligible unit sales and 1,224, respectively, for the three and six months ended June 30, 2018. Average net price per pack (30-day supply) of Adzenys XR-ODT was $117 for the three months ended June 30, 2019, as compared to $95 for the same period in 2018. For Cotempla XR-ODT, average net price per pack (30-day supply) was $127 for the three months ended June 30, 2019, as compared to $89 for the same period in 2018.

In the future, we will seek to generate additional revenue from product sales of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and generic Tussionex. If we are unsuccessful in these efforts, our results of operations and financial position may be adversely impacted.

Research and development

We expense research and development costs as they are incurred. Research and development expenses consist of costs incurred in the discovery and development of our product candidates, and primarily include:

- expenses, including salaries, benefits, and share-based compensation expense, of employees engaged in research and development activities;
- expenses incurred under third party agreements with contract research organizations (“CROs”), and investigative sites that conduct our clinical trials and a portion of our pre-clinical activities;
- cost of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- cost of facilities, depreciation and other allocated expenses;
- fees paid to regulatory authorities for review and approval of our product candidates; and
- expenses associated with obtaining and maintaining patents.

Direct development expenses associated with our research and development activities are allocated to our products and product candidates. Indirect costs related to our research and development activities that are not allocated to a product or product candidate are included in “Other Research and Development Activities” in the table below.

The following table summarizes our research and development expenses for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cotempla XR-ODT	$ 82	$ 550	$ 485	$ 570
Adzenys ER	3	13	7	17
Adzenys XR-ODT	369	495	1,712	895
NT0502	155	—	214	—
Other Research and Development Activities (1)	1,400	1,323	2,788	2,590
	$2,009	$2,381	$5,206	$4,072

(1) Includes unallocated product development cost, salaries and wages, occupancy and depreciation and amortization.

We expect that our research and development expenses will fluctuate over time as we explore new product candidates, but will decrease as a percentage of revenue if Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER are commercially successful. We expect to fund our research and development expenses from our current cash and cash equivalents, sales of our commercial products and, if approved, our product candidates, and the net proceeds from any future equity or debt financings.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, 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.

Selling and marketing

Selling and marketing expenses consist primarily of salaries and related costs for personnel, including share-based compensation expense, commercialization activities for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, pre-commercialization activities and preparation for the launch and commercialization of Adzenys ER, and trade sales expenses for our generic Tussionex. Other selling and marketing expenses include market research, brand development, advertising agency and other public relations costs, managed care relations, medical marketing, sales support tools, sales planning and market data and analysis.

We believe that our selling and marketing expenses may continue at these levels to support the ongoing commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in the United States.

General and administrative

General and administrative expenses consist primarily of salaries and related costs for personnel, including share-based compensation expense, for our employees in executive, finance, information technology and human resources functions. Other general and administrative expenses include facility-related costs not otherwise included in research and development expenses or cost of goods sold, and professional fees for business development, accounting, tax and legal services, expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services, director and officer insurance premiums and investor relations costs, as well as accounting and compliance costs to support the commercialization of our products, and, if approved, our product candidates. In addition, general and administrative expenses include our Paragraph IV litigation costs, if any.

We anticipate that our general and administrative expenses may increase as we incur additional costs and professional fees associated with future business development activities, if any. In addition, although we have settled our recent Paragraph IV litigation cases, we may be subject to future Paragraph IV litigation costs, and could incur material legal fees in the enforcement of our intellectual property rights.

Interest expense, net

Interest expense to date has consisted primarily of interest expense on senior debt, including the amortization of debt discounts, the Note and the capitalized leases from Essex resulting from the sale-leaseback transactions of our newly-acquired property and equipment. We amortize debt issuance costs over the life of the notes which are reported as interest expense in our consolidated statements of operations.

Other income (expense), net

Other income and expense to date has primarily consisted of amortization of the net gain recorded on the sale-leaseback of our property and equipment. The gains on the transactions were recognized on a straight-line basis over the respective 42-month lease term. In February 2017, we entered into an agreement for the sale-leaseback of newly acquired assets of up to $5.0 million to finance our capital expenditures. Under this agreement, we entered into leases and sold assets with a total capitalized cost of $481,000 and $2,742,000 at effective interest rates of 14.3% and 14.9% on February 13, 2017 and June 30, 2017, respectively. The February sale resulted in a net gain of $14,000 which has been deferred and is being amortized over the 36-month term of the lease. There was no gain or loss on the June 2017 sale. (See Notes 6 to the notes to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional details). Other income and expense also includes interest earned, accretion and gains on our cash and cash equivalents and short-term investments and changes resulting from the remeasurement of the fair value of our earnout and derivative liabilities. The primary objective of our investment policy is liquidity and capital preservation.

RESULTS OF OPERATIONS

Three months ended June 30, 2019 compared to the three months ended June 30, 2018

Revenues

The following table summarizes our revenues for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase	% Increase
	2019	2018	(Decrease)	(Decrease)
	(in thousands)			
Net product sales	$15,643	$11,363	$ 4,280	37.7 %

Net product sales were $15.6 million for the three months ended June 30, 2019, an increase of $4.2 million, or 37.7%, compared to $11.4 million for the three months ended June 30, 2018. Sales from Cotempla XR-ODT increased approximately $2.2 million to $6.5 million for the three months ended June 30, 2019, compared to $4.3 million for the three months ended June 30, 2018. Sales from Adzenys XR-ODT increased $0.7 million to $7.2 million for the three months ended June 30, 2019, compared to $6.5 million for the three months ended June 30, 2018. Sales from our generic Tussionex increased $1.3 million to $1.8 million for the three months ended June 30, 2019, compared to $0.5 million for the three months ended June 30, 2018. Sales from Adzenys ER, which launched on February 26, 2018, were $0.1 million for the three months ended June 30, 2019 and were negligible for the three months ended June 30, 2018.

Cost of goods sold

The following table summarizes our cost of goods sold for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase	% Increase
	2019	2018	(Decrease)	(Decrease)
	(in thousands)			
Cost of goods sold	$ 5,099	$ 6,987	$ (1,888)	(27.0)%

Cost of goods sold was $5.1 million for the three months ended June 30, 2019, a decrease of $1.9 million, or 27.0%, compared to $7.0 million for the three months ended June 30, 2018. This decrease was primarily due to a $1.1 million decrease in production costs relating to efficiencies resulting from increased production to meet sales demand from our branded products and $0.8 million decrease in labor and indirect production aggregate costs. The lower cost of goods sold, coupled with the 37.7% higher net product sales, increased our gross profit by 29% for the three months ended June 30, 2019 compared to the same period in 2018.

Research and development expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Research and development expenses	$ 2,009	$ 2,381	$ (372)	(15.6)%

Research and development expenses were $2.0 million for the three months ended June 30, 2019, a decrease of $0.4 million, or 15.6%, compared to $2.4 million for the three months ended June 30, 2018. The decrease was primarily due to a $0.5 million decrease in product development and clinical studies expenses related to our post marketing commitment studies of our ADHD products, partially offset by a $0.2 million increase in professional services expense.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Selling and marketing expenses	$ 7,269	$11,557	$ (4,288)	(37.1)%

Selling and marketing expenses were $7.3 million for the three months ended June 30, 2019, a decrease of $4.3 million, or 37.1%, compared to $11.6 million for the three months ended June 30, 2018. This decrease was primarily driven by lower salary and benefit expenses of $2.4 million, lower marketing expenses of $1.0 million, lower travel and entertainment expenses of $0.8 million, primarily resulting from the restructuring of our sales and marketing organization in the quarter ended December 31, 2018, lower professional services expenses of $0.4 million, lower contract sales organization expenses of $0.4 million due to the internalization of our sales force in April 2018 and lower advertising expenses of $0.2 million. These decreases were partially offset by higher administrative expenses of $0.9 million due to the establishment of our internal sales team in April 2018.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
General and administrative expense	$ 3,712	$ 3,705	$ 7	0.2 %

General and administrative expenses were $3.7 million for each of the three months ended June 30, 2019 and 2018.

Interest expense

The following table summarizes interest expense for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Interest expense	$ 1,987	$ 2,232	$ (245)	(11.0)%

The total interest expense was $2.0 million for the three months ended June 30, 2019, a decrease of $0.2 million, or 11.0%, compared to $2.2 million for the three months ended June 30, 2018, primarily due to the decrease in outstanding principal under the senior secured credit agreement. Interest expense primarily consists of interest on the Facility for both the three months ended June 30, 2019 and 2018.

Other income (expense), net

The following table summarizes our other income (expense) for the three months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Other income, net	$ 670	$ 292	$ 378	129.5 %

Other income, net, was $0.7 million for the three months ended June 30, 2019, an increase of $0.4 million, or 129.5%, compared to $0.3 million for the three months ended June 30, 2018. Other income, net mainly consisted of change in fair value of the Deerfield debt derivative and interest income for both the three months ended June 30, 2019 and 2018.

Six months ended June 30, 2019 compared to the six months ended June 30, 2018

Revenues

The following table summarizes our revenues for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Net product sales	$30,277	$22,092	$ 8,185	37.0 %

Net product sales were $30.3 million for the six months ended June 30, 2019, an increase of $8.2 million, or 37.0%, compared to $22.1 million for the six months ended June 30, 2018. Sales from Cotempla XR-ODT increased approximately $4.3 million to $12.3 million for the six months ended June 30, 2019, compared to $8.0 million for the six months ended June 30, 2018. Sales from Adzenys XR-ODT increased $2.4 million to $13.9 million for the six months ended June 30, 2019, compared to $11.5 million for the six months ended June 30, 2018. Sales from our generic Tussionex increased $1.4 million to $3.8 million for the six months ended June 30, 2019, compared to $2.4 million for the six months ended June 30, 2018. Net sales of Adzenys ER, which launched on February 26, 2018, were $0.3 and $0.2 million for the six months ended June 30, 2019 and 2018, respectively.

Cost of goods sold

The following table summarizes our cost of goods sold for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Cost of goods sold	$11,495	$12,208	$ (713)	(5.8)%

Cost of goods sold was $11.5 million for the six months ended June 30, 2019, a decrease of $0.7 million, or 5.8%, compared to $12.2 million for the six months ended June 30, 2018. This decrease was primarily due to a $2.7 million decrease in production cost relating to efficiencies resulting from increased production to meet sales demand from our branded products. These decreases were partially offset by a $2.0 million increase in labor and indirect production aggregate costs associated with increased manufacturing demand for our products and associated increased finished drug, royalties and logistic costs relating to the 53.8% increase in sales of Cotempla XR-ODT and the 20.8% increase in sales of Adzenys XR-ODT for the six months ended June 30, 2019 as compared to the six months ended June 30, 2018.

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Research and development expenses	$ 5,206	$ 4,072	$ 1,134	27.8 %

Research and development expenses were $5.2 million for the six months ended June 30, 2019, an increase of $1.1 million, or 27.8%, compared to $4.1 million for the six months ended June 30, 2018. The increase was primarily due to the clinical study expenses for our post-marketing commitments for Adzenys XR-ODT and Cotempla XR-ODT.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Selling and marketing expenses	$14,338	$24,547	$(10,209)	(41.6)%

Selling and marketing expenses were $14.3 million for the six months ended June 30, 2019, a decrease of $10.2 million, or 41.6%, compared to $24.5 million for the six months ended June 30, 2018. This decrease was primarily driven by lower contract sales organization expenses of $7.0 million due to the internalization of our sales force in April 2018, lower marketing expenses of $2.0 million, lower professional services expenses of $1.1 million, lower salary and benefit expenses of $0.9 million, lower advertising expenses of $0.4 million and lower travel and entertainment expenses of $0.2 million. These decreases were partially offset by higher administrative expenses of $1.4 million due to the establishment of our internal sales team in April 2018.

General and administrative expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
General and administrative expense	$ 7,505	$ 7,051	$ 454	6.4 %

General and administrative expenses were $7.5 million for the six months ended June 30, 2019, an increase of approximately $0.4 million, or 6.4%, compared to $7.1 million for the six months ended June 30, 2018. The increase was primarily from higher salary and incentive compensation expense of $0.7 million, partially offset by a $0.3 million decrease in professional services expense.

