Neos Therapeutics, Inc.
Form 10-Q
May 10, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended MARCH 31, 2018

OR

o 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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No o

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a Smaller reporting company)	Smaller reporting company o Emerging growth company x

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. x

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

The number of shares outstanding of the registrant s common stock as of May 4, 2018: 28,996,956 shares.

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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, potentia 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 commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or develop and commercialize any other future product or product candidate;

- the timing, cost or other aspects of the commercial launch and future sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER or 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 our 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 manufacture and marketing of Actavis s generic version of Adzenys XR-ODT under the ANDA;

- our product research and development activities, including the timing and progress of our 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

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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.

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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)

	March 31, 2018	December 31, 2017 (as adjusted)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 24,777	$ 31,969
Short-term investments	12,444	18,448
Accounts receivable, net of allowances for chargebacks and cash discounts of $1,435 and $1,154, respectively	19,642	13,671
Inventories	13,399	11,732
Other current assets	2,841	3,575
Total current assets	73,103	79,395
Property and equipment, net	8,173	8,203
Intangible assets, net	15,931	16,348
Other assets	149	162
Total assets	$ 97,356	$ 104,108
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable	$ 10,662	$ 11,460
Accrued expenses	28,580	20,944
Current portion of long-term debt	948	896
Total current liabilities	40,190	33,300
Long-Term Liabilities:		
Long-term debt, net of current portion	58,973	58,938
Derivative liability	1,474	1,660
Deferred rent	1,059	1,083
Other long-term liabilities	179	180
Total long-term liabilities	61,685	61,861
Stockholders Equity (Deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, no shares issued or outstanding at March 31, 2018 and December 31, 2017		
Common stock, $0.001 par value, 100,000,000 authorized at March 31, 2018 and December 31, 2017; 29,030,757 and 28,996,956 issued and outstanding at March 31, 2018,	29	29

respectively; 29,030,757 and 28,996,956 issued and outstanding at December 31, 2017, respectively				
Treasury stock, at cost, 33,801 shares at March 31, 2018 and December 31, 2017		(352)		(352)
Additional paid-in capital		275,551		274,584
Accumulated deficit		(279,744)		(265,308)
Accumulated other comprehensive loss		(3)		(6)
Total stockholders equity (deficit)		(4,519)		8,947
Total liabilities and stockholders equity	$	97,356	$	104,108

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2018	**2017 (as adjusted)**
Revenues:		
Net product sales	$ 10,729	$ 5,631
Cost of goods sold	5,221	4,750
Gross profit	5,508	881
Research and development	1,691	1,724
Selling and marketing expenses	12,990	10,706
General and administrative expenses	3,345	3,539
Loss from operations	(12,518)	(15,088)
Interest expense	(2,220)	(2,211)
Other income, net	302	78
Net loss	$ (14,436)	$ (17,221)
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	28,996,956	19,624,712
Net loss per share of common stock, basic and diluted	$ (0.50)	$ (0.88)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2018	**2017 (as adjusted)**
Net loss	$ (14,436)	$ (17,221)
Other comprehensive income (loss):		
Net unrealized gain (loss) on short-term investments	3	(2)
Total other comprehensive income (loss)	$ 3	$ (2)
Comprehensive loss	$ (14,433)	$ (17,223)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

Three months ended March 31, 2018

(In thousands, except shares)

(unaudited)

	Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Loss)	Equity (Deficit)
Balance, December 31, 2017 (as adjusted)		$	29,030,757	$ 29	(33,801)	$ (352)	$ 274,584	$ (265,308)	$ (6)	$ 8,947
Share-based compensation expense							967			967
Net unrealized gain on investments									3	3
Net loss								(14,436)		(14,436)
Balance, March 31, 2018		$	29,030,757	$ 29	(33,801)	$ (352)	$ 275,551	$ (279,744)	$ (3)	$ (4,519)

See notes to condensed consolidated financial statements.

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Neos Therapeutics, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three months ended March 31,	
	2018	**2017 (as adjusted)**
Cash Flows From Operating Activities:		
Net loss	$ (14,436)	$ (17,221)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	967	985
Depreciation and amortization of property and equipment	421	335
Amortization of patents and other intangible assets	434	408
Changes in fair value of earnout, derivative and warrant liabilities	(186)	
Deferred interest on debt		2,087
Amortization of senior debt discounts	209	81
Amortization of short-term investment purchase discounts	(35)	(6)
Gain on sale of equipment	(1)	(20)
Other adjustments	(24)	(23)
Changes in operating assets and liabilities:		
Accounts receivable	(5,971)	(5,717)
Inventories	(1,667)	298
Deferred contract sales organization fees		597
Other assets	1,154	597
Accounts payable	(1,205)	(1,313)
Accrued expenses	7,636	2,973
Net cash used in operating activities	(12,704)	(15,939)
Cash Flows From Investing Activities:		
Purchases of short-term investments	(10,951)	(8,534)
Sales and maturities of short-term investments	16,993	13,397
Proceeds from sale-leaseback of equipment		481
Capital expenditures	(286)	(198)
Intangible asset expenditures	(17)	
Net cash provided by investing activities	5,739	5,146
Cash Flows From Financing Activities:		
Proceeds from the issuance of common stock, net of issuance costs		30,265
Payments made on borrowings	(227)	(163)
Net cash (used in) provided by financing activities	(227)	30,102
(Decrease) increase in cash and cash equivalents	(7,192)	19,309
Cash and Cash Equivalents:		
Beginning	31,969	24,352
Ending	$ 24,777	$ 43,661

Supplemental Disclosure of Noncash Transactions:				
Prepaid assets included in accounts payable	$	407	$	
Acquired equipment under capital lease	$	105	$	
Capital lease liability from purchase of equipment	$	105	$	
Deferred contract sales organization fees	$		$	500
Capital lease liability from sale-leaseback transactions	$		$	481
Supplemental Cash Flow Information:				
Interest paid	$	2,040	$	19

See notes to condensed consolidated financial statements.

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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 pharmaceuticals in patient- and caregiver-friendly orally disintegrating tablet and liquid suspension dosage forms. The Company has a pipeline of extended-release pharmaceuticals including three approved products for the treatment of attention deficit hyperactivity disorder (ADHD). Adzenys XR-ODT was approved by the US Food and Drug Administration (the FDA) on January 27, 2016 and launched commercially on May 16, 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, on June 19, 2017, the Company initiated an early experience program with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017. Also, the Company received approval from the FDA for Adzenys ER oral suspension (Adzenys ER) on September 15, 2017 and launched this product on February 26, 2018. In addition, the Company manufactures and markets a generic Tussionex (hydrocodone and chlorpheniramine) (generic Tussionex), extended-release liquid suspension for the treatment of cough and upper respiratory symptoms of a cold.

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 months ended March 31, 2018 are not necessarily indicative of the results for the year ending December 31, 2018 or any period thereafter. The audited consolidated financial statements as of and for the year ended December 31, 2017 included information and footnotes necessary for such presentation and were included in the Neos Therapeutics, Inc. Annual Report on Form 10-K and filed with the SEC on March 16, 2018. 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, 2017.

Principles of consolidation: At March 31, 2018 and December 31, 2017 and for the three months ended March 31, 2018 and 2017, the condensed 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.

Reclassifications: In 2017, the Company reclassified certain patents from Other assets to Intangible assets, net as reported on the condensed consolidated balance sheets.

Liquidity: During 2017 and the three months ended March 31, 2018, the Company produced operating losses and used cash to fund operations. Management intends to achieve profitability through revenue growth from pharmaceutical products developed with its extended-release technologies. The Company does not anticipate it will be profitable until after the successful commercialization of its approved products, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. 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

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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 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. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in other income (expense) 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 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 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 (Tussionex ANDA) 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.

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 at a point in time. 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

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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:

	March 31,	
	2018	2017 (as adjusted)
	(in thousands)	
Adzenys XR-ODT	$ 4,992	$ 3,113
Cotempla XR-ODT	3,647	
Adzenys ER	203	
Generic Tussionex	1,887	2,518
	$ 10,729	$ 5,631

Net branded product sales

Net product sales for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER products represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments 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. The Company recognizes branded 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

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.

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Rebates for branded products

The Company s products 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 these rebate accruals are estimated based on information from third-party providers. Estimated rebates payable under such programs are recorded as a reduction of revenue at the time revenues are recorded. Historical trends of estimated rebates will be continually monitored and may result in future adjustments to such estimates.