Interest expense

The following table summarizes interest expense for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Interest expense	$ 4,102	$ 4,452	$ (350)	(7.9)%

The total interest expense was $4.1 million for the six months ended June 30, 2019, a decrease of $0.4 million, or 7.9%, compared to $4.5 million for the six months ended June 30, 2018, primarily due to the decrease in outstanding principal under the senior secured credit agreement. Interest expense primarily consists of interest on the Facility for both the six months ended June 30, 2019 and 2018.

Other income (expense), net

The following table summarizes our other income (expense) for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2019	2018		
	(in thousands)			
Other income, net	$ 1,006	$ 595	$ 411	69.1 %

Other income, net, was $1.0 million for the six months ended June 30, 2019, an increase of $0.4 million, or 69.1%, compared to $0.6 million for the six months ended June 30, 2018. Other income, net mainly consisted of change in fair value of the Deerfield debt derivative and interest income for both the six months ended June 30, 2019 and 2018.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

From our reorganization in 2009 until our initial public offering ("IPO"), we financed our operations primarily through private placements of common stock and redeemable convertible preferred stock and bank and other lender financing. Since that time, we have financed our operations principally through public offerings of our common stock and borrowings under our senior secured credit agreement.

On May 11, 2016, we entered into a $60.0 million senior secured credit facility (the "Facility") with Deerfield Private Design Fund III, L.P. (66 2/3% of Facility) and Deerfield Special Situations Fund, L.P. (33 1/3% of Facility) (collectively, "Deerfield") as lenders. For additional description of this Facility, see "—Credit facilities" below.

In February 2017, we entered into an agreement with Essex for the sale-leaseback of newly acquired assets of up to $5.0 million to finance our capital expenditures. Each lease under this master agreement is for an initial term of 36 months and will have a bargain purchase option at the end of the respective lease. Under this agreement, we entered into leases and sold assets with a total capitalized cost of $481,000 and $2,742,000 at effective interest rates of 14.3% and 14.9% on February 13, 2017 and June 30, 2017, respectively.

In February 2017, we closed an underwritten public offering of 5,750,000 shares of our common stock at a public offering price of $5.00 per share, which includes 750,000 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price on February 17, 2017. Deerfield, our senior lender, participated in the purchase of our common shares as part of this public offering, and as a result, was classified as a related party at the time of the corresponding transactions. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us were approximately $26.7 million.

On June 30, 2017, we closed an underwritten public offering of 4,800,000 shares of our common stock at a price of $6.25 per share for total proceeds of $30.0 million before estimated offering costs of $0.2 million. We also granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of our common stock which the underwriters exercised in full on July 26, 2017. The net proceeds to us from this offering, after deducting offering expenses payable by us, were approximately $34.3 million.

The shares of common stock for both the June 2017 and February 2017 offerings were offered pursuant to a shelf registration statement on Form S-3, including a base prospectus, filed by us on August 1, 2016, and declared effective by the SEC on August 12, 2016. This shelf registration statement covers the offering, issuance and sale by us of up to an aggregate of $125.0 million of our common stock, preferred stock, debt securities, warrants and/or units (the "2016 Shelf").

We simultaneously entered into a sales agreement with Cowen and Company, LLC, as sales agent, to provide for the offering, issuance and sale by us of up to $40.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf (the "Cowen Sales Agreement"). During the year ended December 31, 2017, we sold an aggregate 749,639 shares of common stock under the Cowen Sales Agreement, at an average sale price of approximately $5.01 per share for gross proceeds of $3.7 million and net proceeds of $3.6 million after paying compensation to the sales agent of $0.1 million. During the year ended December 31, 2018, we sold an aggregate 651,525 shares of common stock under the Sales Agreement, at an average sale price of approximately $6.25 per share for gross proceeds of $4.1 million and net proceeds of $3.9 million and paying total compensation to the sales agent and other costs of approximately $0.2 million. On November 5, 2018, we supplemented the 2016 Shelf to reduce the size of the Sales Agreement to up to $7,825,113 of our common stock (inclusive of amounts previously sold thereunder prior to the date hereof), effective on November 5, 2018. As of the date hereof, aggregate gross proceeds of sales of our common stock under the Sales Agreement total $7,825,113, and sales of our common stock under the Cowen Sales Agreement have been suspended.

On November 8, 2018, we closed an underwritten public offering 19,999,999 shares of our common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $43.4 million. Also, on November 5, 2018, we entered into a Second Amendment to the Facility with Deerfield under which we used $7.5 million of proceeds of the offering to prepay $7.5 million of principal on the Facility otherwise due on May 11, 2019. Pursuant to the Second Amendment, the schedule of principal repayments under the facility was further modified to allow for the $15.0 million payment otherwise due on May 11, 2020 to be deferred until either May 2021 or May 2022 if certain revenue milestones for the years ended December 31, 2019 and December 31, 2020 are achieved. Finally, the Second Amendment provides us with a right, subject to the terms and conditions of the

Facility and certain other limitations, to make interest and principal payments through the issuance of our common stock, and provides Deerfield with a right, subject to the terms and conditions of the Facility and the amended and restated convertible notes (the "A&R Notes") issued under the Facility and certain other limitations, to convert principal under the A&R Notes into our common stock, subject to a floor ranging from 95% to 83% of $10.00 per share.

On March 18, 2019, we filed a shelf registration statement covering the offering, issuance and sale by us of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants and/or units (the "2019 Shelf"), which was declared effective by the SEC on May 1, 2019. Effective as of August 12, 2019, the 2016 Shelf is no longer available for further primary offerings or sales of our securities. We simultaneously entered into a sales agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the offering, issuance and sale by us of up to $30.0 million of our common stock from time to time in "at-the-market" offerings under the 2019 Shelf (the "Cantor Sales Agreement").

Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity. Accordingly, our cash equivalents and short-term investments are invested in bank deposits, money market funds, financials and corporate debt securities, all of which are currently providing only minimal returns.

As of June 30, 2019, we had $25.8 million in cash and cash equivalents and $4.5 million in short-term investments. We believe that our existing cash and cash equivalents and short-term investments will be sufficient to fund our operations for at least the next 12 months after the filing date of this Quarterly Report on Form 10-Q.

We may continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funds will be available on terms favorable to us, if at all, or that we will be able to successfully commercialize our product candidates. In addition, we may not be profitable even if we succeed in commercializing Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER.

Cash flows

The following table sets forth the primary sources and uses of cash for the periods indicated:

	Six months ended June 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Net cash (used in) provided by:			
Net cash used in operating activities	$ (7,860)	$ (21,197)	$ 13,337
Net cash (used in) provided by investing activities	(4,855)	7,997	(12,852)
Net cash used in financing activities	(8,006)	(451)	(7,555)
Net decrease in cash and cash equivalents	$ (20,721)	$ (13,651)	$ (7,070)

Cash used in operating activities

Net cash used in operating activities during these periods primarily reflected our net losses, partially offset by changes in working capital and non-cash charges including deferred interest on debt, changes in fair value of earnout, derivative and warrant liabilities, share-based compensation expense, depreciation expense, amortization of patents and other intangible assets and amortization of senior debt fees.

Net cash used in operating activities was $7.9 million and $21.2 million for the six months ended June 30, 2019 and 2018, respectively. The $13.3 million decrease in net cash used in operating activities was due to the $18.3 million decrease in our net losses, as discussed in "Results of Operations" above, a $0.3 million increase in noncash items and a $5.3 million decrease in the provision of cash from working capital.

The decrease in cash provided from working capital changes resulted primarily from a $16.1 million decreased cash usage for accounts payable and accrued expenses due to the timing of vendor invoicing and payments and $1.0

million decrease in inventory, partially offset by a $12.0 million increase in accounts receivable primarily due to increased sales in the first six months of 2019. The increase in noncash items was principally due to a $0.3 million increase in amortization of senior debt fees, a $0.2 million increase in amortization of patents and other intangible assets, a $0.2 million increase in depreciation and amortization of property and equipment. These increases in noncash items were partially offset by a $0.3 million decrease in the fair value change of derivative liabilities and a $0.2 million decrease in share-based compensation expense.

Cash (used in) provided by investing activities

Net cash used in investing activities is generally due to investments of cash in excess of our operating needs as well as purchase of equipment to support our research and development and manufacturing activities.

Net cash used by investing activities of $4.9 million for the six months ended June 30, 2019 was primarily due to a $7.2 million purchase of short-term investments, partially offset by the $2.8 million sales and maturities of short-term investments and $0.4 million of capital expenditure principally for production equipment. Net cash provided by investing activities was $8.0 million for the six months ended June 30, 2018 primarily from $26.7 million of sales and maturities of short-term investments, partially offset by the $17.9 million purchase of short-term investments and $0.8 million of capital expenditure principally for production equipment.

Cash used in financing activities

Net cash used in financing activities of $8.0 million for the six months ended June 30, 2019 was primarily due to $7.5 million principal payment of senior secured debt and $0.5 million principal payment of finance lease obligations. Net cash used in financing activities of $0.5 million for the six months ended June 30, 2018 was for payments under the capital leases.

Credit facilities

Principal on the Facility was initially due in three equal annual installments beginning in May 2019 and continuing through May 2021, with a final payment of principal, interest and all other obligations under the Facility due May 11, 2022. Interest is due quarterly beginning in June 2016, at a rate of 12.95% per year. In connection with the Facility, we paid a $1,350,000 yield enhancement fee to Deerfield and approximately $0.2 million of legal fees. Borrowings under the Facility are collateralized by substantially all of our assets, except the assets under capital lease, and we will maintain cash on deposit of not less than $5.0 million.

We had an option, which we exercised, to defer payment of each of the first four interest payments, adding such amounts to the outstanding loan principal. The aggregate $6.6 million of first year accrued interest (the “Accrued Interest”) was to be paid in cash on June 1, 2017.

However, on June 1, 2017, we entered into an amendment (“the Amendment”) to the Facility to provide a one-year deferral to June 1, 2018, with an option for a second year of deferral to June 1, 2019, at our election, of payment of the Accrued Interest, provided that we met certain sales revenue targets and obtained FDA approval of certain of our product candidates on or before the Prescription Drug User Fee Act (the “PDUFA”) goal date. The right to payment of the $6.6 million of accrued interest was memorialized in the form of senior secured convertible notes (the “Convertible Notes”) issued to Deerfield on the Amendment Date. Interest was due quarterly at a rate of 12.95% per year. Deerfield had an option to convert these notes into our common stock.

The $6.6 million of Convertible Notes were convertible into shares of our common stock at Deerfield’s option at any time up to the close of business on the date that is five days prior to the PIK Maturity Date. The per share conversion price was to be the greater of (A) 95% of the average of the volume weighted average prices per share of our common stock on the NASDAQ Global Market for the three-trading-day period immediately preceding such conversion, and (B) $7.00. On June 30, 2017, we filed a registration statement on form S-3 with the SEC registering 940,924 shares of our common stock that may be offered from time to time by Deerfield, the maximum number of shares of our common stock which would be issued upon conversion of the Convertible Notes assuming the lowest possible

conversion price of $7.00 per share, and such registration was declared effective by the SEC on July 11, 2017. Deerfield cannot own more than 9.985% of our outstanding shares at any one time, and the aggregate conversion could not exceed 19.9% of our outstanding common stock as of June 1, 2017.

The principal amount of the Convertible Notes issued under the Amendment and all accrued and unpaid interest thereon was to become due and payable upon written notice from the Deerfield, and if either (a) we did not meet certain quarterly sales milestones specified in the Amendment or (b) we did not receive and publicly announce FDA approval of the new drug applications on or before the applicable PDUFA goal date as set forth on the schedules to Amendment. Per the Amendment, we will prepay all of the outstanding obligations under the Facility and the Convertible Notes upon the occurrence of a change in control or a sale of substantially all of our assets and liabilities. The Amendment increased the staggered prepayment fees for prepayments due upon a change of control or any other prepayment made or required to be made by us by 300 basis points from June 1, 2017 through the period ending prior to May 11, 2020 for the change in control prepayment fees and through the period ending prior to May 11, 2022 for any other prepayments, respectively (the "Prepayment Premiums"). Such Prepayment Premiums, as amended, ranged from 12.75% to 2%.

On October 26, 2017, Deerfield elected to convert the entire $6.6 million of Convertible Notes into shares of our common stock at a conversion price of $7.08 per share. This resulted in our issuance of 929,967 shares of our common stock to Deerfield on this date and the cancellation of the Convertible Notes.

On November 5, 2018, we entered into a Second Amendment to the Facility with Deerfield under which we used $7.5 million of proceeds of an underwritten public offering of shares of our common stock, which closed on November 8, 2018, to prepay $7.5 million of principal on the Facility otherwise due on May 11, 2019. Pursuant to the Second Amendment, the schedule of principal repayments under the facility was further modified to allow for the $15.0 million payment otherwise due on May 11, 2020 to be deferred until either May 2021 or May 2022 if certain revenue milestones for the years ended December 31, 2019 and December 31, 2020 are achieved. Finally, the Second Amendment provides us with a right, subject to the terms and conditions of the Facility and certain other limitations, to make interest and principal payments through the issuance of our common stock, and provides Deerfield with a right, subject to the terms and conditions of the Facility and the amended and restated convertible notes (the "A&R Notes") and certain other limitations, to convert principal under the A&R Notes into our common stock, subject to a floor ranging from 95% to 83% of $10.00 per share.

Borrowings under the Facility are collateralized by substantially all of our assets, except the assets under capital lease, and we will maintain cash on deposit of not less than $5.0 million. The Facility also contains certain customary nonfinancial covenants, including limitations on our ability to transfer assets, engage in a change of control, merge or acquire with or into another entity, incur additional indebtedness and distribute assets to shareholders. Upon an event of default, the lender may declare all outstanding obligations accrued under the Facility to be immediately due and payable, and exercise its security interests and other rights. As of June 30, 2019, we were in compliance with the covenants under the Facility.

During the year ended December 31, 2017, we entered into an agreement with Essex for the sale-leaseback of newly acquired assets with a total capitalized cost of $3.2 million, with bargain purchase option at the end of the lease. The approximate imputed interest rate on these leases is 14.9%. In addition, during the year ended December 31, 2018 and the quarter ended June 30, 2019, the Company entered into equipment leases with a total capitalized cost of $0.1 million and $0.4 million, respectively, with bargain purchase option at the end of each respective lease. The approximate interest rate on these leases is 5.3% and 6.5%, respectively. These leases were classified as finance leases as of June 30, 2019 and capital leases as of December 31, 2018. See "Contractual Commitments and Obligations" below for future payments under these leases.

Capital resources and funding requirements

On August 1, 2016, we filed a shelf registration statement on Form S-3 with the SEC, which covers the offering, issuance and sale by us of up to an aggregate of $125.0 million of our common stock, preferred stock, debt securities, warrants and/or units. We simultaneously entered into a Sales Agreement with Cowen and Company, LLC, as

sales agent, to provide for the offering, issuance and sale by us of up to $40.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf. The Shelf was declared effective by the SEC on August 12, 2016.

On November 5, 2018, we filed Supplement No. 1 to the prospectus dated August 12, 2016, which reduced the size of our continuous offering of our common stock pursuant to the Sales Agreement. Following the reduction, we are authorized to issue up to $7,825,113 of our common stock pursuant to the Sales Agreement (inclusive of amounts previously sold thereunder prior to the date hereof). As of the date hereof, aggregate gross proceeds of sales of our common stock under the Sales Agreement total $7,825,113, and sales of our common stock under the Sales Agreement have been suspended.

On November 8, 2018, we closed an underwritten public offering of 19,999,999 shares of our common stock at a public offering price of $2.30 per share, which includes 2,608,695 shares of our common stock resulting from the underwriters' exercise of their over-allotment option at the public offering price. The net proceeds to us from this offering, after deducting underwriting discounts and commissions and other offering expenses payable by us, were approximately $43.4 million.

During the year ended December 31, 2018, we sold an aggregate 651,525 shares of common stock under the Sales Agreement, at an average sale price of approximately $6.25 per share for gross proceeds of $4.1 million and net proceeds of $3.9 million and paying total compensation to the sales agent and other costs of approximately $0.2 million.

On March 18, 2019, we filed a shelf registration statement covering the offering, issuance and sale by us of up to an aggregate of $100.0 million of our common stock, preferred stock, debt securities, warrants and/or units (the "Second Shelf"). We simultaneously entered into a sales agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the offering, issuance and sale by us of up to $30.0 million of our common stock from time to time in "at-the-market" offerings under the Second Shelf (the "Cantor Sales Agreement"). The Second Shelf was declared effective by the SEC on May 1, 2019.

We may continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funds will be available on terms favorable to us, if at all. We expect to continue to incur operating losses for the foreseeable future as we seek to increase net sales and profitability of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER and continue the development of our product candidates. There can be no assurance that we will ever attain sufficient levels of net sales of our commercial products to achieve profitability or that we will be successful in developing and attaining regulatory approval of our development candidates.

We believe that our existing cash and cash equivalents and short-term investments will be sufficient to fund our anticipated operating requirements for at least the next twelve months from the date of the filing of this Quarterly Report on Form 10-Q.

We have based our estimate of our future operating requirements on assumptions that may prove to be wrong, resulting in the use of our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our products and product candidates, we are unable to estimate the amount of increased capital required to become profitable. Our future funding requirements will depend on many factors, including:

- the costs of operating our sales, marketing and distribution capabilities;
- the market acceptance of our products and, if approved, product candidates and related success in commercializing and generating sales from our products and, if approved, product candidates, that we may develop;
- the costs of our manufacturing capabilities to support our commercialization activities, including any costs associated with adding new capabilities;
- the costs and timing involved in obtaining regulatory approvals for our new product candidates;

- the timing and number of product candidates for which we obtain regulatory approval;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- the number and characteristics of new product candidates that we pursue; and
- our ability to hire qualified employees at salary levels consistent with our estimates to support our growth and development, including additional general and administrative personnel as a result of increased product sales and commercial operations, as well as sales and marketing personnel to commercialize our approved products.

Accordingly, we may need to obtain additional financing in the future which may include public or private debt and equity financings and/or entrance into product and technology collaboration agreements or licenses and asset sales. There can be no assurance that additional capital will be available when needed on acceptable terms, or at all. The issuance of equity securities may result in dilution to stockholders. If we raise additional funds through the issuance of debt securities, these securities may have rights, preferences and privileges senior to those of our common stock and the terms of the debt securities could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may have to scale back our commercial operations or limit our research and development activities, which would have a material adverse impact on our business prospects and results of operations.

Please see "Risk Factors" for additional risks associated with our substantial capital requirements.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to the notes to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services at a point in time. We make estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees, wholesaler chargebacks and estimated rebates) to be incurred on the selling price of the respective product sales, and recognize the estimated amount as revenue when control of the product transfers to the customers (e.g., upon delivery). Variable consideration is determined using either an expected value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty

associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint will require the use of significant management judgment and other market data. We provide for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. We analyze recent product return history and other market data obtained from our third-party logistics providers ("3PLs") to determine a reliable return rate. Additionally, we analyze historical savings offers and rebate payments based on patient prescriptions dispensed for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER and information obtained from third party providers to determine these respective variable considerations.

We sell our generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to a limited number of pharmaceutical wholesalers, all subject to rights of return. Pharmaceutical wholesalers buy drug products directly from manufacturers. Title to the product passes upon delivery to the wholesalers, when the risks and rewards of ownership are assumed by the wholesaler. These wholesalers then resell the product to retail customers such as food, drug and mass merchandisers.

Net product sales

Net product sales represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER include savings offers, prompt payment discounts, wholesaler fees, estimated rebates to be incurred on the selling price of the respective product sales and estimated allowances for product returns.

Gross to net sales adjustments for generic Tussionex include prompt payment discounts, estimated allowances for product returns, wholesaler fees, estimated government rebates and estimated chargebacks to be incurred on the selling price of generic Tussionex related to the respective product sales.

We recognize total gross product sales less gross to net sales adjustment as revenue based on shipments from 3PLs to our wholesaler customers.

Savings offers for branded products

We offer savings programs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. We record the amount of redeemed savings offers based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustment at the time revenue is recognized.

Prompt payment discounts

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustment at the time revenue is recognized.

Wholesale distribution fees

Wholesale distribution fees are based on definitive contractual agreements for the management of our products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

Rebates

Our branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER are subject to commercial managed care and government managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating managed care organizations and federal and/or state governments. Calculations related to rebate accruals of branded products are estimated based on information from third-party providers.

Our generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Generic Tussionex government rebates are estimated based upon rebate payment data available from sales of our generic Tussionex product over the past three years.

Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. Historical trends of estimated rebates will be continually monitored and may result in future adjustments to such estimates.

Product returns

Wholesalers' contractual return rights are limited to defective product, product that was shipped in error, product ordered by customer in error, product returned due to overstock, product returned due to dating or product returned due to recall or other changes in regulatory guidelines. The return policy for expired product allows the wholesaler to return such product starting six months prior to expiry date to twelve months post expiry date. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

We analyzed recent branded product return history and other market data obtained from our 3PLs as well as data available from sales of our branded products to determine a reliable return rate for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Generic Tussionex product returns were estimated based upon return data available from sales of our generic Tussionex product over the past three years.

Wholesaler chargebacks for generic product

Our generic Tussionex products are subject to certain programs with wholesalers whereby pricing on products is discounted below wholesaler list price to participating entities. These entities purchase products through wholesalers at the discounted price, and the wholesalers charge the difference between their acquisition cost and the discounted price back to us. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustment at the time revenue is recognized based on information provided by third parties.

Due to estimates and assumptions inherent in determining the amount of generic Tussionex returns, rebates and chargebacks, the actual amount of returns, claims for rebates and chargebacks may be different from the estimates, at which time reserves would be adjusted accordingly. Wholesale distribution fees and the allowance for prompt pay discounts are recorded at the time of shipment and such fees and allowances are recorded in the same period that the related revenue is recognized.

Inventories

Inventories are measured at the lower of cost (first in, first out) or net realizable value. Inventories have been reduced by an allowance for excess and obsolete inventories. Cost elements include material, labor and manufacturing overhead. Inventories consist of raw materials, work in process and finished goods.

Until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable, pre-launch inventories are expensed into research and development. Manufacturing costs for the production of Adzenys XR-ODT incurred after the January 27, 2016 FDA approval date, for the production of Cotempla XR-ODT incurred after June 30, 2017, following the FDA approval date of June 19, 2017, and for the production of Adzenys ER incurred after September 30, 2017, following the FDA approval date of September 15, 2017, are being capitalized into inventory.

Research and development expenses

Research and development expenses include costs incurred in performing research and development activities, personnel related expenses, laboratory and clinical supplies, facilities expenses, overhead expenses, fees for contractual services, including preclinical studies, clinical trials and raw materials. We estimate clinical trial expenses based on the services received pursuant to contracts with research institutions and CROs which conduct and manage clinical trials on

our behalf. We accrue service fees based on work performed, which relies on estimates of total costs incurred based on milestones achieved, patient enrollment and other events. The majority of our service providers invoice us in arrears, and to the extent that amounts invoiced differ from our estimates of expenses incurred, we accrue for additional costs. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and cash flows. To date, we have not experienced any events requiring us to make material adjustments to our accruals for service fees. If we do not identify costs that we incurred or if we underestimate or overestimate the level of services performed, our actual expenses could differ from our estimates which could materially affect our results of operations. Adjustments to our accruals are recorded as changes in estimates become evident. In addition to accruing for expenses incurred, we may also record payments made to service providers as prepaid expenses that we will recognize as expense in future periods as services are rendered.

Share-based compensation expense

Share-based compensation awards, including grants of stock options and restricted stock and modifications to existing stock options, are recognized in the statement of operations based on their fair values. Compensation expense related to stock-based awards is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. The fair value of our share-based awards to employees and directors is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

Under recent guidance for accounting for share-based payments, we have elected to continue estimating forfeitures at the time of grant and, if necessary, revise the estimate in subsequent periods if actual forfeitures differ from those estimates. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest.