Product returns of branded products

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 to determine a reliable return rate.

Net generic product sales

Net product sales for generic Tussionex product represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments 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 generic Tussionex total gross product sales less gross to net sales adjustments as revenue based on shipments from 3PLs to the Company s wholesaler customers.

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.

Product returns of generic product

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. 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.

Wholesale distribution fees

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

Rebates for generic product

The Company s generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Estimated government rebates are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. 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. Historical trends of such rebates will be continually monitored and may result in future adjustments to such estimates.

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Wholesaler chargebacks

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 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.

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. The Company recognized advertising costs of $0.2 million during each of the three months ended March 31, 2018 and 2017.

Share-based compensation: Share-based compensation awards, including grants of employee 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 awards to employees 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.

Due to the previous lack of a public market for the trading of its common stock and a lack of company-specific historical and implied volatility data, the Company had, prior to the IPO, historically utilized third party valuation analyses to determine the fair value. 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 new 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. The adoption of this standard in 2017 did not have a material impact on the Company s business, financial position, results of operations or liquidity.

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 March 31, 2018 and December 31, 2017, 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 (NOL s) 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

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outweighing projections for future taxable income. Therefore, at March 31, 2018 and December 31, 2017, 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 March 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2018-05 (ASU 2018-05), *Income Taxes (Topic 740) Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*, which was issued to state the income tax accounting implications of the Tax Cuts and Jobs Act of 2017 (the TCJA). The guidance clarifies the measurement period timeframe, changes in subsequent reporting periods and reporting requirements as a result of the TCJA. The measurement period begins in the period that includes the TCJA s enactment date which was December 22, 2017 and as a result the Company has reflected the impact of this ASU on the deferred tax calculation as of December 31, 2017.

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. The Company will adopt this standard on January 1, 2019. The adoption of this standard will not have a material impact on the Company s consolidated results of operations or financial position.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation Stock Compensation (Topic 718): Scope of Modification Accounting.* This ASU clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the modification. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. This standard became effective for the Company on January 1, 2018. The adoption of this standard does not have a material impact on the Company s consolidated results of operations or financial position.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This ASU was designed to reduce the diversity in practice of how the eight specified items are presented and classified in the statement of cash flows, including debt prepayment or debt extinguishment costs. The amendments are effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those years. This standard became effective for the Company on January 1, 2018. The adoption of this standard does not have a significant effect on the Company s ongoing financial reporting as the Company had classified its debt prepayment and debt extinguishment costs in the Consolidated Statements of Cash Flows in accordance with the amendments.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize the following for all 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 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. The new lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. In January 2018, the FASB issued ASU No. 2018-01, *Land Easement Practical Expedient for Transition to Topic 842, Leases (Topic 842)*, which adds two practical expedients to the new lease guidance. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods

within those years. The new standard must be adopted using a modified retrospective transition and requires application of the new guidance at the beginning of the earliest comparative period presented. The Company is evaluating the effect that the standard will have on its consolidated financial statements and related disclosures and has not determined the expected impact at this time.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (the New Revenue Standard). The New Revenue Standard replaces transaction-and industry-specific revenue recognition guidance under current U.S. GAAP with a principles-based approach for determining revenue recognition. The New Revenue Standard requires an entity to recognize the amount of revenue based on the value of transferred goods or services to customers. There is also additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

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The New Revenue Standard became effective for the Company on January 1, 2018. For purposes of providing comparable periods upon adoption, the Company applied the full retrospective transition method, which required the Company to restate each prior reporting period presented. The impact of the New Revenue Standard relates to the Company s accounting for branded net product sales. There are no changes to the net product sales of generic Tussionex revenue since the Company has estimated product returns since inception of recognizing revenue in August 2014.

The Company implemented internal controls and key system functionality to enable the preparation of financial information and reached conclusions on key accounting assessments related to the New Revenue Standard, including management s assessment that the impact of accounting for costs incurred to obtain a contract is immaterial.

Under the New Revenue Standard, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those good or services. Therefore, the Company is required to make estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler fees and estimated rebates) to be incurred on the selling price of the respective branded product sales, and recognize the estimated amount as revenue, when it transfers control of the product to its customers (e.g., upon shipment or delivery). Variable consideration must be determined using either an expected value or 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 require the use of significant management judgment and other market data. To implement the New Revenue Standard, the Company analyzed recent branded product return history and other market data obtained from its 3PLs to determine a reliable return rate. Additionally, management analyzed historical savings offers, prompt payment discounts, wholesaler fees and rebates payments based on patient prescriptions dispensed of Adzenys XR-ODT, Cotempla XR-ODT and information obtained from third-party providers to determine these respective variable considerations. Management has concluded that estimates of the above variable considerations are reasonably constrained, and estimates can be used for recognizing branded total gross product sales less gross to net sales adjustments as revenue beginning January 1, 2018. Refer to Impacts to Previously Reported Results below for the impact of adoption of the New Revenue Standard included in the Company s condensed consolidated statements of operations.

Impacts to Previously Reported Results

Adoption of the new revenue standard impacted the Company s previously reported results as follows:

	Three Months Ended March 31, 2017		
Condensed consolidated statements of operations	**As Previously Reported**	**New Revenue Standard Adjustment**	**As Adjusted**
	(in thousands, except per share amounts)		
Revenue: net product sales	$ 5,627	$ 4	$ 5,631
Cost of goods sold	4,615	135	4,750
Gross profit	1,012	(131)	881
Net loss attributable to common stock	(17,090)	(131)	(17,221)
Net loss per share of common stock, basic and diluted	(0.87)	(0.01)	(0.88)

Condensed consolidated statements of balance sheet	As Previously Reported	December 31, 2017 New Revenue Standard Adjustment	As Adjusted
		(in thousands)	
Inventories	$ 13,459	$ (1,727)	$ 11,732
Other current assets	5,093	(1,518)	3,575
Total current assets	82,640	(3,245)	79,395
Accrued expenses	10,570	10,374	20,944
Deferred revenue	14,676	(14,676)	
Total current liabilities	37,602	(4,302)	33,300
Accumulated deficit	(266,365)	(1,057)	(265,308)
Total liabilities and stockholder equity	107,353	(3,245)	104,108

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Adoption of the New Revenue Standard had no impact to cash from or used in operating, financing, or investing activities on the Company s consolidated statements of cash flows.

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 plan 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 are vested, 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 March 31, 2018 and 2017 were excluded from consideration in the computation of diluted net loss per share of common stock for the three months ended March 31, 2018 and 2017, respectively, because including them would have been anti-dilutive:

	March 31,	
	2018	**2017**
Series C Redeemable Convertible Preferred Stock Warrants (as converted)	70,833	70,833
Stock options outstanding	3,027,931	2,106,650
RSU s granted, not issued or outstanding	178,750	

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:

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	Fair Value as of March 31, 2018			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Cash and cash equivalents	$ 17,790	$ 6,987	$	$ 24,777
Short-term investments		12,444		12,444
Total financial assets	$ 17,790	19,431		$ 37,221
Earnout liability	$	$	$ 170	$ 170
Derivative liability (see Note 8)			1,474	1,474
Total financial liabilities	$	$	$ 1,644	$ 1,644

	Fair Value as of December 31, 2017			
	Level 1	Level 2	Level 3	Total
		(in thousands)		
Cash and cash equivalents	$ 31,969	$	$	$ 31,969
Short-term investments		18,448		18,448
Total financial assets	$ 31,969	$ 18,448	$	$ 50,417
Earnout liability	$	$	$ 170	$ 170
Derivative liability (see Note 8)			1,660	1,660
Total financial liabilities	$	$	$ 1,830	$ 1,830

The Company s Level 1 assets included bank deposits, certificates of deposit and actively traded money market funds with a maturity of 90 days or less at March 31, 2018 and December 31, 2017. 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 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 March 31, 2018 and December 31, 2017 as shown below:

	March 31, 2018		
	Amortized Cost	Unrealized Gain / (Loss)	Market Value
		(in thousands)	
Bank deposits and money market funds	$ 17,790	$	$ 17,790
Financial and corporate debt securities	19,434	(3)	19,431
	$ 37,224	$ (3)	$ 37,221

	Amortized Cost	December 31, 2017 Unrealized Gain / (Loss) (in thousands)	Market Value
Bank deposits and money market funds	$ 31,969	$	$ 31,969
Financial and corporate debt securities	18,454	(6)	18,448
	$ 50,423	$ (6)	$ 50,417

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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 March 31, 2018 and December 31, 2017.