We calculated the fair value of share-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the input of subjective assumptions, including stock price volatility and the expected life of stock options. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. As a formerly private company, we do not have sufficient history to estimate the volatility of our common stock price or the expected life of our options. We have not paid and do not anticipate paying cash dividends. Therefore, the expected dividend rate is assumed to be 0%. The expected stock price volatility for stock option awards was based on a blended volatility rate of prior studies of historical volatility from a representative peer group of comparable companies' selected using publicly-available industry and market capitalization data and 30 months of our stock price volatility. The risk-free rate was based on the U.S. Treasury yield curve in effect commensurate with the expected life assumption. The average expected life of stock options was determined according to the "simplified method" as described in SAB Topic 110, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. We estimate forfeitures based on our historical analysis of actual stock option forfeitures. We estimate the fair value of all stock option awards on the grant date by applying the Black-Scholes option pricing valuation model. Given the absence of an active market for our common stock prior to our IPO, our board of directors was required to estimate the fair value of our common stock at the time of each option grant primarily based upon valuations performed by a third-party valuation firm. After the closing of our IPO, our board of directors has determined the fair value of each share of underlying common stock based on the closing price of our common stock as reported by the NASDAQ Global Market on the date of grant.

There is a high degree of subjectivity involved when using option-pricing models to estimate share-based compensation. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee stock-based awards is determined using an option-pricing model, such a model value may not be indicative of the fair value that would be observed in a market transaction between a willing buyer and willing seller. If factors change and we employ different assumptions when valuing our

options, the compensation expense that we record in the future may differ significantly from what we have historically reported.

Derivative liabilities

We evaluate our debt and equity issuances to determine if those contracts or embedded components of those contracts qualify as derivatives requiring separate recognition in our financial statements. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as a liability and the change in fair value is recorded in other income (expense) in the consolidated results of operations. In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

When we have determined that the embedded conversion options should not be bifurcated from their host instruments, we record, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption and recorded in interest expense in the consolidated financial statements.

Intangible assets

Intangible assets subject to amortization, which principally include our proprietary modified-release drug delivery technology, the costs to acquire the rights to Tussionex ANDA and patents, are recorded at cost and are amortized over the estimated lives of the assets, which primarily range from 10 to 20 years.

CONTRACTUAL COMMITMENTS AND OBLIGATIONS

The following tables reflect summaries of our estimates of future material contractual obligations as of June 30, 2019. Future events could cause actual payments to differ from these estimates.

	Total	< 1 Yr.	1-3 Yrs.	3-5 Yrs.	Thereafter
			(In thousands)		
Deerfield senior secured facility	$ 57,243	$20,811	$36,432	$ —	$ —
Texas facility operating lease	5,705	980	2,036	2,136	553
Finance leases for equipment	1,937	1,511	234	192	—
Pennsylvania facility operating lease	284	154	130	—	—
Equipment operating leases	187	79	108	—	—
Earnout liability	37	—	—	—	37
	$ 65,393	$23,535	$38,940	$ 2,328	$ 590

We had borrowed $60.0 million under the Deerfield Facility. On November 5, 2018, we amended the facility and prepaid $7.5 million otherwise due in May 2019. Pursuant to the terms of the Facility, as amended, we made a $7.5 million principal payment in May 2019, and we currently have a balance of $45.0 million of senior secured credit as of June 30, 2019. The payments above are inclusive of related interest amounts as of June 30, 2019.

In addition to the commitments shown above, in response to a lawsuit brought against us by Shire LLC (“Shire”) for infringement of certain of Shire’s patents, we entered into a Settlement Agreement and an associated License Agreement (the “2014 License Agreement”) with Shire for a non-exclusive license to certain patents for certain

activities with respect to our New Drug Application (the "NDA") No. 204326 for an extended-release orally disintegrating amphetamine polistirex tablet in July 2014. Under the terms of the 2014 License Agreement, following FDA approval of our NDA for Adzenys XR-ODT, in the first quarter of 2016, we paid a lump sum, non-refundable license fee to Shire of an amount less than $1.0 million. This license fee was capitalized and is being amortized over the life of the longest associated patent. We are paying a single digit royalty to Shire on our net sales of Adzenys XR-ODT during the life of the licensed patents.

On March 6, 2017, after our NDA submission for Adzenys ER requiring a Paragraph IV certification notification to the producer of Adderall XR, Shire Pharmaceuticals, in accordance with the Hatch-Waxman Amendments, we entered into a License Agreement (the "2017 License Agreement") with Shire. Pursuant to this agreement, Shire granted us a non-exclusive license to certain patents owned by Shire for certain activities with respect to our NDA No. 204325 for an extended-release amphetamine liquid suspension. Under the terms of the 2017 License Agreement, following FDA approval of our NDA for Adzenys ER, in October 2017, we paid a lump sum, non-refundable license fee to Shire of an amount less than $1.0 million. This license fee was capitalized and is being amortized over the life of the longest associated patent. We are paying a single digit royalty to Shire on our net sales of Adzenys ER during the life of the licensed patents.

Due to the uncertainty of the amount and timing of the royalty payments for Adzenys XR-ODT and Adzenys ER, we have not presented such amounts in the table above. The license fees are paid and recorded as an intangible asset and amortized over the term of the license. The royalties are being recorded as cost of goods sold in the same period as the net sales upon which they are calculated.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, including any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

RECENT ACCOUNTING PRONOUNCEMENTS

See Note 2 to the notes to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further discussion of recent accounting pronouncements.

JOBS ACT

In April 2012, the Jumpstart Our Business Startups Act (the "JOBS Act"), was enacted in the United States. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk

We are exposed to market risk related to changes in interest rates as it impacts our interest income. As of June 30, 2019, we had cash and cash equivalents of $25.8 million and short-term investments of $4.5 million. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates as our cash equivalents are invested in interest-bearing money market funds. The goals of our investment policy are liquidity and capital preservation to fund our operations. Due to the short-term duration and low risk profile of

our cash equivalents and short-term investments portfolios, a 10% change in interest rates would not have a material effect on interest income we recognize or the fair market value of our investments. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates.

Interest risk

The interest rates on our notes payable are fixed. Therefore, we are not exposed to market risk from changes in interest rates as it relates to these interest-bearing obligations.

Effects of Inflation

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act of 1934, as amended, (the "Exchange Act"), our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We implemented internal controls to ensure we adequately evaluated our contracts and properly assessed the impact of the new accounting standards related to lease accounting on our financial statements to facilitate their adoption on January 1, 2019. There were no significant changes to our internal controls over financial reporting due to the adoption of the new standard.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. We may file infringement claims against third parties for the infringement of our patents, such as the lawsuits against Actavis Laboratories FL, Inc. ("Actavis") and Teva Pharmaceuticals USA, Inc. ("Teva") discussed below. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

On July 25, 2016, we received a paragraph IV certification from Actavis advising us that Actavis has filed an ANDA with the FDA for a generic version of Adzenys XR-ODT. On September 1, 2016, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Actavis, Inc. alleging that Actavis infringed our Adzenys XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Adzenys XR-ODT prior to the expiration of our patents.

On October 17, 2017, we entered into the Actavis Agreement with Actavis, which resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a paragraph IV certification from Teva advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva alleging that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents.

On December 21, 2018, we entered into the Teva Agreement with Teva, which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

On March 7, 2018 and April 18, 2019, we received citations advising us that the County of Harris Texas ("Harris County") and the County of Walker Texas ("Walker County") filed lawsuits on December 13, 2017 and January 11, 2019, respectively, against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through these lawsuits, each of Harris County and Walker County seek to recoup as damages some of the expenses they allegedly have incurred to combat opioid use and addiction. Each of Harris County and Walker County also seeks punitive damages, disgorgement of profits and attorneys' fees. While we believe that these lawsuits are without merit and we intend to vigorously defend against them, we are not able to predict at this time whether these proceedings will have a material impact on our financial condition or results of operations.

ITEM 1A. RISK FACTORS.

We operate in an industry that involves numerous risks and uncertainties. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q and in our other public filings, before making a decision to invest in our common stock. If any of the risks actually occur, our business, financial condition, results of operations and prospects could be harmed. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment.

RISKS RELATED TO COMMERCIALIZATION

We are heavily dependent on the commercial success of our branded commercial products. We have not generated substantial revenues from the sales of these products, or any sales revenues from any of our product candidates, if approved, and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenues from sales of Adzenys XR-ODT, our amphetamine extended-release orally disintegrating tablet ("XR-ODT"), Cotempla XR-ODT, our methylphenidate XR-ODT, Adzenys ER, our amphetamine XR oral suspension (which we collectively refer to as our "Branded Products") for the treatment of attention deficit hyperactivity disorder, or ADHD, and, if approved, any other product candidates that we may develop. We have limited commercial experience, having only generated revenues from the sale of our generic Tussionex since we acquired it in 2014, and Adzenys XR-ODT, Cotempla XR-ODT, and Adzenys ER, which we commenced commercializing in May 2016, September 2017, and February 2018, respectively. None of our marketed products have thus far generated product sales revenues at levels sufficient for us to attain profitability. We have not generated any revenues from product sales of any other product candidates and, to date, have incurred significant operating losses.

Our ability to generate product revenues is dependent on our ability to successfully commercialize our Branded Products, and any other product candidates that we may identify and develop or for which we may obtain approval. Our ability to successfully commercialize our products and product candidates depends on, among other things, our ability to:

- manufacture commercial quantities of our Branded Products and, if approved, any other product candidates that we may develop at acceptable cost levels; and
- successfully establish and/or maintain sales and marketing capabilities to commercialize our Branded Products and, if approved, any other product candidates that we may develop.

We have incurred, and anticipate continuing to incur, significant costs associated with commercialization of our approved products and, if approved, any other product candidates that we may develop. It is possible that we will never attain sufficient product sales revenues to achieve profitability.

If our sales and marketing efforts for our Branded Products are not successful, and if we are unable to establish and maintain sales and marketing capabilities or enter into agreements with third parties to market, distribute and sell our other product candidates, if approved, we may be unable to generate significant revenue.

We have only recently established internal and external capabilities for the sale, marketing and distribution of our Branded Products, and there is no guarantee that we will be successful in the commercialization of our products. We currently have a limited sales history for our Branded Products. Additionally, in the future, we may need to expand or build additional sales, marketing and distribution capabilities for our products. Although we have established a focused, specialty sales and marketing organization of approximately 75 representatives to promote our approved products in the United States, these commercialization capabilities have only been recently established, and we may need to significantly expand our sales force if we decide to undertake additional commercialization activities on our own, which will be costly and time-consuming. We cannot be certain that we will reap the benefits of our commercialization efforts of our Branded Products compared to the cost of such efforts. Our prior experience in the marketing, sale and distribution of pharmaceutical products is limited to our generic Tussionex, and, before the commercial launch of Adzenys XR-ODT, we had no prior experience, as a company, in marketing, sale and distribution of branded pharmaceutical products. There are significant risks involved in building and managing a sales organization, including our ability to successfully hire, retain and incentivize qualified individuals, generate sufficient and appropriate customer targets, provide adequate training to sales and marketing personnel, effectively manage a geographically dispersed sales and marketing team and successfully negotiate with managed care and third-party payors. Any failures associated with the operation or expansion of our internal and external sales, marketing and distribution capabilities could adversely impact the commercialization of these products.

In addition, while we realigned our commercial operations in November 2018 to deploy our resources to what we believe are the most appropriate regions and physician targets, there can be no assurances that we will realize the intended benefits of this realignment or that our strategy will improve our operating results. As part of this realignment, we also reduced the size of our commercialization organization resulting in approximately $1.0 million of severance and employee related costs. The realignment, and the resulting reduction of the size of our salesforce may result in fewer prescriptions written for our marketed products.

We also may enter into strategic partnerships with third parties to commercialize our Branded Products and our other product candidates, if approved, outside of the United States and intend to also enter into strategic partnerships with third parties for certain aspects of our commercialization efforts within the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Even though we have established an internal marketing and sales team, we may be unable to compete successfully against these more established companies.

Our business is subject to extensive regulatory requirements, and our approved products and any product candidates that obtain approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we remain subject to ongoing FDA, and other regulatory requirements governing, among other things, the production, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved new drug application ("NDA") is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval.

For example, a product's approval may contain requirements for potentially costly post-approval trials and surveillance to monitor the safety and efficacy of the product or the imposition of a Risk Evaluation and Mitigation Strategy, or REMS, program.

Prescription drug advertising, marketing and promotion are subject to federal, state and foreign regulations that include requirements for direct-to-consumer advertising and promotional activities involving the Internet and social media. In the United States, prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure they are marketed only for their approved indications and in accordance with the provisions of the approved label. Any promotion for uses or in patient populations not described in the approved labeling, known as "off-label" promotion, is impermissible and could subject us to enforcement actions and significant penalties for off-label marketing. The FDA has also provided guidance on industry-sponsored scientific and educational activities to ensure such activities are not promotional.