The fair value of the derivative liability was determined after taking into consideration valuations using the Monte Carlo method based on assumptions at December 31, 2017 and March 31, 2018. There were no significant changes in the pricing assumptions during the three months ended March 31, 2018. 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	3/31/2018	12/31/2017
Valuation Method	Monte Carlo	Monte Carlo
Volatility (annual)	N/A	N/A
Time period from valuation until maturity of debt (yrs.)	4.113	4.360
Cumulative probability of a change in control prepayment implied by model	27%	27%
Cumulative probability of other accelerated prepayments implied by model	16%	17%
Discount rate	16.53%	16.20%
Fair value of liability at valuation date (thousands)	$1,474	$1,660

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, 2017	$ 1,830
Change in fair value	(186)
Balance at March 31, 2018	$ 1,644

Note 5. Inventories

Inventories at the indicated dates consist of the following:

	March 31, 2018	December 31, 2017 (as adjusted)
	(in thousands)	

Raw materials	$	3,921	$	3,476
Work in progress		6,254		6,155
Finished goods		3,834		2,470
Inventory at cost		14,009		12,101
Inventory reserve		(610)		(369)
	$	13,399	$	11,732

Note 6. Sale-leaseback transaction

The Company accounts for the sale and leaseback transactions discussed below as capital leases under the provisions of Accounting Standards Codification (ASC) Topic 840-40, *Leases Sale Leaseback Transactions*. 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 12). Lease payments are applied using the effective interest rate inherent in the leases. Depreciation of the property

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and equipment is included within depreciation and amortization in the consolidated statements of operations and consolidated statements of cash flows.

In 2012, the Company negotiated financing arrangements with a related party which provided for the sale-leaseback of up to $6.5 million of the Company s property and equipment with a bargain purchase option at the end of the respective lease. These financing arrangements were executed in five separate tranches that occurred in February, July and November 2013, and March 2014. The two February leases and the July lease had been fully satisfied before 2017. The November 2013 leases for a total of $1.0 million of assets expired in April 2017 and the related $161,000 gain was fully amortized at that time and the $100,000 lease buy-out option liability was fully satisfied. The March 2014 lease for $795,000 of assets expired in September 2017 and the related $116,000 gain was fully amortized at that time and the lease buy-out option liability of $79,000 was fully satisfied.

In February 2017, the Company entered into an agreement with a related party 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 the three months ended March 31, 2018 and 2017, approximately $1,000 and $20,000, respectively, 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 March 31, 2018 and December 31, 2017 consist of the following:

	March 31, 2018	December 31, 2017 (as adjusted)
	(in thousands)	
Accrued savings offers	$ 11,893	$ 7,168
Accrued rebates	5,300	4,008
Accrued customer returns	3,340	2,711
Accrued wholesaler fees	3,020	2,345
Accrued payroll and benefits	2,014	2,534
Other accrued expenses	3,013	2,178
Total accrued expenses	$ 28,580	$ 20,944

Note 8. Long-term debt

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

	March 31, 2018	December 31, 2017
	(in thousands)	
Deerfield senior secured credit facility, net of discount of $2,635 and $2,843, respectively	$ 57,364	$ 57,156
Capital leases, maturing through May 2020	2,557	2,678
	59,921	59,834
Less current portion	(948)	(896)
Long-term debt	$ 58,973	$ 58,938

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 9). 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.

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Approximately $33 million of the $60 million Facility proceeds was used to prepay the existing $24.3 million principal and $0.1 million of accrued interest related to the senior Loan and Security Agreement (the LSA) with Hercules Technology III, L.P., (Hercules), the $1.1 million LSA end of term fee, a LSA prepayment charge of $243,000 and the $5.9 million of principal and $1.3 million of interest on the 10% related party amended and restated subordinated note (the Note) that was issued by the Company to Essex Capital Corporation (Essex), which were otherwise payable in 2016 and 2017. Principal on the Facility is 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 may be 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 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 (the PDUFA) goal date as set forth on the schedules to 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, range 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 is 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.

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 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 Financial Industry Regulatory Authority (FINRA) requests. The Company s obligations with respect to each

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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 transferee or assignee under the 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 currently expects to satisfy all of its obligations under this Registration Agreement and does not expect to pay any damages pursuant to this agreement; therefore, no liability has been recorded (see Note 12).

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% (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 will be 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 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.

Pursuant to the Convertible Notes, if the Company had failed to provide the number of conversion shares, then the Company would have paid damages to Deerfield or subsequent holder or any designee (Holder) for each day after the third business day after receipt of notice of conversion (the Share Delivery Date) that such conversion was 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 March 31, 2018, 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 and 25.35% on the Convertible Notes, charged to interest expense and totaled $209,000 for the three months

ended March 31, 2018 and $1,316,000 for the year ended December 31, 2017, respectively.

Capital lease obligations to related party: As described in Notes 6 and 11, during the years ended December 31, 2017, 2014 and 2013, the Company entered into agreements with Essex for the sale-leaseback of existing and newly acquired assets with a total capitalized cost of $3.2 million, $795,000 and $5.5 million, respectively, which are classified as capital leases. The approximate imputed interest rate on these leases is 14.9%, 14.5% and 14.5%, respectively. Interest expense on these leases was $98,000 and 19,000 for the three months ended March 31, 2018 and 2017, respectively.

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

Period ending:		**March 31, (in thousands)**
2019	$	948
2020		16,115
2021		15,459
2022		15,020
2023		15,014
Thereafter		
Future principal payments	$	62,556
Less unamortized debt discount related to long-term debt		(2,635)
Less current portion of long-term debt		(948)
Total long-term debt	$	58,973

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Note 9. Common stock

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 included 750,000 shares of its common stock resulting from the underwriters exercise of their over-allotment option on February 17, 2017. 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. 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 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.

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 the Company of up to an aggregate of $125.0 million of its common stock, preferred stock, debt securities, warrants and/or units (the 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 Shelf (the Sales Agreement).

During the year ended December 31, 2017, the Company sold an aggregate 749,639 shares of common stock under the 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. No sales have been made under the Sales Agreement during the three months ended March 31, 2018. As of March 31, 2018, $58.0 million of the Company s common stock, preferred stock, debt securities, warrants and/or units remained available to be sold pursuant to the Shelf, including $36.2 million of the Company s common stock which remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

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.

Note 10. Share-based Compensation

Share-based Compensation Plans

In July 2015, the Company adopted the Neos Therapeutics, Inc. 2015 Stock Option and Incentive Plan (the 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, 2018 and 2017, the Company added 1,449,847 shares and 803,049 shares, respectively, to the option pool. The 2015 Plan superseded the Neos

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Therapeutics, Inc. 2009 Equity Plan (the 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. The Company s compensation committee 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 March 31, 2018, the Company has granted options, restricted stock and RSUs. 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, 2017, 9,304 shares related to forfeited 2009 Plan options and 33,801 shares related to the surrender of restricted stock were added to the shares available under the 2015 Plan. During the three months ended March 31, 2018, 5,000 shares related to forfeited 2009 Plan options were added to the shares available under the 2015 Plan. As of March 31, 2018, 1,377,804 shares of common stock remain available for grant under the 2015 Plan.

Share-based Compensation Expense

The Company has reported share-based compensation expense for the three months ended March 31, 2018 and 2017, respectively, in its condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Cost of goods sold	$ 119	$ 84
Research and development	78	79
Selling and marketing	257	197
General and administrative	513	625
	$ 967	$ 985

The total share based compensation expense included in the table above is attributable to stock options and RSUs of $931,000 and $36,000 for the three months ended March 31, 2018, respectively. The total share based compensation expense included in the table above is attributable to stock options and restricted stock of $963,000 and $22,000 for the three months ended March 31, 2017, respectively.

As of March 31, 2018, there was $8.9 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

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average period of 2.5 years for stock options and 3.6 years for RSUs. There is no unrecognized compensation cost associated with grants of restricted stock.

Stock Options

During the three months ended March 31, 2018, the Company s board of directors granted 608,753 options.