In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices ("cGMPs"). These cGMP regulations cover all aspects of manufacturing relating to our generic Tussionex, our Branded Products. As such, we are subject to continual review and periodic inspections to assess compliance with cGMP and must continue to expend time, money and resources in all areas of regulatory compliance, including manufacturing, production and quality control. As a result of the Consent Decree entered into by our predecessor that we were previously subject to, we were required to have a cGMP expert conduct an annual audit and submit those audit reports and our responses to the FDA for a period of five years. Although for our most recent and last annual audit by the cGMP expert in November 2014, the expert concluded that our corrective actions satisfactorily addressed the observations noted in its report, on May 22, 2015, the FDA's Dallas District Office identified three ongoing cGMP deviations in our

response to the audit related to batch failure investigations, quality control unit procedures, and in-process specifications. We implemented corrective actions and submitted additional information in our response to the FDA pursuant to the Consent Decree and the FDA closed the matter.

The facilities used by us to manufacture our products and any product candidates that we may develop are subject to inspections, including pre-approval inspections following our submission of any NDAs to the FDA for any product candidates that we may develop. For example, in connection with a general cGMP and pre-approval inspection for Adzenys ER from July 11 to July 25, 2017, we received a Form FDA 483 with one observation related to complaint records failing to document the reason and the individual making the decision not to conduct a complaint investigation. We implemented corrective action related to this observation and responded to the FDA. The FDA's most recent inspections in 2018 did not result in a Form FDA 483.

If we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our product candidates. If the FDA finds deficiencies at our manufacturing facility and does not approve our NDA for any of our future product candidates or if it withdraws any such approval in the future for our products, our ability to develop or market any of our products or any product candidates that we may develop will be significantly impacted.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including notice to physicians, withdrawal of the product from the market or suspension of manufacturing. Manufacturers are also subject to annual prescription drug product program fee. If we are unable to generate sales of our product candidates, the user fee requirements could be difficult to pay.

If we fail to comply with applicable regulatory requirements, the FDA may, for example:

- issue untitled or warning letters asserting that we are in violation of the Federal Food, Drug and Cosmetic Act (the "FDCA");
- impose restrictions on the marketing or manufacturing of any product or product candidate that we may develop;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, or require disgorgement;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us with respect to any product candidate that we may develop; or
- seize the product.

Moreover, any violation of these and other laws and regulations could result in exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, require curtailment or restructuring of our operations and prohibit us from entering into government contracts.

Similar requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in

response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations or policies may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

The commercial success of our Branded Products depends upon attaining market acceptance by physicians, patients, third-party payors and the medical community.

To date, we have expended significant time, resources, and effort on the development of our Branded Products, and a substantial majority of our resources are now focused on the commercialization of these products in the United States. Accordingly, our ability to generate significant product revenue and ultimately to attain profitability will depend almost entirely on our ability to successfully commercialize our Branded Products.

Our ability to successfully commercialize our Branded Products will depend on, among other things, our ability to:

- establish relationships with third-party suppliers for the active pharmaceutical ingredient ("API"), in our Branded Products;
- manufacture and produce, through a validated process, sufficiently large quantities and inventory of our Branded Products to permit successful commercialization;
- establish and/or build and maintain a wide variety of internal and external sales, distribution and marketing capabilities sufficient to support commercial sales of our products;
- establish collaborations with third parties for the commercialization of our products in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure widespread acceptance of our products by physicians, health care payors, patients and the medical community;
- properly price and obtain adequate coverage and reimbursement of the product by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing FDA labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements; and
- manage our spending related to our commercialization efforts.

There are no guarantees that we will be successful in completing these tasks. Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective. If we are unable to successfully complete these tasks, we may not be able to continue to commercialize our Branded Products, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

In addition, we will need to continue investing substantial financial and management resources to maintain and optimize our commercial infrastructure and to recruit, retain, and train qualified marketing, sales and other personnel to support the ongoing commercialization of our Branded Products. In addition, we have certain internal revenue expectations with respect to the sale of our Branded Products. If we cannot successfully commercialize and achieve those revenue expectations with respect to our Branded Products, our anticipated revenues and liquidity will be materially adversely impacted.

Moreover, even if we are able to successfully commercialize our Branded Products, their continued commercial success may be largely dependent on the capability of our third-party collaborators. Such third-party collaborators may not deploy the resources we would like them to, and our revenue would then suffer. In addition, we could become embroiled in disputes with these parties regarding the terms of any agreements, their performance or intellectual property rights. Any dispute could disrupt the sales of our products and adversely affect our reputation and revenue. In addition, if any of our manufacturing or collaboration partners fail to effectively perform under our arrangements for any reason, we may not be able to find a suitable replacement partner on a timely basis, on acceptable terms, or at all.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face significant existing competition in the United States and, if approved, would face significant competition in markets outside the United States, from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example:

- amphetamine XR is currently marketed in the United States by (i) Takeda Pharmaceutical Company Limited under the brand names Adderall XR®, Vyvanse®, and Mydayis and (ii) Tris Pharma, Inc. or Tris, under the brand name Dyanavel XR®; and

- methylphenidate is marketed in the United States by (i) Janssen Pharmaceuticals, Inc. under the brand name Concerta®, (ii) Tris under the brand names Quillivant XR®, and QuilliChew ER®, (iii) Rhodes Pharmaceuticals LP under the brand name Aptensio XR®, (iv) Ironshore Pharmaceuticals Inc. under the brand name Jornay PM™, (v) Osomotica Pharmaceuticals plc under the name Methylphenidate HCl ER 72 mg Tablets and (vi) Novartis under the brand names Focalin XR® and Ritalin LA®. Also, on March 1, 2019, Adlon Therapeutics L.P., a subsidiary of Purdue Pharma L.P., announced that the FDA approved Adhansia XR, its methylphenidate product for the treatment of ADHD.

Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Sunovion, Supernus, KemPharm and Neurovance.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our XR-ODT or XR oral suspension, or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our products, or the nonclinical studies or clinical trials that support their approval, contain deficiencies or that new regulatory requirements

be placed on the product candidate or drug class of the product candidate. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

We believe that our ability to successfully compete will depend on, among other things:

- the ability to commercialize and market any of our products and product candidates that receive regulatory approval;
- the price paid by customers for our products and product candidates that receive regulatory approval, including in comparison to branded or generic competitors;
- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval;
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicaid and Medicare; and
- the ability to protect intellectual property rights related to our product and product candidates.

If our competitors market products that are more effective, safer or less expensive than our products or that reach the market sooner than our products we may enter the market too late in the cycle and may not achieve commercial success, or we may have to reduce our price, which would impact our ability to generate revenue and obtain profitability. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

If we are unable to differentiate our products or product candidates from branded drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, our ability to successfully commercialize such products or product candidates would be adversely affected.

We expect to compete against branded drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our Branded Products and product candidates are or will be differentiated from branded drugs and their generic counterparts, if any, including through clinical efficacy or through improved patient compliance and ease of administration, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products and product candidates against other drugs, the opportunity for our products and, if approved, product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

After an NDA, including a 505(b)(2) application, is approved, the covered product becomes a “listed drug” that, in turn, can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA.

The FDCA, implementing regulations and other applicable laws provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as the listed drugs, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices.

Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as our Branded Products, can be lost to the generic version. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates.

For example, on July 25, 2016, we received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising us that Actavis had filed an ANDA with the FDA for a generic version of Adzenys XR-ODT.

On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement with Actavis, pursuant to which we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances.

On October 31, 2017, we received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT.

On December 21, 2018, we entered into a Settlement Agreement and a Licensing Agreement with Teva, pursuant to which we have granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances.

The design, development, manufacture, supply and distribution of our products and product candidates are highly regulated processes and technically complex.

We are subject to extensive regulation in connection with the preparation and manufacture of our products, product candidates and potential product candidates for clinical trials and commercial sale. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMPs and equivalent foreign standards. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products and product candidates that may not be detectable in final product testing. The development, manufacture, supply and distribution of our approved products as well as any of our future potential product candidates, are highly regulated processes and technically complex. We, along with our third-party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. For instance, because each of our Branded Products is a regulated drug product and subject to the U.S. Drug Enforcement Administration ("DEA") regulation, we have had to, and will continue to, need to secure state licenses from each state in which we intend to sell such product allowing us to distribute a regulated drug product in such state.

We must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to applicable parts of the FDA's Good Laboratory Practices, or GLP, and cGMP requirements enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure to comply with cGMP requirements or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. For example, in connection with a

general cGMP and pre-approval inspection for Adzenys ER in mid-2017, we received a Form FDA 483 with one observation related to complaint records failing to document the reason and the individual making the decision not to conduct a complaint investigation. We implemented corrective action related to this observation and responded to the FDA. The FDA has conducted additional inspections in 2018 that have not resulted in Form FDA 483s. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of our facility. Any such remedial measures imposed upon us could materially harm our business. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

For our approved products, we must comply with the requirements of the Drug Supply Chain Security Act (the "DSCSA"), which outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

For our approved drugs, we must comply with the requirements of the DSCSA, including those related to product tracing, verification, and authorized trading partners. Signed into law on November 27, 2013, the DSCSA amended the FSCA and is being implemented over a ten-year period. The law's requirements include the ability to quarantine and promptly investigate suspect product, such as potentially counterfeit, diverted or stolen product, to determine if it is illegitimate, and notify our trading partners and the FDA of any illegitimate product. As required by the DSCSA, we now place on each prescription drug package a unique product identifier consisting of the National Drug Code, serial number, lot number and expiration date, in the form of a 2-dimensional data matrix barcode that can be easily read electronically. If at any point our drug products fail to bear this unique product identifier, they would be misbranded under the FDCA, our drug products may not be accepted into the supply chain, and we may be subject to an enforcement action. In addition, the DSCSA imposes additional requirements on manufacturers and others in the supply chain that must be implemented by certain dates over the next several years. We are working to meet these new requirements in the time frames required. If we are unsuccessful in these efforts, we may be subject to enforcement, including the removal of our approved product from the market.

We rely on limited sources of supply for our Branded Products and our generic Tussionex, and any disruption in the chain of supply may impact production and sales of our Branded Products and our generic Tussionex, and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized products.

Our approved NDAs for our Branded Products, include our proposed manufacturing process for each product. Any change to our manufacturing process, facilities or suppliers could require that we supplement our approved NDA. Also, because of our proprietary processes for manufacturing our product candidates, we cannot immediately transfer manufacturing activities for our Branded Products or our generic Tussionex to an alternate supplier, and a change of facilities would be a time-consuming and costly endeavor.

Any changes to our manufacturing process would involve substantial cost and could result in a delay in our desired clinical and commercial timelines. We are also reliant on a limited number of suppliers for resin, drug compounds, coating and other component substances of our final product candidates and products. If any of these single-source suppliers were to breach or terminate its supply agreement, if any, with us or otherwise not supply us, we would need to identify an alternative source for the supply of component substances for our product candidates and products.

Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our product candidates or products could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our approved products or product candidates or a decrease in sales of our approved products, which could harm our financial position and commercial potential for our product candidates and products. Any alternative vendor would also need to be qualified through an NDA supplement, which could result in further delay, including delays related to additional clinical trials. The FDA, DEA, or other regulatory agencies outside of the United States may also require additional studies if we enter into agreements with new suppliers for the manufacture of our Branded Products and our generic Tussionex that differ from the suppliers used for clinical development of such product candidates.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our products and product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our Branded Products, our generic Tussionex and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

If we fail to produce our products or product candidates in the volumes that we require on a timely basis, we may face penalties from wholesalers and contracted retailers of our products and delays in the development and commercialization of our product candidates.

We currently depend on third-party suppliers for the supply of the APIs for our products and product candidates, including drug substance for nonclinical research, clinical trials and commercialization. For our Branded Products and our generic Tussionex, we currently rely on single suppliers for raw materials including APIs, which we use to manufacture, produce and package final dosage forms. In particular, we have an exclusive supply agreement with Coating Place, Inc. ("CPI"), pursuant to which CPI (i) is the exclusive supplier of the active ingredient complexes in our generic Tussionex and (ii) has agreed to not supply anyone else engaged in the production of generic Tussionex with such active ingredient complexes. Any future curtailment in the availability of raw materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs. We are subject to penalties from wholesalers and contracted retailers if we do not deliver our generic Tussionex, our Branded Products in quantities that meet their demand. Any such delays could trigger these penalty provisions, which would have a negative impact on our business.