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:

	Three Months Ended March 31, 2018
Estimated dividend yield	0.00%
Expected stock price volatility	60.00%
Weighted-average risk-free interest rate	2.65%
Expected life of option in years	6.25
Weighted-average option fair value at grant	$ 4.87

A summary of outstanding and exercisable options as of March 31, 2018 and December 31, 2017 and the activity from December 31, 2017 through March 31, 2018, is presented below:

	Number of Options	Weighted-Average Exercise Price	Intrinsic Value (in thousands)
Outstanding at December 31, 2017	2,454,973	$ 11.195	$ 4,764
Exercisable at December 31, 2017	1,137,766	$ 10.919	$ 2,890
Granted	608,753	$ 8.35	
Exercised			
Expired, forfeited or cancelled	(35,795)	10.28	
Outstanding at March 31, 2018	3,027,931	$ 10.63	$ 2,582

Exercisable at March 31, 2018	1,210,149	$	10.80	$	1,905

The weighted-average remaining contractual life of options outstanding and exercisable on March 31, 2018 was 8.1 and 7.0 years, respectively. The option exercise prices for all options granted January 1, 2018 through March 31, 2018 ranged from $8.30 per share to $10.40 per share. The weighted-average remaining contractual life of options outstanding and exercisable on December 31, 2017 was 7.9 and 7.2 years, respectively. The option exercise price for all options granted in the year ended December 31, 2017 ranged from $7.00 to $9.10 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 had not issued any RSUs previously.

A summary of outstanding RSUs as of March 31, 2018 and December 31, 2017 and the activity from December 31, 2017 through March 31, 2018, is presented below:

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	Number of RSUs	Weighted-Average Fair Value
Outstanding at December 31, 2017	85,000	$ 7.15
Granted	93,750	8.30
Exercised		
Expired, forfeited or cancelled		
Outstanding at March 31, 2018	178,750	$ 7.76

The weighted-average remaining contractual life of RSUs outstanding on March 31, 2018 was 9.5 years.

Restricted stock

The Company did not issue any shares of restricted stock for the three months ended March 31, 2018, or for the year ended December 31, 2017. No vested restricted stock awards were settled during the three months ended March 31, 2018.

The Company had no unvested restricted stock as of March 31, 2018 and December 31, 2017. For the three months ended March 31, 2018, there were no shares of restricted stock granted or forfeited.

Note 11. 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 December 31, 2017 and March 31, 2018.

Note 12. Commitments and contingencies

Registration Payment Arrangement: In June 2017, in conjunction with the Amendment to the Facility and the related issuance of the Convertible Notes, the Company entered into the 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 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 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 transferee or assignee 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 had filed an Abbreviated New Drug Application (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. The certification notice alleged that the three U.S. patents listed in the FDA s Orange Book for Cotempla XR-ODT, one with an expiration date in April 2026 and two with expiration dates in June 2032, will not be infringed by Teva s proposed product, are invalid and/or are unenforceable. On

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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 by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of the Company s patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. The Company intends to vigorously enforce its intellectual property rights relating to Cotempla XR-ODT.

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 ANDA with the FDA for a generic version of Adzenys XR-ODT. The certification notice alleged that the four U.S. patents listed in the FDA s Orange Book for Adzenys XR-ODT, one with an expiration date in April 2026 and three with expiration dates in June 2032, will not be infringed by Actavis s proposed product, are invalid and/or are unenforceable. On September 1, 2016, the Company filed a patent infringement lawsuit in federal district court in the District of Delaware against Actavis alleging that Actavis infringed the Company s 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 the Company s patents. On October 17, 2017, the Company entered into a Settlement Agreement (the Settlement Agreement) and a Licensing Agreement (the Licensing Agreement and collectively with the Settlement Agreement, the Agreement) with Actavis. The Agreement resolves all ongoing litigation involving the Company s Adzenys XR-ODT patents and Actavis s ANDA. Under the 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 Agreement has been submitted to the applicable governmental agencies.

Other Litigation: On March 7, 2018, the Company received a citation advising the Company that the County of Harris Texas (the County) filed a lawsuit on December 13, 2017 against the Company and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through this lawsuit, the County seeks to recoup as damages some of the expenses it allegedly has incurred to combat opioid use and addiction. The County also seeks punitive damages, disgorgement of profits and attorneys fees. While the Company believes that the lawsuit is without merit and intends to vigorously defend against it, the Company is not able to predict at this time whether this proceeding 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 office space in Blue Bell, Pennsylvania for its commercial operations, which commenced on May 1, 2016. The Company accounts 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 $1,059,000 million at March 31, 2018 and $1,083,000 million at December 31, 2017, respectively. 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 $54,000 and $59,000 for the three months ended March 31, 2018 and 2017, respectively. Rent expense for these leases, excluding the share of operating expenses, was $253,000 and $252,000 for the three months ended March 31, 2018 and 2017, respectively.

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 $344,000 and $327,000 of compensation expense for the three months ended March 31, 2018 and 2017,

respectively, under the Bonus Plan.

Note 13. License agreements

On October 17, 2017, the Company entered into the Agreement with Actavis. Under the 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 12).

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

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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 January 26, 2017, the Company sent a letter to Shire, notifying Shire that the Company had made a Paragraph IV certification to the FDA that in the Company s opinion and to the best of its knowledge, the patents owned by Shire that purportedly cover the Company s product, 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, 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 liquid 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 will also pay a single digit royalty on net sales of Adzenys ER during the life of the relevant Shire 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 14. Related party transactions

As described in Note 6, in February 2017, the Company entered into an agreement with a related party for the sale-leaseback of newly acquired assets of up to $5.0 million to finance the Company s capital expenditures. Each lease under this master agreement will be for an initial term of 36 months and will have an option to purchase the equipment at the end of the respective lease that management considers to be bargain purchase option. Under this master 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 total lease obligation under all related party financing arrangements was $2,467,000 and $2,678,000 at March 31, 2018 and December 31, 2017, respectively.

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 (see Note 9). 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. 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 (see Note 9). 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, was classified as a related party at the time of the corresponding transactions. 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 be 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).

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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, 2017 and 2016 and notes thereto included in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission (the SEC) on March 16, 2018. 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 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 proprietary modified-release drug delivery 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 launched the commercialization of this product on May 16, 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. We initiated an early experience program with limited product availability on September 5, 2017 before launching this product nationwide on October 2, 2017. Also, we received approval from the FDA for Adzenys ER, our amphetamine extended-release liquid suspension, on September 15, 2017, and launched the commercialization of this product on February 26, 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.

We are commercializing Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in the United States using our own commercial infrastructure. We are manufacturing 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, thereby obtaining our products at cost without manufacturer s margins and better controlling supply quality and timing. We also currently use these facilities to manufacture our generic equivalent to the branded product, Tussionex, an XR liquid suspension of hydrocodone and chlorpheniramine indicated for the relief of cough and upper respiratory symptoms of a cold (generic Tussionex).

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 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 a Settlement Agreement and a Licensing Agreement (collectively, the Agreement) with Actavis. The Agreement resolves all ongoing litigation involving our Adzenys XR-ODT patents and Actavis s ANDA. Under the 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 Agreement has been submitted to the applicable governmental agencies.

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. We have new product exclusivity for a three-year period from the date of approval for Cotempla XR-ODT. The certification notice alleges that the three U.S. patents listed in the FDA s Orange Book for Cotempla XR-ODT, one with an expiration date in April 2026 and two with expiration dates in June 2032, will not be infringed by Teva s proposed product, are invalid and/or are unenforceable. 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. This lawsuit automatically stayed, or barred, the FDA from approving Teva s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. We intend to vigorously enforce our intellectual property rights

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relating to Cotempla XR-ODT. We are unable to predict the timing or outcome of these proceedings at this time. We anticipate incurring increasing amounts of legal fees in the enforcement of our intellectual property rights.

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 and to our commercial products and product candidates which consist of implementation of our commercialization strategies, research and development activities, clinical trials for our product candidates, the general and administrative support of these operations and intellectual property protection and maintenance. 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.

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.

We have incurred significant losses in each year since our reorganization in 2009. Our net losses were $14.4 million and $65.8 million for the three months ended March 31, 2018 and the year ended December 31, 2017, respectively. As of March 31, 2018 and December 31, 2017, we had accumulated deficits of approximately $279.7 million and $265.3 million, respectively. We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- operate commercial infrastructure to support sales and marketing for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER;

- continue research and development activities for new product candidates;

- conduct post-marketing approval research activities for our approved products;

- manufacture supplies for our preclinical studies and clinical trials;

- continue to enforce our intellectual property rights; and

- operate as a public company.

FINANCIAL OPERATIONS OVERVIEW

Revenue

During 2015 and 2016, 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 our acquisition of all of the rights to commercialize and derive future

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profits from the Tussionex ANDA, the continuing commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, we expect our future revenue to increase from historical levels.