If we fail to manufacture our Branded Products or product candidates in sufficient quantities and at acceptable quality and pricing levels, or fail to obtain adequate DEA quotas for controlled substances, or to fully comply with cGMP regulations, we may face delays in the commercialization of these products or our product candidates, if approved, or be unable to meet market demand, and may be unable to generate potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our raw material manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our products and product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and/or clinical trials, increase the costs associated with conducting our bioequivalence and/or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial. We purchase raw materials and components from various suppliers in order to

manufacture our Branded Products. If we are unable to source the required raw materials from our suppliers, or if we do not obtain DEA quotas or receive inadequate DEA quotas, we may experience delays in manufacturing our Branded Products, and may not be able to meet our customers' demands for our products.

In addition, we must comply with federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. We may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such products or product candidate or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical development, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our products or product candidates. In connection with a general cGMP and pre-approval inspection for Adzenys ER from July 11 to July 25, 2017, we received a Form FDA 483 with one observation related to complaint records failing to document the reason and the individual making the decision not to conduct a complaint investigation. We implemented corrective action related to this observation and responded to the FDA. The FDA has conducted additional inspections in 2018 that have not resulted in FDA Form 483s. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

Our Grand Prairie facility was formerly operated by our predecessor, PharmaFab, Inc., or PharmaFab. In April 2007, the FDA announced entry of a Consent Decree of Permanent Injunction, or the Consent Decree, against PharmaFab, one of its subsidiaries and two of its officials, including Mark Tengler, a former officer of ours who was, at the time, PharmaFab's president, and Russ McMahen, our Senior Vice President of Scientific Affairs, who held a similar position at the time with PharmaFab, or jointly, the Defendants. The Consent Decree arose out of several perceived cGMP deficiencies related to the manufacture of unapproved drugs or Drug Efficacy Study Implementation ("DESI"), drugs that we no longer manufacture. Pursuant to the Consent Decree, the Defendants were permanently restrained and enjoined from directly or indirectly manufacturing, processing, packing, labeling, holding or distributing any prescription drugs that are not the subject of an NDA or an abbreviated NDA. Among other things, the Consent Decree also granted the FDA the ability to, without prior notice, inspect PharmaFab's place of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of the Consent Decree. The FDA has inspected the Grand Prairie facility several times since the Consent Decree was entered. Although we have concluded the annual audit program prescribed by the Consent Decree entered into by our predecessor, our facilities may be inspected by the FDA at any time as a result of the Consent Decree. Although for our most recent annual audit by the cGMP expert in November 2014, the expert concluded that our corrective actions satisfactorily addressed the observations noted in its report, on May 22, 2015, the FDA's Dallas District Office identified three ongoing cGMP deviations in our response to the audit related to batch failure investigations, quality control unit procedures, and in-process specifications. We implemented corrective actions and submitted additional information in our response to the FDA pursuant to the Consent Decree and the FDA closed the matter. On June 20, 2018, we wrote to the Department of Justice and the FDA and explained we wished to move the court for relief from the Consent Decree, and asked the FDA to recognize the appropriateness of this request and not oppose the motion. In July 2019, we filed a motion with the U.S. District Court of North Texas to vacate the Consent Decree, which was unopposed by the Department of Justice and the FDA and was granted by the court on July 11, 2019. While the Consent Decree was vacated, there can be no assurance that we will not become subject to similar orders in the future, which may result in us continuing to expend resources and attention to observe their terms, and there can be no assurance that we will be in compliance with their requirements.

If we are unable to support demand for our Branded Products and any future product candidates, including ensuring that we have adequate capacity to meet any future increase in demand, or we are unable to successfully manage the evolution of our drug delivery technology platform, our business could suffer.

If sales of our approved products grow, we will need to continue to increase our workflow capacity for customer service, improve our billing and general process, expand our internal quality assurance program and extend our platform to support product production at a larger scale within expected turnaround times. We may need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our Branded Products. Portions of our process are not automated and will require additional personnel to scale. We may also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our facilities to accommodate such required expansion.

As additional product candidates, if approved, are commercialized, we will need to incorporate new equipment, implement new technology systems and laboratory processes and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

If our sole manufacturing facility becomes damaged or inoperable or we are required to vacate our facility, our ability to manufacture our Branded Products, our generic Tussionex or future potential product candidates for clinical development, may be jeopardized. Our inability to continue manufacturing adequate supplies of our products could adversely affect our ability to generate revenues.

All of our manufacturing capabilities are housed in our sole manufacturing facility located in Grand Prairie, Texas. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, tornado, power loss, communications failure or terrorism, any of which may render it difficult or impossible for us to operate our drug delivery technology platform and manufacture our product candidates or products for some period of time. While we seek to maintain finished goods inventory of our products outside of this facility, it is unlikely that the level of such inventory would be sufficient if we were to sustain anything other than a short-term disruption in our ability to manufacture our products and product candidates at our Grand Prairie, Texas facility. The inability to manufacture our products and product candidates if our facility or our equipment is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facility and the equipment we use to manufacture our products and product candidates could become damaged and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility or repair or replace our equipment or license or transfer our proprietary technology to a third-party, particularly in light of the requirements for a DEA-registered manufacturing and storage facility like ours. If we are required to change or add a new manufacturer or supplier, the process would likely require prior FDA, DEA and/or equivalent foreign regulatory authority approval, and would be very time consuming. Even in the unlikely event we are able to find a third party with such qualifications to enable us to manufacture our products or product candidates, we may be unable to negotiate commercially reasonable terms.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. An inability to continue manufacturing adequate supplies of our Branded Products or our generic Tussionex at our Grand Prairie, Texas facility could result in a disruption in the supply of our Branded Products, or our generic Tussionex to physicians and pharmacies, which would adversely affect our ability to generate revenues.

If other forms of our product candidates are approved and successfully commercialized by other third parties, especially if approved before we can successfully commercialize our products and product candidates, our business would be materially harmed.

Other third parties may seek approval to manufacture and market their own versions of product candidates in our product pipeline in the United States. If any of these parties obtain FDA approval of such a competitive product before we do, they may be entitled to three years of marketing exclusivity. Such exclusivity would, for example, delay the commercialization of our product candidates and, as a result, we may never achieve significant market share for these products. Consequently, revenues from product sales of these products would be similarly delayed and our business, including our development programs, and growth prospects would suffer. Even if any of our product candidates are approved before a competitor's product candidate, we may not be entitled to any marketing exclusivity and, other than under circumstances in which third parties may infringe or are infringing our patents, we may not be able to prevent the submission or approval of another full NDA for any competitor's product candidate.

Amphetamine, methylphenidate and hydrocodone are Schedule II controlled substances under the Controlled Substances Act, and any failure to comply with this Act or its state equivalents would have a negative impact on our business.

Amphetamine, methylphenidate and hydrocodone, which are the active ingredients in our Adzenys XR-ODT, Adzenys ER, Cotempla XR-ODT and generic Tussionex products, are listed by the DEA as a Schedule II controlled substance under the Controlled Substances Act ("CSA"). The DEA classifies substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, distribution and physician prescription procedures. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. In addition to federal scheduling, some drugs may be subject to state-controlled substance laws and regulations and more extensive requirements than those determined by the DEA and FDA. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug when the DEA does so, other states require additional state rulemaking or legislative action, which could delay commercialization. Some state and local governments also require manufacturers to operate a drug stewardship program that collects, secures, transports and safely disposes of unwanted drugs.

Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, including those for thefts or losses of any controlled substances, and to obtain authorization to destroy any controlled substances.

Registered entities are subject to DEA inspection and also must follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration. The DEA also has a production and procurement quota system that controls and limits the availability and production of Schedule I or II controlled substances. If we or any of our suppliers of raw materials that are DEA-classified as Schedule I or II controlled substances are unable to receive any quota or a sufficient quota to meet demand for our products, if any, our business would be negatively impacted.

Public concern over the abuse of medications that are controlled substances, including increased legislative, legal and regulatory action, could negatively affect our business.

Product containing controlled substances may generate public controversy. Certain governmental and regulatory agencies, as well as state and local jurisdictions, are focused on the abuse of controlled substances such as opioids in the

United States. State and local governmental agencies have commenced investigations into pharmaceutical companies and others in the supply chain in connection with the distribution of opioid medications. For example, on March 7, 2018 and April 18, 2019, we received citations advising us that the County of Harris Texas and the County of Walker Texas filed lawsuits on December 13, 2017 and January 11, 2019, respectively, against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through these lawsuits, each of Harris County and Walker County seek to recoup as damages some of the expenses they allegedly have incurred to combat opioid use and addiction. Each of Harris County and Walker County also seeks punitive damages, disgorgement of profits and attorneys' fees. In addition, multiple lawsuits have been filed against pharmaceutical companies alleging, among other claims, failures to provide effective controls and procedures to guard against the diversion of controlled substances, negligence by distributing controlled substances to pharmacies that serve individuals who abuse controlled substances, and failures to report suspicious orders of controlled substances in accordance with regulations. In the future, political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of our product or product candidates, the withdrawal of currently approved products from the market, or result in other legal action.

In addition, we are aware of other legislative, regulatory or industry measures to address the misuse of prescription opioid medications which could affect our business in ways that we may not be able to predict. For example, the State of New York has undertaken efforts to create an annual surcharge on all manufacturers and distributors licensed to sell or distribute opioids in New York, as well as a tax on sales of opioids in the state. Other states are also considering legislation that could require us to pay taxes, licensing fees, or assessments on the distribution of opioid medications in those states. These proposed bills vary in the amounts and the means of calculation. Liabilities for taxes or assessments under any such laws will likely have an adverse impact on our results of operations, unless we are able to mitigate them through operational changes or commercial arrangements where permitted, and may result in us ceasing to continue to sell our products in these jurisdictions.

Legislative or regulatory reform of the health care system in the United States may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "Affordable Care Act" or "ACA"), was signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

- mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans.
- the 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities.
- pharmaceutical companies are required to offer discounts on branded drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "Donut Hole."
- pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded drugs to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregated industry-wide fee is expected to total $28.0 billion through 2019.

Despite initiatives to invalidate the Affordable Care Act, the U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate."

However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. On July 9, 2019, a Fifth Circuit US Court of Appeals hearing was held to determine whether certain states and the House of Representatives have standing to appeal the lower court decision. It is unclear when a Court will render its decision and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017 and again on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In 2019, Congress may consider other legislation to repeal and replace elements of the Affordable Care Act, and litigation and legislation over the Affordable Care Act are likely to continue, with unpredictable and uncertain results. Changes to the Affordable Care Act or other existing health care regulations could significantly impact our business and the pharmaceutical industry. Although it is too early to determine the effect of legal challenges, pending legislation, and executive action on the Affordable Care Act, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Right to Try Act of 2018 provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. Individual states in the United States have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, there has been heightened governmental scrutiny over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump Administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Further, on January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Further, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, have been designed to encourage importation from other countries and bulk purchasing. We anticipate pricing scrutiny will continue and escalate, including on a global basis. As a result, our business and reputation may be harmed, our stock price may be adversely impacted and experience periods of volatility, and our results of operations may be adversely impacted.

CMS may also develop new payment and delivery models, such as bundled payment models. CMS finalized regulations that give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Additionally, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the rule allows Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for five of the six protected classes of drugs and, with certain exceptions and permits plans to implement PA and ST in Medicare Part B drugs. CMS is still considering proposed changes to the definition of "negotiated prices" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business and ability to receive adequate reimbursement for our products.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with REMS approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Inadequate funding for the FDA and other government agencies could prevent our new products, services and product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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 government agencies on which our operations may rely, including those 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 could adversely affect our business. Any government shutdown or other disruption of normal activities at these regulatory agencies, such as the FDA, could lead to a delay or stop in critical activities. If a prolonged government shutdown were to occur, 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or, if approved, product candidates their commercial success may be severely hindered.

Successful sales of our products and any product candidates that receive regulatory approval depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find

unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our Branded Products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our relationships with customers, healthcare providers and third-party payors are 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.