We expect the number of prescriptions filled for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to continue to increase. In addition, we expect product shipments to our wholesalers to correspondingly increase. For the three months ended March 31, 2018, wholesalers purchased 58,139 units of Adzenys XR-ODT as compared to 36,714 units for the same period one year ago. Unit shipments of Cotempla XR-ODT for the three months ended March 31, 2018 were 52,221; Cotempla XR-ODT launched in the third quarter of 2017. Unit shipment of Adzenys ER, which launched commercially on February 26, 2018, were 1,422 for the three months ended March 31, 2018.

In the future, we will seek to generate additional revenue from product sales of generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. If we fail to successfully market generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, our inability to generate future revenue from product sales may adversely affect our results of operations and financial position.

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 and benefits, which includes 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 product candidates. Indirect costs related to our research and development activities that are not allocated to a product candidate are included in Other Research and Development Activities in the table below.

Prior to 2016 and the launch of Adzenys XR-ODT, the largest component of our total operating expenses had been our investment in research and development activities including the clinical development of our product candidates. The following table summarizes our research and development expenses for the periods indicated:

	Three Months Ended March 31,	
	2018	2017
NT-0102 Cotempla XR-ODT	$ 20	$ 10
NT-0201 Adzenys ER	4	22
NT-0202 Adzenys XR- ODT	400	94
Other Research and Development Activities (1)	1,267	1,598
	$ 1,691	$ 1,724

(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, a portion of the net proceeds from our public offerings of common stock and debt financing and revenues, if

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any, from Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER and, if approved, our product candidates that we may develop.

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 for Adzenys ER, commercial sales organization costs incurred in the preparation for and in the commercialization of Adzenys XR-ODT and Cotempla XR-ODT, and in the 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 with the continuing commercialization of Adzenys XR-ODT and Cotempla XR-ODT, and the launch and commercialization of 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.

We anticipate that our general and administrative expenses will increase due to increased 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, as a result of our Paragraph IV litigation costs, we have incurred increasing amounts of legal fees in the enforcement of our intellectual property rights.

Interest expense, net

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. Deerfield participated in the purchase of our common shares as part of our February 2017 public offering, and as a result, was classified as a related party at the time of the corresponding transactions. Approximately $33.0 million of the Facility proceeds were used to prepay the existing senior Loan and Security Agreement (the LSA) with Hercules Technology III, L.P. (Hercules) and the 10% related party subordinated debt (the Note) issued by Excess Capital Corporation (Excess) that was otherwise payable in 2016 and 2017. We entered into an amendment (the Amendment) to the Facility on June 1, 2017 (the Agreement Date) to provide a one-year deferral, with an option for a second year of deferral, of payment of the first year accrued interest of $6.6 million (the Accrued Interest), provided that we met certain sales revenue targets and obtain FDA approval of certain of our product candidates on or before the Prescription Drug User Fee Act (the PDUFA) goal date. Before the Amendment, this accrued interest had been deferred until June 1, 2017 per the terms of the Facility. 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. On October 26, 2017, Deerfield provided a conversion notice electing 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 issuing 929,967 shares of our common stock to Deerfield on this date and the Convertible Notes were cancelled.

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 a related party resulting from the sale-leaseback transactions of our

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existing and 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 first sale-leaseback financings occurred in five separate transactions in 2013 and 2014, each with a 42-month lease term. 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 additional 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 and 13 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 March 31, 2018 compared to the three months ended March 31, 2017

Revenues

The following table summarizes our revenues for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,			
	2018	2017 (as adjusted)	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Product	$ 10,729	$ 5,631	$ 5,098	90.5%

Total product revenues were $10.7 million for the three months ended March 31, 2018, an increase of $5.1 million or 90.5% from the $5.6 million for the three months ended March 31, 2017. The increase was primarily due to a $3.6 million increase in net sales of Cotempla XR-ODT which commenced on September 5, 2017 with an early experience program. Sales from Adzenys XR-ODT increased $1.9 million to $5.0 million for the three months ended March 31, 2018 from $3.1 million for the three months ended March 31, 2017. Net sales of Adzenys ER which launched on February 26, 2018 were $0.2 million. The increase was partially offset by a $0.6 million decrease in net sales of our generic Tussionex to 1.9 million for the three months ended March 31, 2018 from $2.5 million for the three months ended March 31, 2017 primarily due

to alternative treatments options for this product.

Cost of goods sold

The following table summarizes our cost of goods sold for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,			
	2018	2017 (as adjusted)	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Cost of goods sold	$ 5,221	$ 4,750	$ 471	9.9%

The total cost of goods sold was $5.2 million for the three months ended March 31, 2018, an increase of $0.5 million or 9.9%, from the $4.8 million for the three months ended March 31, 2017. This increase was primarily from a $3.2 million increase in product costs and an associated increase of $0.8 million of royalty fees, freight and logistics costs relating to the sales of Cotempla XR-ODT which commenced on September 5, 2017 with an early experience program, increased sales from Adzenys XR-ODT which launched on May 16, 2016 and sales from Adzenys ER which launched on February 26, 2018. There were no costs in cost of goods sold associated with Cotempla XR-ODT and Adzenys ER in the quarter ended March 31, 2017, which was prior to the approvals of Cotempla XR-ODT and Adzenys ER. Partially offsetting these increased costs were lower production cost of $3.5 million relating to efficiencies from increased production to meet sales demand for the three branded products.

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Research and development expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2018	2017		
	(in thousands)			
Research and development expenses	$ 1,691	$ 1,724	$ (33)	(1.9)%

Research and development expenses stayed flat at $1.7 million for the three months ended March 31, 2018 and 2017.

Selling and marketing expenses

The following table summarizes our selling and marketing expenses for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2018	2017		
	(in thousands)			
Selling and marketing	$ 12,990	$ 10,706	$ 2,284	21.3%

The total selling and marketing expenses were $13.0 million for the three months ended March 31, 2018, an increase of $2.3 million or 21.3%, from the $10.7 million for the three months ended March 31, 2017. The increase was primarily due to an increase of $0.8 million in marketing expense, $0.8 million in the commercial sales organization salesforce costs, $0.3 million in salaries and benefits and $0.3 million in professional sales and marketing services. The increased selling and marketing expenses were to support the sales of Cotempla XR-ODT which commenced on September 5, 2017 and Adzenys ER which launched on February 26, 2018, whereas we had only one commercially-available branded product, Adzenys XR-ODT, in the same period of 2017.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,			
	2018	2017	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
General and administrative	$ 3,345	$ 3,539	$ (194)	(5.5)%

The total general and administrative expenses were $3.3 million for the three months ended March 31, 2018, a decrease of $0.2 million or 5.5%, from the $3.5 million for the three months ended March 31, 2017. The decrease was primarily from lower salary and compensation expense.

Interest expense

The following table summarizes interest expense for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,			
	2018	2017	Increase (Decrease)	% Increase (Decrease)
	(in thousands)			
Interest expense	$ 2,220	$ 2,211	$ 9	0.4%

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The total interest expense was $2.2 million for each of the three months ended March 31, 2018 and 2017, primarily from interest on the Facility (see Note 8 to the notes to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional details).

Other income (expense), net

The following table summarizes our other income (expense) for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2018	2017		
	(in thousands)			
Other income, net	$ 302	$ 78	$ 224	287.2%

Other income, net was $0.3 million for the three months ended March 31, 2018, an increase of $0.2 from the $0.1 million of net income for the three months ended March 31, 2017. Other income, net for the three months ended March 31, 2018 consisted of $0.2 million of change in fair value of the Deerfield debt derivative and $0.1 million of interest income. Other income, net for the three months ended March 31, 2017 was primarily from interest income, as there was no Deerfield debt derivative in that time period.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

Since 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. On July 28, 2015, we closed our IPO whereby we sold 5,520,000 shares of our common stock, at a public offering price of $15.00 per share, which includes 720,000 shares of our common stock resulting from the underwriters exercise of their over-allotment option at the IPO price on July 23, 2015. We received aggregate net proceeds of $75.0 million from the offering, after deducting underwriting discounts and commissions of $5.8 million and offering expenses of approximately $2.0 million. The securities described above were offered by us pursuant to a registration statement on Form S-1 declared effective by the SEC on July 22, 2015.