For our product and any product candidates that obtain regulatory approval and are marketed in the United States, our arrangements with third-party payors, healthcare providers, 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. In addition, we may be subject to health information privacy and security regulation by U.S. federal and state governments and foreign jurisdictions in which we conduct our business. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

- The federal Anti-Kickback Statute, makes it illegal for any person, including a prescription drug or biologic manufacturer (or a party on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward referrals, either the referral of an individual, or the purchase, recommendation, order or prescription of a particular item, drug or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. Violations of this law are punishable by prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

- The federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare 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. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare

programs and the potential implication of various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors, or falsifying, concealing or covering up a material fact, or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items, or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose, among other things, specified requirements on covered entities and their business associates, relating to the privacy, and security of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties applicable to business associates, and gave state attorneys general new authority to file civil actions for damage or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act which imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program for certain payments and other "transfers of value" provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. Such laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. State and foreign laws also govern the privacy and security of health information in certain circumstances. Such data privacy and security laws may differ from one another in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the E.U. adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the E.U. as well as to those outside the E.U. if they collect and use personal data in connection with the offering goods or services to individuals in the E.U. or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations

associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we operate in.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do 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 related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Efforts to ensure that our business arrangements comply with applicable healthcare laws and regulations, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face a risk of product liability exposure related to the testing of our product candidates in clinical trials and face even greater risks related to the commercialization of our products and upon any commercialization by us of our future products and, if approved, our product candidates, such as claims related to opioid abuse. For example, on March 7, 2018, we received a citation advising us that the County of Harris Texas filed a lawsuit on December 13, 2017 against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. On April 18, 2019, we received a citation advising us that the County of Walker Texas filed a lawsuit on January 11, 2019 against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products.

Our product liability insurance coverage may not be adequate to cover any and all liabilities that we may incur.

We currently have $10.0 million in product liability insurance coverage in the aggregate, which may not be adequate to cover any and all liabilities that we may incur. Insurance coverage is increasingly expensive and difficult to obtain. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. In addition, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products. For example, we have experienced increasing difficulty in procuring insurance coverage for our products, in particular, our opioid-based product, due to their status as controlled substances.

RISKS RELATED TO THE CLINICAL DEVELOPMENT, REGULATORY REVIEW AND APPROVAL OF OUR PRODUCT CANDIDATES

Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates. We are exploring various therapeutic opportunities for our pipeline and proprietary technologies. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. For example, we may fail to realize the anticipated benefits of the license of NT0502, our in-licensed product candidate, and there is no assurance that we will be able to maintain the license for NT0502 on commercially reasonable terms or at all. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and other regulatory authorities.

Premarket review of our product candidates by the FDA or other regulatory authorities is a lengthy and uncertain process and approval may be delayed, limited or denied, any of which would adversely affect our ability to generate future operating revenues.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the 505(b)(2) regulatory approval pathway for any future product candidate that we may identify and develop;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate safety and effectiveness of any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the safety risks outweigh clinical and other benefits of our product candidates;
- may require us to conduct additional bioequivalence studies to demonstrate that the proposed commercial product is bioequivalent to the batch used in clinical trials;
- may disagree with our trial design or our interpretation of data from nonclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we inappropriately relied on a certain listed drug or drugs for our 505(b)(2) NDA or that approval of our applications for any future product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the API used in our product candidates;
- may identify deficiencies in our own manufacturing processes or our proposed scale-up of the manufacturing processes or facilities for the production of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

Notwithstanding the approval of many products by the FDA pursuant to 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of 505(b)(2). If the FDA changes its interpretation of 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any 505(b)(2) application that we submit. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

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

We intend to seek FDA approval through the 505(b)(2) regulatory approval pathway for each of our future product candidates in our product pipeline. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Amendments, added 505(b)(2) to the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant does not have a right of reference.

If we cannot pursue the 505(b)(2) regulatory approval pathway for our product candidates as we intend, we may need to conduct additional nonclinical studies or clinical trials, provide additional data and information and meet additional requirements for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates likely would increase substantially. Moreover, the inability to pursue the 505(b)(2) regulatory approval pathway could result in new competitive products reaching the market before our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory approval pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, our competitors may file citizen petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical trials that support their approval, contain deficiencies or that new regulatory requirements be placed on the product candidate or drug class of the product candidate. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under 505(b)(2).

An NDA submitted under 505(b)(2) may subject us to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

We plan to submit our product candidates to the FDA for approval under 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. An NDA under 505(b)(2) would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the previously approved drug.

For NDAs submitted under 505(b)(2), the patent certification and related provisions of the Hatch-Waxman Amendments apply. Accordingly, we may be required to include certifications, known as Paragraph IV certifications, that certify that any patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Amendments, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the listed drug has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The

FDA also may reject any future 505(b)(2) submissions and require us to submit traditional NDAs under 505(b)(1), which would require extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and additional costs. These factors, among others, may limit our ability to commercialize our product candidates successfully.

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

As with many pharmaceutical products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although our products and product candidates contain active ingredients that have already been approved, meaning that the side effects arising from the use of the active ingredient or class of drug in our product candidates is generally known, our products or product candidates still may cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, institutional review boards, or IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, if the product candidate is approved, or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we may need to voluntarily recall our products
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

We will need to obtain FDA approval of any proposed names for our product candidates that gain marketing approval, and any failure or delay associated with such naming approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA, regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product names, including an evaluation of whether proposed names may be confused with other product names. In addition, the FDA may object to any product name we submit if it believes the name inappropriately implies medical claims.

If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates, which could result in further evaluation of proposed names with the potential for additional delays and costs.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Even if we obtain and maintain regulatory approval of our product candidates in one jurisdiction, such approval does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as investigations conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We are heavily dependent on the success of our product candidates. We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized.

Our business and future success are substantially dependent on our ability to timely obtain regulatory approval for and commercialize any product candidates that we may identify and pursue. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. We cannot predict whether we will obtain regulatory approval to commercialize our product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any delay or setback in the regulatory approval or commercialization of any of these product candidates could adversely affect our business.

The commencement and completion of clinical trials can be delayed or prevented for a number of reasons.

We intend to identify, develop and market additional product candidates; however, we may not be able to commence or complete the clinical trials that would support the submission of an NDA to the FDA. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Clinical trials can be delayed or prevented for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;

- difficulties obtaining IRB approval to conduct a clinical trial at a prospective site;
- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- difficulties maintaining contact with subjects after treatment, which results in incomplete data;
- receipt by a competitor of marketing approval for a product targeting an indication that our product targets;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

Positive results in previous nonclinical studies and clinical trials of any of our product candidates may not be replicated in future clinical trials of the same product candidates, which could result in development delays or a failure to obtain marketing approval.

Positive results in nonclinical studies and clinical trials of any of our product candidates may not be predictive of similar results in future clinical trials. Also, interim results during a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from any completed nonclinical studies and clinical trials for any of our product candidates may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products.

RISKS RELATED TO OUR BUSINESS AND FINANCIAL POSITION

We have incurred significant operating losses since our inception and may never achieve or maintain profitability.

We have incurred significant net losses of $11.4 million for the six months ended June 30, 2019, and $51.7 million for the year ended December 31, 2018. As of June 30, 2019 and December 31, 2018, we had accumulated deficits of $328.4 million and $317.0 million, respectively. To date, we have financed our operations primarily through the sale of equity and debt securities and payments received under collaborative arrangements. Our company has limited

operating history commercializing branded products, and our Branded Products will require substantial investment in the future as we seek to grow net sales from these products and achieve profitability. In addition, our product candidates will require substantial additional investment in the future. Despite this investment, we may never secure regulatory approvals or, even if approved, generate product sales from these product candidates. In the near term, we expect to continue to incur substantial operating expenses in connection with the manufacturing and commercialization of our products, the development of our product candidates and the operation of our business. Because of the numerous risks and uncertainties associated with our commercial products and the development of our product candidates, we are unable to accurately predict the timing or amount of our revenues and expenses, whether we will have sufficient funding available to us, or when, if ever, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock, would necessitate our need to obtain additional funding for us to continue operations, and could impair our ability to raise capital, expand our business, continue our development efforts, or diversify our product offerings, among other things. A decline in the value of our company also could cause you to lose all or part of your investment.

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing future potential product candidates, conducting clinical trials, establishing raw material supplier relationships and manufacturing, selling and marketing drugs are expensive and uncertain processes. Although we believe our cash, cash equivalents and marketable securities and anticipated future product revenues will be sufficient to allow us to fund the commercialization of our Branded Products and service our existing debt, we may need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

In addition, unforeseen circumstances may arise, or our strategic imperatives could change, causing us to consume capital significantly faster than we currently anticipate, requiring us to seek to raise additional funds sooner than expected. We have no committed external sources of funds.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the expenses associated with our sales, marketing, distribution and commercial manufacturing efforts for our Branded Products and any other potential product candidates;
- our ability to successfully commercialize our Branded Products, and to continue to increase the level of sales in the marketplace;
- the rate of progress and cost of our trials and other product development programs for our other product candidates;
- the costs and timing of in-licensing additional product candidates or acquiring other complementary technologies, assets or companies;
- the actions of our competitors and their success in selling competitive product offerings; and
- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

Additional financing may not be available when we need it or may not be available on terms that are favorable to us. 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. If adequate funds are not available to us on a timely basis, or at all, we may be required to delay, reduce the scope of or eliminate commercialization efforts for one or more of our products or development programs for future potential product candidates.

We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

To raise additional funds to support our operations, we may sell additional equity or incur additional debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our existing and future indebtedness at the time any such repayment is required (causing a default under such indebtedness), which could have a material adverse effect on our business, financial condition and results of operations.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

On May 11, 2016, we entered into a senior secured credit facility with Deerfield as lender of which $45.0 million of senior secured credit is outstanding as of June 30, 2019. Under our agreement, we are required to make payments of $15.0 million in each of May 2020 and May 2021, and a final payment of principal, interest and all other obligations under the facility due on May 11, 2022. Interest is due quarterly at a rate of 12.95% per year. All obligations under our credit facility are secured by substantially all of our existing property and assets subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. Since our inception, we have had significant operating losses. As of June 30, 2019 and December 31, 2018, we had accumulated deficit of $328.4 million and $317.0 million, respectively. Although we have strategies and plans to achieve profitability through revenue growth, we expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to market our approved products and continue to develop and seek marketing approval for our product candidates.

As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our credit facility with Deerfield. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, finance our operations, our research and development efforts and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail or eliminate one or more of our programs.

Failure to satisfy our current and future debt obligations under our credit facility with Deerfield could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under our credit facility as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. Based on the historical data from our currently marketed products, we expect that any revenues we generate will fluctuate from quarter to quarter and year to year as a result of the timing of our commercialization efforts and seasonal trends with respect to ADHD

diagnosis and use of medicinal products in the management of this disorder. Our net loss and other operating results will be affected by numerous factors, including:

- our ability to establish and maintain an effective sales and marketing infrastructure;
- variations in the level of expenses related to our commercialization efforts and the development of additional clinical programs;
- competition from existing products or new products that may emerge;
- the level of market acceptance for any approved product candidates and underlying demand for that product, seasonality in the use of that product by end-users and wholesalers' buying patterns;
- regulatory developments affecting our products and product candidates;
- our dependency on third-party manufacturers to supply components of our product candidates;
- potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- any delays in regulatory review and approval of our product candidates;
- any intellectual property infringement lawsuit in which we may become involved; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our ability to use our net operating loss carry-forwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carry-forwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. We have in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, pursuant to the Tax Cuts and Jobs Act of 2017, we may not carry back net operating losses to prior years and we may not use net operating losses generated in 2018 and later to reduce our taxable income in any year by more than 80%. Net operating losses generated prior to 2018 are available to fully offset future taxable income. These new rules apply regardless of the occurrence of an "ownership change."

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our executive officers are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense

and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical trials or to receive regulatory approval for our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. We have established an annual SOX Risk Assessment and Control Effectiveness Test Cycle that is designed to timely identify deficiencies to management for remediation to comply with Section 404 of the Sarbanes-Oxley Act of 2002 (or the "SOX Act"). We may discover additional deficiencies in our internal controls over financial reporting, including those identified through testing conducted by us in connection with Section 404 of the SOX Act. Such deficiencies may be deemed to be significant deficiencies or material weaknesses that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further remedial action. Failures of internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our business and operations would suffer in the event of system failures.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from such cyber attacks, including computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. For example, the loss of data from completed clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could suffer reputational harm or face litigation or adverse regulatory action and the development of our product candidates could be delayed.