On May 11, 2016, we entered into the Facility with Deerfield. Approximately $33 million of the $60 million Facility proceeds was used to prepay the existing $24.3 million principal and $0.1 million of accrued interest related to the LSA, the $1.1 million LSA end of term fee, an LSA prepayment charge of $243,000 and the $5.9 million of principal and $1.3 million of interest on the Note that was issued by us to Essex, which payments were otherwise payable in 2016 and 2017. Principal on the Facility is 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. We had an option, which we exercised, to defer payment of each of the first four interest payments under the Facility, adding such amounts to the outstanding loan principal. The aggregate $6.6 million Accrued

Interest was to be paid in cash on June 1, 2017.

On the Amendment Date, we entered into the Amendment to the Facility with Deerfield which extended the date to repay the Accrued Interest under the Facility to June 1, 2018 (the PIK Maturity Date), which may have been extended to June 1, 2019 at our election if certain conditions had been met as specified in the Amendment. The right to payment of the Accrued Interest was memorialized in the Convertible Notes issued to Deerfield on the Amendment Date. Interest was due quarterly at a rate of 12.95% per year.

The $6.6 million of Convertible Notes were convertible into shares of our 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 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

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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 statement was declared effective by the SEC on July 11, 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.

In February 2017, we entered into an agreement with a related party 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 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 Sales Agreement). During the year ended December 31, 2017, we sold an aggregate 749,639 shares of common stock under the 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. No sales have been made under the Sales Agreement during the three months ended March 31, 2018.

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 March 31, 2018, we had $24.8 million in cash and cash equivalents and $12.4 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 filing 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:

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	Three months ended March 31,		
	2018	2017	Increase (Decrease)
	(in thousands)		
Net cash (used in) provided by:			
Net cash used in operating activities	$ (12,704)	$ (15,939)	$ 3,235
Net cash provided by investing activities	5,739	5,146	593
Net cash (used in) provided by financing activities	(227)	30,102	(30,329)
Net (decrease) increase in cash and cash equivalents	$ (7,192)	$ 19,309	$ (26,501)

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 $12.7 million and $15.9 million for the three months ended March 31, 2018 and 2017, respectively. The $3.2 million decrease in net cash used from operating activities was due to the $2.8 million decrease in our net losses, as discussed in Results of Operations above, a $2.1 million decrease in noncash items and a $2.5 million increase in the provision of cash from working capital.

The increase in cash provided by working capital changes resulted primarily from $4.8 million decreased cash usage for accounts payable and accrued expenses due to the timing of vendor invoicing and payments and $0.6 million decrease from other assets mainly associated with prepared expenses. These increases were partially offset by $2.0 million from increased inventories due to increased production volume for our branded products, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, whereas we only had one commercially-available branded product, Adzenys XR-ODT, in the first quarter of 2017, $0.6 million decrease from the discontinued deferred commercial sales organization costs due to the building up of our sales organization in the first quarter of 2018 and $0.3 million for accounts receivable primarily due to increased sales in the first quarter of 2018. The decrease in noncash items was principally due to a $2.1 million decrease in deferred interest on debt and a $0.2 million decrease in the fair value change of earnout, derivative and warrant liabilities, partially offset by a $0.1 million increase in amortization of senior debt fees.

Cash provided by investing activities

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

Net cash provided by investing activities was $5.7 million for the three months ended March 31, 2018 primarily due to $17.0 million of sales and maturities of short-term investments, partially offset by the $11.0 million purchase of short-term investments and $0.3 million of capital expenditures principally for production equipment. Net cash provided by investing activities was $5.1 million for the three months ended March 31, 2017 primarily due to $13.4 million of sales and maturities of short-term investments and $0.5 million of proceeds from

sale-leaseback of equipment, partially offset by the $8.5 million purchase of short-term investments and $0.2 million of capital expenditures.

Cash (used in) provided by financing activities

Net cash used in financing activities of $0.2 million in the three months ended March 31, 2018 was for the principal payments under the sales-leasebacks. Net cash provided by financing activities of $30.1 million in the three months ended March 31, 2017 included $30.3 million of proceeds from the issuance of common stock net of related underwriting discounts, commissions and issuance costs, partially offset by $0.2 million of principal payments under the sales-leasebacks.

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Credit facilities

On May 11, 2016, we entered into the Facility with Deerfield. Approximately $33 million of the proceeds was used to repay the existing $24.3 million principal and $0.1 million of accrued interest related to the LSA, the $1.1 million LSA end of term fee, an LSA prepayment charge of $243,000 and the $5.9 million of principal and $1.3 million of interest on the Note that was issued by us to Essex which was to mature in March 2017, which were otherwise payable in 2016 and 2017. Principal on the Facility is 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 $1.35 million 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 Accrued Interest was to be paid in cash on June 1, 2017.

On June 1, 2017, we entered into the Amendment to the Facility which extended the PIK Maturity Date to June 1, 2018, which may have been extended to June 1, 2019 at our election if certain conditions had been met as specified in the Amendment. The right to payment of the Accrued Interest was memorialized in the Convertible Notes issued to Deerfield on the Amendment Date. Interest was due quarterly at a rate of 12.95% per year.

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, range from 12.75% to 2%.

On October 26, 2017, Deerfield elected 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. This resulted in issuing 929,967 shares of the Company s common stock to Deerfield on this date and the

Convertible Notes were cancelled.

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 March 31, 2018, we were in compliance with the covenants under the Facility.

We had a Note in the aggregate principal amount of $5.9 million that was issued by us to Essex which was to mature in March 2017. Interest was to be accrued and added to the principal balance until such time as we achieved positive EBITDA for three consecutive months. The $5.9 million Note and the related $1.3 million of accrued interest were repaid on May 11, 2016 with proceeds from the Facility as mentioned above.

During the years ended December 31, 2017, 2014 and 2013, we entered into agreements with Essex for the sale-leaseback of existing and newly acquired assets with a total capitalized cost of $3.2 million, $795,000 and $5.5 million,

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respectively, with bargain purchase options at the end of each respective lease, all of which are classified as capital leases. The two February 2013 leases for a total of $3.5 million of assets expired in July 2016, the July 2013 lease for a total of $1.0 million of assets expired in December 2016, the November 2013 lease for a total of $1.0 million of assets expired in April 2017, the March 2014 lease for a total of $795,000 of assets expired in September 2017, and all lease buy-out liabilities were satisfied. The approximate imputed interest rate on these leases is 14.9%, 14.5% and 14.5%, respectively. 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.

In February 2017, pursuant to the Shelf, 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. 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, pursuant to the Shelf, 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.

During the year ended December 31, 2017, we sold an aggregate 749,639 shares of common stock under the Sales Agreement at an average sale price of approximately $5.01 per share. No sales have been made under the Sales Agreement during the three-month period ended March 31, 2018. As of March 31, 2018, $58.0 million of our common stock, preferred stock, debt securities, warrants and/or units remained available to be sold pursuant to the Shelf, including $36.2 million of common stock which remained available to be sold under the Sales Agreement, subject to certain conditions specified therein.

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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or, if approved, our new product candidates. In addition, we may not be profitable even if we succeed in commercializing Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or, if approved, any of our new product candidates. We expect to continue to incur operating losses over the next several years as we seek regulatory approval for our product candidates and build and operate commercial infrastructure to support sales and marketing of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, our product candidates that we may develop. 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. We have based this estimate 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;

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- 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 becoming a public company, and sales and marketing personnel to commercialize our approved products.

We may not generate a sufficient amount of product revenues from sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to finance our cash requirements. Until we obtain regulatory approval to market our new product candidates, if ever, we cannot generate revenues from sales of those products. Even if we are able to sell our products, including Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, we may not generate a sufficient amount of product revenues to finance our cash requirements. 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.

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 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. 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

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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 branded product sales

Net product sales for branded Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER products represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments 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. We recognize branded total gross product sales less gross to net sales adjustments as revenue based on shipments from 3PLs to our wholesaler customers.

Savings offers

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 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 for branded products

Our products 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 these rebate accruals are estimated based on information from third-party providers. Estimated rebates payable under such programs are recorded as a reduction of revenue at the time revenues are recorded. Historical trends of estimated rebates will be continually monitored and may result in future adjustments to such estimates.

Product returns of branded products

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. We analyzed recent branded product return history and other market data obtained from our 3PLs to determine a reliable return rate.

Net generic product sales

Net product sales for our generic Tussionex product represent total gross product sales less gross to net sales adjustments. Gross to net sales adjustments 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

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Tussionex related to the respective product sales. We recognize generic Tussionex total gross product sales less gross to net sales adjustments as revenue based on shipments from our 3PLs to our wholesaler customers.

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.