We rely on third parties to perform many essential services for our commercial products, including distribution, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to continue to commercialize our Branded Products will be significantly impacted and we may be subject to regulatory sanctions.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our Branded Products, key aspects of which will be out of our direct control. These service providers may provide key services related to, among other things, distribution, customer service, accounts receivable management and cash collection. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, our ability to deliver product to meet commercial demand may be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by

these service providers is insufficient or if they fail to comply with various requirements, we could be subject to regulatory sanctions.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If our intellectual property related to our products or product candidates is not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products, product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Due to legal standards relating to patentability, validity, enforceability and scope of claim, patents covering pharmaceutical and biotechnology inventions involve complex legal, scientific and factual questions. Formulation of drug products such as ours with complex release profiles is an area of intense research, publishing and patenting, which limits the scope of any new patent applications. As a result, our ability to obtain, maintain and enforce patents is uncertain and any rights under any existing patents, or any patents we might obtain or license, may not provide us with sufficient protection for our products and product candidates to afford a commercial advantage against competitive products or processes. The patent applications that we own or license may fail to result in issued patents in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge their patentability, validity (e.g., by discovering previously unidentified prior art, or a patent-barring event such as a prior public disclosure, use, sale or offer for sale of the invention), enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. For example, we are aware that certain patent rights that are in-licensed for NT0502 may be limited by prior art, which may reduce or eliminate the scope of coverage for this product candidate. In addition, U.S. patents may be challenged by third parties via *inter partes* review, post grant review, derivation or interference proceedings at the USPTO, and European patents may be challenged via an opposition proceeding at the European Patent Office. Furthermore, if we were to assert our patent rights against a competitor, the competitor could challenge the validity and/or enforceability of the asserted patent rights. Although a granted U.S. patent is entitled to a statutory presumption of validity, its issuance is not conclusive as to its validity or its enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products.

If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our products and product candidates is successfully challenged, we may face unexpected competition that could have a material adverse impact on our business. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. For example, a third party may develop a competitive product that provides therapeutic benefits similar to our products or product candidates, but is sufficiently different to fall outside the scope of our patent protection.

Furthermore, if we encounter delays in our clinical trials or entry onto the market in a particular jurisdiction, the period of time during which we could market a particular product under patent protection would be reduced.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering a product or our technology, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description, non-enablement or a patent-barring event, such as a public disclosure, use or sale of the invention more than a year before the filing date of the application. Grounds for an unenforceability assertion could, for example, be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution, or that a

third party challenging one of our patents would not assert that a patent-barring event had occurred. If a plaintiff or a defendant were to prevail on a legal assertion of invalidity and/or unenforceability against one or more of our patents, we would lose at least part, and perhaps all, of the patent protection for one or more of our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

For example, on July 25, 2016, we received a paragraph IV certification from Actavis advising us that Actavis filed an ANDA with the FDA for a generic version of Adzenys XR-ODT. On September 1, 2016, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Actavis, Inc. This case alleged that Actavis infringed our Adzenys XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Adzenys XR-ODT prior to the expiration of our patents.

On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Actavis Agreement") with Actavis, which resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we have granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a paragraph IV certification from Teva advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva. This case alleged that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents.

On December 21, 2018, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the "Teva Agreement") with Teva, which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, we have granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

There can be no assurance that the Actavis Agreement or Teva Agreement will be approved by such agencies. In addition, there can be no assurance that we would not face future litigation regarding our Branded Products or any future product candidates.

Such litigation is often time-consuming and costly and its outcome would be unpredictable; however, we intend to vigorously enforce our intellectual property rights relating to our products. We would expect to face generic competition for our products if such patents are not upheld or if a filer of a Paragraph IV certification is found not to infringe such patents. The resulting loss of exclusivity would impact pricing and our sales of our products, which could have a material adverse impact on our business.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in reexamination, *inter partes* review, or interference proceedings challenging our patent rights. Patents based on applications that we file in the future may also be subject to derivation and/or post-grant review proceedings. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights and allow third parties to commercialize our technology or products and compete directly with us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even where we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may possibly export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from competing with us.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we have, and may in the future, choose not to seek patent protection in certain countries. Furthermore, while we intend to protect our intellectual property rights in certain markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our and their approved products and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our products and product candidates may give rise to claims of infringement of the patent rights of others. There may, for example, be issued patents of third parties of which we are currently unaware, that may be infringed by our products or product candidates, which could prevent us from being able

to commercialize our products or product candidates, respectively. Because patent applications can take many years to issue, there may be currently pending applications which may later result in issued patents that our products or product candidates may infringe.

The pharmaceutical industry is rife with patent litigation between patent holders and producers of follow-on drug products. The possibility of blocking FDA approval of a competitor's product for up to 30 months provides added incentive to litigate over Orange Book patents, but suits involving non-Orange Book patents are also common in the ADHD space. There have been multiple patent litigations involving nearly all of the medications for treatment of ADHD. This trend may continue and, as a result, we may become party to legal matters and claims arising in the ordinary course of business.

We may be exposed to, or threatened with, future litigation by third parties alleging that our products or product candidates infringe their intellectual property rights. If one of our products or product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable approved products and product candidates unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our approved products, pending a trial on the merits, which may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- third parties bringing claims against us may have more resources than us to litigate claims against us;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling our product or any product candidate approved in the future, if any, unless the third party licenses its rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- redesigning any of our products and product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory approval pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which would be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory approval pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will

not be infringed by the manufacture, use or sale of our proposed drug product. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit. For example, when we initially submitted our Adzenys XR-ODT NDA in December 2012 and in response to our Paragraph IV certification, Shire initiated a lawsuit against us claiming patent infringement against certain of Shire's patents. We settled with Shire in July 2014. As part of our settlement, among other things, we stipulated that the commercial manufacture, use, selling, offering for sale or importing of Adzenys XR-ODT would infringe on certain Shire patents and that such patent claims are valid and enforceable with respect to our Adzenys XR-ODT NDA, but that such stipulations do not preclude us from filing new regulatory applications containing a Paragraph IV certification citing such patents. We also entered into a non-exclusive License Agreement (the "2014 License Agreement") with Shire for certain of Shire's patents with respect to our Adzenys XR-ODT NDA. Under the terms of the 2014 License Agreement, upon obtaining FDA approval of our Adzenys XR-ODT NDA, we were required to pay a lump-sum, non-refundable license fee no later than thirty days after receiving such approval and are required to pay a single-digit royalty on net sales of Adzenys XR-ODT during the life of the patents. In addition, on January 26, 2017, we sent a letter to Shire, notifying Shire that we have made a Paragraph IV certification to the FDA that in our opinion and to the best of our knowledge, the patents owned by Shire that purportedly cover our Adzenys ER are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Adzenys ER. On March 6, 2017, we entered into a License Agreement (the "2017 License Agreement") with Shire, pursuant to which Shire granted us a non-exclusive license to certain patents owned by Shire for certain activities with respect to Adzenys ER. Under the terms of the 2017 License Agreement, we were required to pay a lump sum, non-refundable license fee no later than thirty days after receiving regulatory approval and are required to pay a single digit royalty on net sales of the Adzenys ER during the life of the relevant patents. Additionally, each of the 2014 License Agreement and 2017 License Agreement contains a covenant from Shire not to file a patent infringement suit against us alleging that Adzenys XR-ODT or Adzenys ER, respectively, infringes the Shire patents.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees were previously employed at other companies, including actual or potential competitors. We may also engage advisors and consultants who are concurrently employed at other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants 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, advisors, or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former employer or in violation of an agreement with or legal obligation in favor of another party. Litigation may be necessary to defend against these claims.

In addition, while we generally require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer or former employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OUR COMMON STOCK

The market price of our common stock may be highly volatile and investors in our common stock could incur substantial losses.

The trading price of our common stock is likely to be volatile. Since shares of our common stock were sold in our initial public offering, in July 2015 at a price of $15.00 per share, our stock price has ranged from $1.13 to $28.99, through August 2, 2019. Our stock price could be subject to wide fluctuations in the future in response to a variety of factors, including the following:

- failure to successfully execute our commercialization strategy with respect to our Branded Products, or any other approved potential product candidate in the future;
- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our products and product candidates;
- inability to manufacture adequate amounts of product supply or obtain adequate amounts of components of our product supply for our products, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to the use of our generic Tussionex, our Branded Products or any future potential product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;

- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors, or perceptions regarding unsolicited public acquisition proposals of our company;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, the stock market in general, and the NASDAQ Global Market ("NASDAQ") in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

As of June 30, 2019, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 34% of our outstanding voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, 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 believe are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. Shares held by our affiliates will be subject to volume limitations and other conditions pursuant to Rule 144 of the Securities Act. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock. On November 5, 2018, we amended a $60.0 million senior secured credit facility with Deerfield as lender, pursuant to which we were afforded the right, subject to the terms and conditions of the facility and certain other limitations, to make interest and principal payments owed to Deerfield through the issuance of our common stock, and provided Deerfield with a right, subject to the terms and conditions of the facility and the amended and restated convertible notes issued under the facility and certain other limitations, to convert principal under the amended and restated convertible notes into our common stock, subject to a floor of 95% of $10.00 per share.

Potential uncertainty resulting from unsolicited acquisition proposals and related matters may adversely affect our business.

In the past we have received, and in the future we may receive, unsolicited proposals to acquire our company or our assets. For example, in June 2017 and in October 2017, the Board of Directors received an unsolicited non-binding

proposal for the acquisition of all of our stock. The review and consideration of acquisition proposals and related matters could require the expenditure of significant management time and personnel resources. Such proposals may also create uncertainty for our employees, customers and vendors. Any such uncertainty could make it more difficult for us to retain key employees and hire new talent, and could cause our customers and vendors to not enter into new arrangements with us or to terminate existing arrangements. Additionally, we and members of our Board of Directors could be subject to future lawsuits related to unsolicited proposals to acquire us. Any such future lawsuits could become time consuming and expensive.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses. In addition, the SOX Act, as well as rules subsequently implemented by the Securities and Exchange Commission (the "SEC") and NASDAQ, have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the SOX Act and reduced disclosure obligations regarding executive compensation in the Annual Report on Form 10-K and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) in 2020, (b) in which we have total annual gross revenue of at least $1.07 billion (as inflation-adjusted by the SEC from time to time), or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements. We cannot predict if investors will find our common stock less attractive because we may 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.

Under the JOBS Act, emerging growth companies can also 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.

We do not intend to pay 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 dividend on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, as currently in effect, provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors,

officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Exhibit No.	Description	Incorporated by Reference to: Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-Q	3.1	9/4/15	001-37508
3.2	Amended and Restated By-Laws of the Registrant.	10-Q	3.2	9/4/15	001-37508
4.1	Specimen Common Stock Certificate of the Registrant.	S-1	4.1	7/13/15	333-205106
10.1#	Neos Therapeutics, Inc. Non-Employee Director Compensation Policy.	8-K	10.1	6/13/19	001-37508
31.1	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
31.2	Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.				
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Link Document.				

* The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

\# Management contract or compensatory plan, contract or arrangement.

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.

Neos Therapeutics, Inc.

Date: August 9, 2019

By: /s/ Richard Eisenstadt
Richard Eisenstadt
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gerald McLaughlin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neos Therapeutics, Inc.;

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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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: August 9, 2019

By: /s/ Gerald McLaughlin
Gerald McLaughlin
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Eisenstadt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neos Therapeutics, Inc.;

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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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: August 9, 2019

By: /s/ Richard Eisenstadt
Richard Eisenstadt
Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Neos Therapeutics, Inc. for the quarterly period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Gerald McLaughlin, as President and Chief Executive Officer of Neos Therapeutics, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Neos Therapeutics, Inc.

Date: August 9, 2019

By: /s/ Gerald McLaughlin
Gerald McLaughlin
President and Chief Executive Officer
(Principal Executive Officer)

In connection with the Quarterly Report on Form 10-Q of Neos Therapeutics, Inc. for the quarterly period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Richard Eisenstadt, as Chief Financial Officer of Neos Therapeutics, Inc., hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Neos Therapeutics, Inc.

Date: August 9, 2019

By: /s/ Richard Eisenstadt
Richard Eisenstadt
Chief Financial Officer (Principal Financial Officer)