Product returns of generic products

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. Generic Tussionex product returns were estimated based upon return data available from sales of our generic Tussionex product over the past three years.

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 for generic products

Our generic Tussionex product is subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. Estimated government rebates are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized. Generic Tussionex government rebates are estimated based upon rebate payment data available from sales of our generic Tussionex product over the past three years. Historical trend of such rebates will be continually monitored and may result in future adjustments to such estimates.

Wholesaler chargebacks

Our 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 returns, rebates and chargebacks, the actual amount of returns and 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 and all other accruals 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.

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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 employee 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 awards to employees 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. Due to the previous lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, prior to the IPO, we have historically utilized third party valuation analyses to determine the fair value.

Under new 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. The adoption of this standard in 2017 did not have a material impact on our business, financial position, results of operations or liquidity.

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

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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 March 31, 2018. 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	$ 81,244	$ 7,878	$ 40,630	$ 32,736	$

Capital leases for equipment	3,039	1,257	1,746	36	
Earnout liability	170				170
Texas facility operating lease	6,899	955	1,973	2,073	1,898
Pennsylvania office space lease	473	150	310	13	
Equipment operating leases	167	73	91	3	
	$ 91,992	$ 10,313	$ 44,750	$ 34,861	$ 2,068

We had borrowed all $60.0 million under the Deerfield Facility as of March 31, 2018. The payments above are inclusive of related interest amounts as of March 31, 2018.

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 license agreement, after receiving regulatory approval by the FDA of our NDA for Adzenys XR-ODT, in the first quarter of 2016, we paid a lump sum, non-refundable license fee 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 on net sales of Adzenys XR-ODT during the life of the 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-

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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 agreement, after receiving regulatory approval by the FDA of our NDA for Adzenys ER, in October 2017, we paid a lump sum, non-refundable license fee 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 will also pay a single digit royalty on net sales of the Adzenys ER during the life of the relevant Shire patents.

Due to the uncertainty of when these royalty payments will be made for Adzenys XR-ODT and Adzenys ER, they are not presented 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 March 31, 2018, we had cash and cash equivalents of $24.8 million and short-term investments of $12.4 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.

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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 revenue recognition on our financial statements to facilitate their adoption on January 1, 2018. There were no significant changes to our internal controls over financial reporting due to the adoption of the new standard.

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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 lawsuit 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 Laboratories FL, Inc. (Actavis) advising us that Actavis has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (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 alleges 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. This lawsuit automatically stayed, or barred, the FDA from approving Actavis s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

On October 17, 2017, we entered into a Settlement Agreement (the Settlement Agreement) and a Licensing Agreement (the Licensing Agreement and collectively with the Settlement Agreement, the Agreement) with Actavis. This Agreement resolves all ongoing litigation involving our Adzenys XR-ODT patents and Actavis s ANDA. Under the 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 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. We have new product exclusivity for a three-year period from the date of approval for Cotempla XR-ODT. The certification notice alleges that the three U.S. patents listed in the FDA s Orange Book for Cotempla XR-ODT, one with an expiration date in April 2026 and two with expiration dates in June 2032, will not be infringed by Teva s proposed product, are invalid and/or are unenforceable. 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. This lawsuit automatically stayed, or barred, the FDA from approving Teva s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. We intend to vigorously enforce our intellectual property rights relating to Cotempla XR-ODT. We cannot predict the timing or outcome of these proceedings.

On March 7, 2018, we received a citation advising us that the County of Harris, Texas (the County) filed a lawsuit on December 13, 2017 against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through this lawsuit, the County seeks to recoup as damages some of the expenses it allegedly has incurred to combat opioid use and addiction. The County also seeks punitive damages, disgorgement of profits and attorneys fees. While we believe that the lawsuit is without merit and intend to vigorously

defend against it, we are not able to predict at this time whether this proceeding will have a material impact on our 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.

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RISKS RELATED TO COMMERCIALIZATION

We are heavily dependent on the success of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. We have not generated substantial revenues from the sales of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, any sales revenues from any of our product candidates, 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, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop. We have limited experience in generating revenues from our marketed products, having only generated revenues from the sale of our generic Tussionex since we acquired it in 2014, and Adzenys XR-ODT, which we commenced commercializing in May 2016, and from which we have not generated substantial product sales revenues. We launched Cotempla XR-ODT in September 2017 and Adzenys ER in February 2018, and as a result have generated minimal sales revenue for these products to date. We have not generated any revenues from product sales of any other product candidates that we may develop and, to date, have incurred significant operating losses.

Our ability to generate product revenues is dependent on our ability to successfully commercialize Adzenys XR-ODT, our amphetamine extended-release orally disintegrating tablet (XR-ODT), Cotempla XR-ODT, our methylphenidate XR-ODT, and Adzenys ER, our amphetamine XR liquid suspension, for the treatment of attention deficit hyperactivity disorder, or ADHD, and any other product candidates that we may identify, develop and obtain approval of. Our ability to successfully commercialize our products and product candidates depends on, among other things, our ability to:

- manufacture commercial quantities of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop at acceptable cost levels; and

- successfully establish and maintain sales and marketing capabilities to commercialize Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER 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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and, if approved, any other product candidates that we may develop. It is possible that we will never have sufficient product sales revenues to achieve profitability.

If our sales and marketing efforts for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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 and sell our other product candidates, if approved, we may be unable to generate significant revenue.

We have only recently completed building an organization for the sale, marketing and distribution of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, and there is no guarantee that we will be successful in the commercialization of Adzenys XR-ODT, which we launched in

May 2016, Cotempla XR-ODT, which was launched in September 2017, and Adzenys ER, which we launched in February 2018. We currently have a limited sales history for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Additionally, 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 125 representatives to promote our approved products in the United States, these commercialization capabilities have only been recently established, and we may need to 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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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 launching the commercialization of Adzenys XR-ODT, we had no prior experience 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 hire, retain and incentivize qualified individuals and in the appropriate numbers, generate sufficient sales leads, 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 failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

We also intend to enter into strategic partnerships with third parties to commercialize Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and our 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

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well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, 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 will 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, which 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, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. 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, which is discussed below, 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, the FDA conducted a cGMP and pre-approval inspection related to our NDA for Cotempla XR-ODT from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer

systems in order to assure that changes in records are instituted only by authorized personnel. We implemented corrective action related to this observation and responded to the FDA, and the FDA closed the inspection. In addition, 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.

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 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

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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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, and a substantial majority of our resources are now focused on the commercialization in the United States of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. Accordingly, our ability to generate significant product revenue will depend almost entirely on our ability to successfully commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER.

Our ability to successfully commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER will depend on, among other things, our ability to:

- establish relationships with third-party suppliers for the active pharmaceutical ingredient (API), in Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER;

- manufacture and produce, through a validated process, sufficiently large quantities and inventory of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER to permit successful commercialization;

- build and maintain a wide variety of internal sales, distribution and marketing capabilities sufficient to build commercial sales of our products;

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- 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 growth and spending as costs and expenses increase due to commercialization.

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 commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in a timely manner, or at all, 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 build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel to support the commercialization of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. In addition, we have certain revenue expectations with respect to the sale of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. If we cannot successfully commercialize and achieve those revenue expectations with respect to Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, our anticipated revenues and liquidity will be materially adversely impacted.

Moreover, even if we are able to commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, their continued commercial success may be largely dependent on the capability of 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 or on acceptable terms.

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 expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, amphetamine XR is currently marketed in the United States by Shire under the brand names Adderall XR, Vyvanse and Mydayis and by Tris Pharmaceuticals, or Tris, under the brand name Dyanavel XR, a liquid suspension, and methylphenidate is marketed in the United States by Janssen under the brand name Concerta, by Pfizer under the brand name Quillivant XR, a reconstituted liquid suspension, and QuilliChew ER, a chewable formulation, by Rhodes Pharmaceuticals under the brand name Aptensio XR, a capsule, and by Novartis under the brand names Focalin XR and Ritalin LA. 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 Sunovian, 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 liquid suspension, or any product

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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 of 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 products and product candidates 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.

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Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as Adzenys XR-ODT, Cotempla XR-ODT or Adzenys ER 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 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. This lawsuit automatically stayed, or barred, the FDA from approving Actavis s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement (collectively, the Agreement) with Actavis. This Agreement resolves all ongoing litigation involving our Adzenys XR-ODT patents and Actavis s ANDA. Under the 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 Agreement has been submitted to the applicable governmental agencies.

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, in connection with seeking to market its product prior to the expiration of patents covering 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 alleges 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. This lawsuit automatically stayed, or barred, the FDA from approving Teva s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. We intend to vigorously enforce our intellectual property rights relating to Cotempla XR-ODT.

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 generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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, the FDA conducted a cGMP and pre-approval inspection related to our NDA for Cotempla XR-ODT from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We implemented corrective action related to this observation and responded to the FDA, and the FDA closed the inspection. Additionally, in connection with a

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general cGMP and pre-approval inspection for Adzenys ER from July 11, 2017 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. 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, 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 Drug Supply Chain Security Act, including those related to product tracing, verification, and authorized trading partners. Signed into law on November 27, 2013, the Drug Supply Chain Security Act 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. By November 27, 2017, we were required to place a unique product identifier on prescription drug packages, and such requirement will be enforced beginning November 2018. This identifier consists 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 our drug products fail to bear this unique product identifier, they would be misbranded under the FDCA and our drug products may not be accepted into the supply chain.

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

Our approved NDAs for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, include our proposed manufacturing process for each product candidate. 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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER 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 generic Tussionex, 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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and our generic Tussionex that differ from the suppliers used for clinical development of such product candidates.

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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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, 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, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, 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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER 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, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in quantities that meet their demand. Any such delays could trigger these penalty provisions, which would have a negative impact on our business.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. 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.

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through their facilities inspection programs. 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 product candidates. The FDA conducted a cGMP and pre-approval inspection related to our NDA for Cotempla XR-ODT from May 27 to June 4, 2015. At the end of the inspection, the agency issued a Form FDA 483 with one observation finding that appropriate controls are not exercised over one of our computer systems in order to assure that changes in records are instituted only by authorized personnel. We implemented corrective action related to this observation and responded to the FDA, and the FDA closed the inspection. In addition, 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.

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If we fail to manufacture Adzenys XR-ODT, Cotempla XR-ODT or, Adzenys ER 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. In order to meet anticipated demand for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER we have installed specialized processing equipment in our Grand Prairie, Texas facilities, which we believe will produce sufficient quantities of our products for commercialization. We purchase raw materials and components from various suppliers in order to manufacture Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER. 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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, 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. Any failure to comply with applicable regulations 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, and would limit the availability of our products. 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, and we have been able to manufacture and ship our generic Tussionex, Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER for commercial distribution and drug products for our clinical trials. 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. Although we may apply for relief from the Consent Decree in the future, there is no guarantee that such relief will be granted or that we will be in compliance with the requirements of the Consent Decree.

If we are unable to produce the required commercial quantities of Adzenys XR-ODT, Cotempla XR-ODT or Adzenys ER to meet market demand for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of Adzenys XR-ODT, Cotempla XR-ODT or Adzenys ER, we will suffer damage to our reputation and commercial prospects and we will be unable to generate potential revenues.

If we are unable to support demand for Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER and any future product candidates, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our drug delivery technology platform, our business could suffer.

As our volume grows, 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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys

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ER. 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 products, such as Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, 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 facility becomes damaged or inoperable or we are required to vacate our facility, our ability to manufacture Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, 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. 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 Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or our generic Tussionex at our Grand Prairie, Texas facilities could result in a disruption in the supply of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, or our generic Tussionex to physicians and pharmacies, which would adversely affect our ability to generate revenues.

If other forms of our products and 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 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

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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 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.

Products containing controlled substances may generate public controversy. As a result, these products may have their marketing approvals withdrawn. 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.

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), 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. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

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, the new presidential administration has indicated that enacting changes to the Affordable Care Act is a legislative priority, and has discussed repealing and replacing the Affordable Care Act or amending the Affordable Care Act. For example,

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Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing the individual mandate, effective January 1, 2019. 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. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. 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. In addition, CMS has recently proposed regulations that would 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. In 2018, 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 2025 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 Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

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. 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

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,

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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.

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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER 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.

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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, 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 up to five years in 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 of between $11,781and $22,363 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

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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. 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.

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 upon any commercialization by us of our products and product candidates. 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. 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 and product candidates 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

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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. 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 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;

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- 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.

Our product candidates will be submitted 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.

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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. 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.

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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;

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- 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 anticipate that we will continue to incur losses for the foreseeable future.

Our company has limited operating history commercializing branded products. Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER require substantial resources as we implement commercialization strategies to seek to begin generating substantial revenue from product sales. In addition, our product candidates will require substantial additional resources before we will be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales, if approved. There can be no assurance that any of our product candidates will ever achieve regulatory approval or generate any substantial revenue or revenue at all. We do not anticipate generating substantial revenue from sales of Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, if any, or any of our other product candidates in the near term, if ever. We have incurred significant net losses of $14.4 million for the three months ended March 31, 2018, and $65.8 million and $82.8 million for the years ended December 31, 2017 and 2016, respectively. As of March 31, 2018 and December 31, 2017, we had accumulated deficits of $279.7 million and $265.3 million, respectively. We have devoted most of our financial resources to implementation of our commercialization strategies, manufacturing operations and product development. To date, we have financed our operations primarily through the sale of equity and debt securities and payments received under collaborative arrangements. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our increased expenses, but we expect to continue to incur substantial expenses, which we expect will increase as we expand our development activities and operate a specialty sales force and commercialization infrastructure. Our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to the clinical trials we have already completed. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

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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 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 Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, 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 costs of establishing and operating sales, marketing, distribution and commercial manufacturing capabilities for Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER and any other potential product candidates;

- our ability to successfully commercialize Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, 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 potential 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 product candidates 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.

In order to raise additional funds to support our operations, we may sell additional equity or incur 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 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 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.

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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 $60 million senior secured credit facility with Deerfield as lender. Approximately $33 million of the proceeds was used to repay the existing senior and subordinated debt that was otherwise payable in 2016 and 2017. Principal on the new debt is due in three equal annual installments beginning in May 2019 and continuing through May 2022, with a final payment of principal, interest and all other obligations under the facility due on May 11, 2022. Interest is due quarterly beginning in June 2016, 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 March 31, 2018 and December 31, 2017, we had accumulated deficits of $279.7 million and $265.3 million, respectively. 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. 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

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- 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 employees 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 SOX. 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. 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.

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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 may rely on third parties to perform many essential services for any products that we commercialize, 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 commercialize Adzenys XR-ODT, Cotempla XR-ODT or Adzenys ER will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management and cash collection. We would substantially rely on these third-party providers to perform services for us. 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 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, 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

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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 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. 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. This lawsuit automatically stayed, or barred, the FDA from approving Actavis s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier.

On October 17, 2017, we entered into a Settlement Agreement (the Agreement) with Actavis. This Agreement resolves all ongoing litigation involving our Adzenys XR-ODT patents and Actavis s ANDA. Under the 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 Agreement has been submitted to the applicable governmental agencies. There can be no assurance that the Agreement will be approved by such agencies. In addition, there can be no assurance that we would not face future litigation regarding Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER or any future product candidates.

For example, 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, in connection with seeking to market its product prior to the expiration of patents covering Cotempla XR-ODT. A paragraph IV certification is a certification by a generic applicant that in the opinion of that applicant, the patent(s) listed in the Orange Book for a branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva. This case alleges 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. This lawsuit automatically stayed, or barred, the FDA from approving Teva s ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. 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 Cotempla XR-ODT. We would expect to face generic competition for our Cotempla XR-ODT product if such patents are not upheld or if Teva is found not to infringe such patents. The resulting loss of exclusivity would impact pricing and our sales of Cotempla XR-ODT, 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

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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

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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

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remains even after the expiry of the 45-day limit. By way of 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 Shire s 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 Shire patents. Additionally, each of the 2014 and 2017 License Agreements 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.

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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 (IPO), in July 2015 at a price of $15.00 per share, our stock price has ranged from $4.85 to $28.99, through May 4, 2018. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to successfully execute our commercialization strategy with respect to Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER, 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, Adzenys XR-ODT, Cotempla XR-ODT, Adzenys ER 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.

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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 March 31, 2018, 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.

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

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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 March 31st, 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 including exemption from compliance with the auditor attestation requirements of Section 404 of the SOX Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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.

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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
31.1	Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.				

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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.

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SIGNATURES

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

Neos Therapeutics, Inc.

Date: May 10, 2018 By: /s/ Vipin Garg
Vipin Garg
President and Chief Executive Officer

Date: May 10, 2018 By: /s/ Richard Eisenstadt
Richard Eisenstadt
Chief Financial Officer
(*Principal Financial and Accounting Officer*)